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Federal Register

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

## DEPARTMENT OF AGRICULTURE

### Farm Service Agency

### 7 CFR Part 772

**RIN 0560–AG67**

### Servicing Minor Program Loans

**AGENCY:** Farm Service Agency, USDA.

**ACTION:** Correcting amendment.

**SUMMARY:** This document corrects the final regulations published December 16, 2003 (68 FR 69948), which consolidated servicing regulations for the Minor Loan Programs currently administered by the Farm Service Agency. This amendment corrects an editorial mistake relating to a regulatory reference.

**EFFECTIVE DATE:** April 8, 2004.

**FOR FURTHER INFORMATION CONTACT:** Mel Thompson, Senior Loan Officer, Farm Service Agency; telephone: 202–720–7862; Facsimile: 202–690–1196; E-mail: *mel_thompson@wdc.fsa.usda.gov.* Persons with disabilities who require alternative means for communication (Braille, large print, audio tape, etc.) should contact the USDA Target Center at (202) 720–2600 (voice and TDD).

**SUPPLEMENTARY INFORMATION:** This document corrects final regulations that consolidated and clarified the servicing policies of the Farm Service Agency's Minor Loan Programs published in the **Federal Register** on December 16, 2003. Section 772.8(a)(1)(ii) as promulgated states, in part, "The instrument of conveyance will contain the nondiscrimination covenants contained in 7 CFR 1951.204.'' This document removes the reference to the Rural Development regulation at 7 CFR 1951.204, and replaces it with the actual language from that regulation.

■ For the reason stated above, 7 CFR 772.8 is corrected by making the following amendment:

### PART 772—[AMENDED]

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

**Authority:** 5 U.S.C. 301, 7 U.S.C. 1989, 25 U.S.C. 490.

■ 2. Revise paragraph 772.8(a)(1)(ii) to read as follows:

**§ 772.8 Sale or exchange of security property.**

(a) * * *

(1) * * *

(ii) The sale will not prevent carrying out the original purpose of the loan. The borrower must execute an Assurance Agreement as prescribed by the Agency. The covenant involved will remain in effect as long as the property continues to be used for the same or similar purposes for which the loan was made. The instrument of conveyance will contain the following nondiscrimination covenant:

The property described herein was obtained or improved with Federal financial assistance and is subject to the non-discrimination provisions of title VI of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, section 504 of the Rehabilitation Act of 1973, and other similarly worded Federal statutes, and the regulations issued pursuant thereto that prohibit discrimination on the basis of race, color, national origin, handicap, religion, age, or sex in programs or activities receiving Federal financial assistance. Such provisions apply for as long as the property continues to be used for the same or similar purposes for which the Federal assistance was extended, or for so long as the purchaser owns it, whichever is later.

Signed in Washington, DC, on March 31, 2004.

**James R. Little,**

*Administrator, Farm Service Agency.*

[FR Doc. 04–7930 Filed 4–7–04; 8:45 am]

BILLING CODE 3410–05–P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### 14 CFR Part 73

**[Docket No. FAA–2004–17177; Airspace Docket No. 04–ASO–4]**

**RIN 2120–AA66**

### Revocation of Restricted Area 2938, Horseshoe Beach; FL

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** This action revokes Restricted Area 2938 (R–2938), Horseshoe Beach, FL. The FAA is taking this action at the request of the U.S. Air Force (USAF), which no longer requires the airspace. This action returns the formerly restricted airspace to the National Airspace System.

**EFFECTIVE DATE:** 0901 UTC, June 10, 2004.

**FOR FURTHER INFORMATION CONTACT:** Paul Gallant, Airspace and Rules, Office of System Operations and Safety, ATO–R, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8783.

**SUPPLEMENTARY INFORMATION:**

#### The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) part 73 (part 73) by revoking R–2938, Horseshoe Beach, FL. The FAA is taking this action at the request of the USAF, which no longer requires the airspace.

Since this action reduces restricted airspace, the solicitation of comments would only delay the return of airspace to public use without offering any meaningful right or benefit to any segment of the public, notice and public procedure under 5 U.S.C. 553(b) are unnecessary.

Section 73.29 of part 73 of Title 14 Code of Federal Regulations was republished in FAA Order 7400.8L, dated October 7, 2003.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this action: (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.

**Environmental Review**

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1D, Policies and Procedures for Considering Environmental Impacts. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

**List of Subjects in 14 CFR Part 73**

Airspace, Navigation (air).

**Adoption of the Amendment**

■ In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73 as follows:

## PART 73—SPECIAL USE AIRSPACE

■ 1. The authority citation for part 73 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.

**§ 73.29 [Amended]**

■ 2. Section 73.29 is amended as follows:

* * * * *

**R–2938 Horseshoe Beach, FL (Revoked)**

* * * * *

Issued in Washington, DC, on April 1, 2004.

**Reginald C. Matthews,**

*Manager, Airspace and Rules.*

[FR Doc. 04–7959 Filed 4–7–04; 8:45 am]

BILLING CODE 4910–13–P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### 14 CFR Part 135

**[Docket No. FAA–2004–17119]**

### Manual Requirements in Part 135; Correction

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Correction; technical amendment.

**SUMMARY:** This document makes corrections to the final regulations published in the **Federal Register** on March 19, 1997, (62 FR 13257). The regulations are related to what information is required to be included in a certificate holder's manual under part 135.

**DATES:** Effective upon publication.

**FOR FURTHER INFORMATION CONTACT:** John Chescavage; 202–267–9783; *john.chescavage@faa.gov*

**SUPPLEMENTARY IMFORMATION:**

**Background**

The most recent edition of Title 14 of the Code of Federal Regulations (14 CFR) published in 2003 included an error that, when corrected, produced another error that now needs to be corrected. The original error was that we listed § 135.423 as the section number for two different sections that should have had separate section numbers. These two sections were supposed to be numbered 135.423 and 135.424. In 2003, we corrected this error by changing the section numbers so that the following headings went with the appropriate number:

- § 135.423 Aging airplane inspections and records reviews for multiengine airplanes certificated with nine or fewer passenger seats (Eff. Dec. 8, 2003)
- § 135.424 Maintenance, preventive maintenance, and alteration organization

In February 2004, it was brought to our attention that there was a reference to § 135.423 in the regulations found in § 135.427(a). The reference to § 135.423 was accurate before we corrected the two similar section numbers, but since the numbers have been corrected, the reference is now wrong. The reference in § 135.427(a) is meant to point the reader to the section on "Maintenance, preventive maintenance, and alteration organization,'' which is now § 135.424.

**Need for Correction**

As published, the final regulations in § 135.427(a) are misleading and send the reader to the wrong section when referring to what is required in their manual. The incorrect section number referenced in § 135.427(a) does not direct the reader to the right information and could result in the reader not meeting the requirements of the section. This reference needs to be corrected so that the reader is directed to the correct section and provided with the correct information necessary to meet the requirements for a certificate holder's manual.

**List of Subjects in 14 CFR Part 135**

Air taxis, Aircraft, Airmen, Alcohol abuse, Aviation safety, Drug abuse, Drug testing, Reporting and recordkeeping requirements.

■ Accordingly, 14 CFR part 135 is corrected by making the following correcting amendment:

## PART 135—OPERATING REQUIREMENTS: COMMUTER AND ON DEMAND OPERATIONS AND RULES GOVERNING PERSONS ON BOARD SUCH AIRCRAFT

■ 1. The authority citation for 14 CFR part 135 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 41706, 44113, 44101, 44701–44702, 44705, 44709, 44711–44713, 44715–44717, 44722.

■ 2. Revise paragraph (a) of section 135.427 to read as follows:

**§ 135.427 Manual Requirements.**

(a) Each certificate holder shall put in its manual the chart or description of the certificate holder's organization required by § 135.424 and a list of persons with whom it has arranged for the performance of any of its required inspections, other maintenance, preventive maintenance, or alterations, including a general description of that work.

* * * * *

Issued in Washington, DC on April 2, 2004.

**Donald P. Byrne,**

*Assistant Chief Counsel for Regulations.*

[FR Doc. 04–7960 Filed 4–7–04; 8:45 am]

BILLING CODE 4910–13–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 807

### Medical Device Reports; Reports of Corrections and Removals; Establishment Registration and Device Listing: Premarket Approval Supplements; Quality System Regulation; Importation of Electronic Products; Technical Amendment; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of March 10, 2004 (69 FR 11310). That document corrected some inadvertent typographical errors and some technical errors. That document published with an inadvertent error. This document corrects that error.

**EFFECTIVE DATE:** April 8, 2004.

**FOR FURTHER INFORMATION CONTACT:** Joyce A. Strong, Office of Policy and Planning (HF–27), Food and Drug

Administration, Piccard Dr., Rockville, MD 20857, 301–827–7010.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 04–5302, appearing on page 11310 in the **Federal Register** of Wednesday, March 10, 2004, the following correction is made:

**§ 807.22 [Corrected]**

On page 11311, in the third column, in part 807, amendatory instruction no. 6 is corrected to read as follows:

■ "6. Section 807.22 is amended by revising paragraphs (a) and (b) to read as follows:

**§ 807.22 How and where to register establishments and list devices.**

(a) The first registration of a device establishment shall be on Form FDA–2801 (Initial Registration of Device Establishment). Forms are available upon request from the Office of Compliance, Center for Devices and Radiological Health (HFZ–308), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–4015, or from Food and Drug Administration district offices. Subsequent annual registration shall be accomplished on Form FDA–2891a (Annual Registration of Device Establishment), which will be furnished by FDA to establishments whose registration for that year was validated under § 807.35(a). The forms will be mailed to the owner or operators of all establishments via the official correspondent in accordance with the schedule as described in § 807.21(a). The completed form shall be mailed to the address designated in this paragraph 30 days after receipt from FDA.

(b) The initial listing of devices and subsequent June and December updatings shall be on form FDA–2892 (Medical Device Listing). Forms are obtainable upon request as described in paragraph (a) of this section. A separate form FDA–2892 shall be submitted for each device or device class listed with the Food and Drug Administration. Devices having variations in physical characteristics such as size, package, shape, color, or composition should be considered to be one device: *Provided*, The variation does not change the function or intended use of the device. In lieu of form FDA–2892, tapes for computer input or hard copy computer output may by submitted if equivalent in all elements of information as specified in form FDA–2892. All formats proposed for use in lieu of form FDA–2892 require initial review and approval by the Food and Drug Administration.''

Dated: April 2, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–8022 Filed 4–7–04; 8:45 am]

BILLING CODE 4160–01–S

## DEPARTMENT OF HOMELAND SECURITY

## Coast Guard

## 33 CFR Part 117

**[CGD07–04–035]**

## Drawbridge Operation Regulations; Jensen Beach (SR 707) Bridge, Atlantic Intracoastal Waterway Mile 981.4, Stuart, FL

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of temporary deviation from regulations.

**SUMMARY:** The Commander, Seventh Coast Guard District, has approved a temporary deviation from the regulations governing the operation of the Jensen Beach (SR 707a) (Frank A. Wacha) Bridge across the Atlantic Intracoastal Waterway, mile 981.4, Stuart, Florida. This deviation allows the bridge to operate only a single-leaf opening with a double-leaf opening available with a three-hour notice to the bridge tender during certain times of the day.

**DATES:** This deviation is effective from 8 a.m. on March 31 until 5 p.m. on April 30, 2004.

**ADDRESSES:** Material received from the public, as well as documents indicated in this preamble as being available in the docket [CGD07–04–035] will become part of this docket and will be available for inspection or copying at Commander (obr), Seventh Coast Guard District, 909 S.E. 1st Avenue, Miami, Florida 33131–3050 between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal Holidays.

**FOR FURTHER INFORMATION CONTACT:** Mr. Michael Lieberum, Project Officer, Seventh Coast Guard District, Bridge Branch at (305) 415–6744.

**SUPPLEMENTARY INFORMATION:** The Jensen Beach (SR 707a) (Frank A. Wacha) Bridge across the Atlantic Intracoastal Waterway, mile 981.4, Stuart, Florida, is a double-leaf bascule bridge with a vertical clearance of 24 feet above mean high water (MHW) measured at the fenders in the closed position with a horizontal clearance of 90 feet. The current operating regulation in 33 CFR 117.261(o) requires that the draw shall open on signal; except that from December 1 through May 1, from 7 a.m. to 6 p.m., Monday through Friday, except Federal holidays, the draw need open only on the hour and half-hour.

On February 4, 2004, the bridge owner, Florida Department of Transportation, requested a deviation from the current operating regulations to allow the owner and operator to only open a single-leaf of this bridge from 7 a.m. to 6 p.m. daily, Monday through Friday, March 23 through April 30, 2004, with a double-leaf opening available with a three hour notice to the bridge tender. This deviation is necessary to protect workers' safety during the construction of the new fender system. The Commander, Seventh Coast Guard District, has granted a temporary deviation from the operating requirements listed in 33 CFR 117.261(o) to complete repairs to the bridge fender system. Under this deviation, the Jensen Beach (SR 707) Bridge, Atlantic Intracoastal Waterway mile 981.4, Stuart, Florida, shall only open a single-leaf of this bridge from 7 a.m. to 6 p.m. daily, Monday through Friday, March 31 through April 30, 2004, with a double-leaf opening available with a three hour notice to the bridge tender.

Dated: March 29, 2004.

**Greg Shapley,**

*Chief, Bridge Administration, Seventh Coast Guard District.*

[FR Doc. 04–7957 Filed 4–7–04; 8:45 am]

BILLING CODE 4910–15–P

## DEPARTMENT OF HOMELAND SECURITY

## Coast Guard

## 33 CFR Part 165

**[COTP San Francisco Bay 04–006]**

**RIN 1625–AA00**

## Security Zone; Suisun Bay, Concord, CA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing temporary security zones in the navigable waters of the United States adjacent to two piers at the Military Ocean Terminal Concord (MOTCO), California (formerly United States Naval Weapons Center Concord, California). In light of recent terrorist actions against the United States, these security zones are necessary to ensure the safe onloading and offloading of military equipment and to ensure the safety of the public from potential

subversive acts. The security zones will prohibit all persons and vessels from entering, transiting through or anchoring within portions of the Suisun Bay within 600 yards of Pier Two or Pier Three at the MOTCO facility unless authorized by the Captain of the Port (COTP) or his designated representative.

**DATES:** This rule is effective from 7 a.m. PDT on April 8, 2004, to 11:59 p.m. PDT on May 6, 2004. If the need for these security zones ends before the scheduled termination time, the Captain of the Port will cease enforcement of the security zones and will announce that fact via Broadcast Notice to Mariners.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket are part of docket [COTP San Francisco Bay 04–006] and are available for inspection or copying at Coast Guard Marine Safety Office San Francisco Bay, Coast Guard Island, Alameda, California 94501, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Lieutenant Doug Ebbers, U.S. Coast Guard Marine Safety Office San Francisco Bay, at (510) 437–3073.

**SUPPLEMENTARY INFORMATION:**

## Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a NPRM because the duration of the NPRM rulemaking process would extend beyond the actual period of the scheduled operations and defeat the protections afforded by the temporary rule to the cargo vessels, their crews, the public and national security.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register** as the schedule and other logistical details were not known until a date fewer than 30 days prior to the start date of the military operation. Delaying this rule's effective date would be contrary to the public interest since the safety and security of the people, ports, waterways, and properties of the Port Chicago and Suisun Bay areas would be jeopardized without the protection afforded by this security zone.

## Background and Purpose

Since the September 11, 2001 terrorist attacks on the World Trade Center in New York, the Pentagon in Arlington, Virginia and Flight 93, the Federal Bureau of Investigation (FBI) has issued several warnings concerning the potential for additional terrorist attacks within the United States. In addition, the ongoing hostilities in Afghanistan and the conflict in Iraq have made it prudent for U.S. ports to be on a higher state of alert because Al-Qaeda and other organizations have declared an ongoing intention to conduct armed attacks on U.S. interests worldwide.

The threat of maritime attacks is real as evidenced by the attack on the USS Cole and the subsequent attack in October 2002 against a tank vessel off the coast of Yemen. These threats manifest a continuing threat to U.S. assets as described in the President's finding in Executive Order 13273 of August 21, 2002 (67 FR 56215, September 3, 2002) that the security of the U.S. is endangered by the September 11, 2001 attacks and that such aggression continues to endanger the international relations of the United States. See also Continuation of the National Emergency with Respect to Certain Terrorist Attacks (67 FR 58317, September 13, 2002), and Continuation of the National Emergency with Respect to Persons Who Commit, Threaten To Commit, Or Support Terrorism (67 FR 59447, September 20, 2002). The U.S. Maritime Administration (MARAD) in Advisory 02–07 advised U.S. shipping interests to maintain a heightened status of alert against possible terrorist attacks. MARAD more recently issued Advisory 03–05 informing operators of maritime interests of increased threat possibilities to vessels and facilities and a higher risk of terrorist attack to the transportation community in the United States. The ongoing foreign hostilities have made it prudent for U.S. ports and waterways to be on a higher state of alert because the Al-Qaeda organization and other similar organizations have declared and ongoing intention to conduct armed attacks on U.S. interests worldwide.

In its effort to thwart terrorist activity, the Coast Guard has increased safety and security measures on U.S. ports and waterways. As part of the Diplomatic Security and Antiterrorism Act of 1986 (Pub. L. 99–399), Congress amended section 7 of the Ports and Waterways Safety Act (PWSA), 33 U.S.C. 1226, to allow the Coast Guard to take actions, including the establishment of security and safety zones, to prevent or respond to acts of terrorism against individuals, vessels, or public or commercial structures. The Coast Guard also has authority to establish security zones pursuant to the Act of June 15, 1917, as amended by the Magnuson Act of August 9, 1950 (50 U.S.C. 191 *et seq.*) and implementing regulations promulgated by the President in subparts 6.01 and 6.04 of part 6 of title 33 of the Code of Federal Regulations.

In this particular rulemaking, to address the aforementioned security concerns, United States Army officials have requested that the Captain of the Port, San Francisco Bay, California, establish temporary security zones in the navigable waters of the United States within 600 yards of Pier Two and Pier Three at the Military Ocean Terminal Concord (MOTCO), California, to safeguard vessels, cargo and crew engaged in military operations. These temporary security zones are necessary to safeguard the MOTCO terminal and the surrounding property from sabotage or other subversive acts, accidents or criminal acts. These zones are also necessary to protect military operations from compromise and interference and to specifically protect the people, ports, waterways, and properties of the Port Chicago and Suisun Bay areas.

## Discussion of Rule

In this temporary rule, the Coast Guard is establishing fixed security zones encompassing the navigable waters, extending from the surface to the sea floor, within 600 yards of any portion of both Pier Two and Pier Three at Military Ocean Terminal Concord (MOTCO), California. There are 3 existing piers at the MOTCO facility. Originally there were 4 piers, numbered One through Four from west to east, but Pier One was destroyed in an explosion in 1944. Therefore, Pier Two and Pier Three are now the 2 easternmost piers. Because of the close proximity of these 2 piers, there is a portion of these two security zones that overlap. The area encompassed by these two security zones includes portions of the Port Chicago Reach and the Roe Island Channel sections of the deepwater channel. Persons and vessels are prohibited from entering, transiting through or anchoring within these security zones unless authorized by the Captain of the Port (COTP) or his designated representative.

Vessels or persons violating this section will be subject to the penalties set forth in 33 U.S.C. 1232 and 50 U.S.C. 192. Pursuant to 33 U.S.C. 1232, any violation of the security zones described herein, is punishable by civil penalties (not to exceed $32,500 per violation, where each day of a continuing violation is a separate violation), criminal penalties (imprisonment up to 6 years and a maximum fine of $250,000), and in rem liability against the offending vessel. Any person who violates this section using a dangerous weapon, or who engages in conduct that causes bodily injury or fear of imminent

bodily injury to any officer authorized to enforce this regulation, will also face imprisonment up to 12 years. Vessels or persons violating this section are also subject to the penalties set forth in 50 U.S.C. 192: Seizure and forfeiture of the vessel to the United States, a maximum criminal fine of $10,000, and imprisonment up to 10 years, and a civil penalty of not more than $25,000 for each day of a continuing violation. The Captain of the Port will enforce these zones and may enlist the aid and cooperation of any Federal, State, county, municipal, and private agency to assist in the enforcement of the regulation. This regulation is proposed under the authority of 33 U.S.C. 1226 in addition to the authority contained in 50 U.S.C. 191 and 33 U.S.C. 1231.

**Regulatory Evaluation**

This rule is not a "significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not "significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS).

Although this regulation restricts access to portions of navigable waters, the effect of this regulation will not be significant because mariners will be advised about the zones via public notice to mariners, and the zones will encompass only a small portion of the waterway for a short duration. In addition, vessels and persons may be allowed to enter these zones on a case-by-case basis with permission of the Captain of the Port or his designated representative.

The size of the zones is the minimum necessary to provide adequate protection for MOTCO, vessels engaged in operations at MOTCO, their crews, other vessels operating in the vicinity, and the public. The entities most likely to be affected are commercial vessels transiting to or from Suisun Bay via the Port Chicago Reach section of the channel.

**Small Entities**

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule will affect the following entities, some of which may be small entities: The owners and operators of vessels intending to anchor or transit to or from Suisun Bay via the Port Chicago Reach section of the channel. Although the security zones will occupy a section of the navigable channel (Port Chicago Reach) adjacent to the Marine Ocean Terminal Concord (MOTCO), vessels may receive authorization to transit through the zones by the Captain of the Port or his designated representative on a case-by-case basis. Additionally, vessels engaged in recreational activities, sightseeing and commercial fishing will have ample space outside of the security zones to engage in those activities. Small entities and the maritime public will be advised of these security zones via public notice to mariners.

**Assistance for Small Entities**

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. If the rule will affect your small business, organization, or government jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** for assistance in understanding this rule.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

**Collection of Information**

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

**Federalism**

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

**Unfunded Mandates Reform Act**

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

**Taking of Private Property**

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

**Civil Justice Reform**

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

**Protection of Children**

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

**Indian Tribal Governments**

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does 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.

**Energy Effects**

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant

energy action'' under that order because it is not a "significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

**Environment**

We have analyzed this rule under Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation because we are establishing a security zone.

A final "Environmental Analysis Check List'' and a final "Categorical Exclusion Determination'' are available in the docket where located under **ADDRESSES.**

**List of Subjects in 33 CFR Part 165**

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

## PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T11–008 to read as follows:

**§ 165.T11–008 Security Zones; Navigable Waters of the United States Surrounding Pier Two and Pier Three at Military Ocean Terminal Concord (MOTCO), Concord, California.**

(a) *Location.* The security zones, which will be marked by lighted buoys, will encompass the navigable waters, extending from the surface to the sea floor, within 600 yards of any portion of both Pier Two and Pier Three at Military Ocean Terminal Concord (MOTCO), California.

(b) *Regulations.* (1) In accordance with the general regulations in § 165.33 of this part, entering, transiting through or anchoring in these zones is prohibited unless authorized by the Coast Guard Captain of the Port, San Francisco Bay, or his designated representative.

(2) Persons desiring to transit the area of these security zones may contact the Patrol Commander on scene on VHF-FM channel 13 or 16 or the Captain of the Port at telephone number 415–399–3547 to seek permission to transit the area. If permission is granted, all persons and vessels must comply with the instructions of the Captain of the Port or his designated representative.

(c) *Effective period.* This section becomes effective at 7 a.m. PDT on April 8, 2004, and terminates at 11:59 p.m. PDT on May 6, 2004. If the need for these security zones ends before the scheduled termination time, the Captain of the Port will cease enforcement of the security zones and will announce that fact via Broadcast Notice to Mariners.

Dated: March 31, 2004.

**Gerald M. Swanson,**

*Captain, U.S. Coast Guard, Captain of the Port, San Francisco Bay, California.*

[FR Doc. 04–7996 Filed 4–7–04; 8:45 am]

BILLING CODE 4910–15–P

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## DEPARTMENT OF HOMELAND SECURITY

## Coast Guard

## 33 CFR Part 167

**[USCG–2001–11201]**

## Port Access Routes Study; Along the Sea Coast and in the Approaches to the Cape Fear River and Beaufort Inlet, NC

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of study results.

**SUMMARY:** The Coast Guard announces the completion of a Port Access Route Study that evaluated the need for modifications to current vessel routing and traffic management measures along the sea coast and in the approaches to the Cape Fear River and Beaufort Inlet, North Carolina. The study was completed in February 2004. This notice summarizes the study recommendations, which include the creation of a traffic separation scheme and an offshore anchorage area in the approach to the Cape Fear River and an offshore anchorage area in the vicinity of Beaufort Inlet, North Carolina.

**ADDRESSES:** Comments and material received from the public, as well as the actual study and other documents mentioned in this notice, are part of docket USCG–2001–11201 and are available for inspection or copying at the Docket Management Facility, U.S. Department of Transportation, room PL–401, 400 Seventh Street SW., Washington, DC, 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at *http://dms.dot.gov.*

**FOR FURTHER INFORMATION CONTACT:** For further information on this notice, contact John Walters, Aids to Navigation and Waterways Management Branch, Fifth Coast Guard District, telephone 757–398–6230, e-mail *Jwalters@lantd5.uscg.mil;* or George Detweiler, Office of Vessel Traffic Management, Coast Guard, telephone 202–267–0416, e-mail *Gdetweiler@comdt.uscg.mil.* For questions on viewing the docket, contact Andrea M. Jenkins, Program Manager, Docket Operations, telephone 202–366–0271.

**SUPPLEMENTARY INFORMATION:** You may obtain a copy of the Port Access Route Study by contacting either person listed under the **FOR FURTHER INFORMATION CONTACT** section. A copy is also available in the public docket at the address listed under the **ADDRESSES** section and electronically on the DMS Web Site at *http://dms.dot.gov.*

**Definitions**

The following definitions are from the International Maritime Organization's (IMO's) "Ships' Routeing Guide'' (except those marked by an asterisk) and should help you review this notice:

*Offshore anchorage area** means an anchorage area located in the 3-to-12-nautical-mile belt of the territorial sea in which vessels directed by the Captain of the Port (COTP) to await further orders before entering a U.S. port may stand-by or anchor.

*Precautionary area* means a routing measure comprising an area within defined limits where vessels must navigate with particular caution and within which the direction of traffic flow may be recommended.

*Separation Zone or separation line* means a zone or line separating the traffic lanes in which vessels are proceeding in opposite or nearly opposite directions; or from the adjacent sea area; or separating traffic lanes designated for particular classes of vessels proceeding in the same direction.

*Traffic lane* means an area within defined width in which one-way traffic is established. Natural obstacles,

including those forming separation zones, may constitute a boundary.

*Traffic Separation Scheme or TSS* means a routing measure aimed at the separation of opposing streams of traffic by appropriate means and by the establishment of traffic lanes.

*Vessel routing system* means any system of one or more routes or routing measures aimed at reducing the risk of casualties; it includes traffic separation schemes, two-way routes, recommended tracks, areas to be avoided, inshore traffic zones, roundabouts, precautionary areas, and deep-water routes.

**Background and Purpose**

*When Did the Coast Guard Conduct This Port Access Route Study (PARS)?*

We announced the PARS in a notice published in the **Federal Register** on January 18, 2002, (67 FR 2616). This notice had a comment submission deadline of March 19, 2002. On April 16, 2002, we reopened the comment period in a notice published in the **Federal Register** (67 FR 18527). The submission deadline for this comment period was May 19, 2002.

*What is the Study Area?*

The study area encompassed the area bounded by a line connecting the following geographic points (All coordinates are NAD 1983.):

| Latitude | Longitude |
|---|---|
| 34°40′ N | 77°00′ W |
| 34°40′ N | 76°15′ W |
| 34°10′ N | 76°15′ W |
| 33°15′ N | 77°30′ W |
| 33°00′ N | 78°20′ W |
| 33°50′ N | 78°20′ W |
| 33°50′ N | 77°55′ W |

The study area encompasses the approaches to the Cape Fear River and Beaufort Inlet, as well as the area offshore of North Carolina used by commercial, private, recreation, fishing, and public vessels transiting to and from these ports.

*Why Did the Coast Guard Conduct This PARS?*

The approaches to the Cape Fear River and Beaufort Inlet, NC were last studied in 1981, and the final results were published in the **Federal Register** on July 22, 1982 (47 FR 31766). The study concluded that "there is no need to impose new ship routing measures such as TSS's or shipping safety fairways where fixed structures would be prohibited, in any'' area off the North Carolina coast.

Vessel size, traffic density and channel depth and width have changed since the 1981 study. Major channel depth, width and alignment changes are currently underway in the Cape Fear River and port of Wilmington, NC. A PARS was initiated in 1996 (61 FR 35703; July 8, 1996), but was not completed due to personnel and funding issues. The U.S. Army Corps of Engineers' (ACoE) report, "Waterborne Commerce of the United States'' reports that, from 1981 to 1999, annual trips to and from the Port of Wilmington, NC, increased from 10,060 to 24,190 or 140% and the number of trips to and from Morehead City, NC, decreased from 7,842 to 3,388 or 57%.

Since 1981 the North Carolina State Ports Authority (NCSPA) has initiated a capital improvement program to reinvest in its ports. The entire Cape Fear River Channel has been deepened to 42 feet with portions of the channel to be widened for a passing lane in 2005. The approaches over Bald Head Shoals have been realigned to take advantage of the original riverbed with depths of 44 feet. The new alignment at the approaches was opened to marine traffic in December 2003. In addition to the ACoE's newly deepened channel, the U.S. Coast Guard has made improvements to 8 aids to navigation ranges, and is planning to improve an additional 13 ranges to enhance the safety of marine navigation on the river. The ACoE expects the deepening project to produce estimated annual benefits of $34 million per year compared to the estimated annual cost of $26 million. Additionally, NCSPA estimates the deepened channel will allow container ships to carry up to an additional $12 million of cargo to and from the port of Wilmington. The NCSPA is expecting shipping companies not now calling at Wilmington to consider making Wilmington a regular call due to the deepened channel.

The Port of Wilmington opened a new facility to handle the export and import of grain and other bulk commodities in May 2003. The port of Wilmington has four container cranes with capacity up to 50 long-tons, four gantry cranes with capacity up to 225 tons, one 140 ton mobile crane, 59 lift trucks with 3,000 to 52,000 pound capacities, nine top-lift container handlers and two 30-ton mobile cranes.

The Port of Morehead City has recently been receiving cargoes of domestic scrap metals via ocean barges or vessels for transshipment via river barge to mills via the Intracoastal Waterway and is planning improvements to the Radio Island property. This port has one 40 long-ton container crane, two 115-ton capacity gantry cranes, and 36 lift trucks with 4,000 to 70,000 pound capacities. Both ports have truck and rail connections.

The safety and security of the United States is a top priority for our nation. As the awareness of threats to this country increases, the plans for preparedness and prevention of emergency situations have evolved to address threats against America's shorelines. Since every scenario cannot be perfectly planned for, it is important to provide flexibility for alternatives. As an example, if an inbound vessel is denied permission to enter the Cape Fear River or Beaufort Inlet, that vessel needs a designated place to anchor or maintain station so as not to introduce an increased navigational threat to other vessels transiting the approaches. In a designated area, the position and status of a vessel may be monitored and easily accessed by security or inspection personnel.

Within the study area, there exist grounds that could support anchoring any of the largest vessels that call upon the Port of Wilmington now or in the future. No designated anchorages exist off Beaufort Inlet that can be used by naval and commercial vessels. An existing anchorage ground adjacent to the Cape Fear River became obsolete since available water depths are less than the drafts of current and expected larger ships of the future. An offshore anchorage area off the Cape Fear River approaches should be established for munitions ships to await favorable conditions to berth at the U.S. Army's Military Ocean Terminal Sunny Point. Designating an anchorage area off Beaufort Inlet also provides a temporary place for vessels carrying munitions or other hazardous cargoes to be directed. Both anchorages will provide a temporary place for vessels to be directed while the appropriate authorities determine their situation under the authority of the Magnuson Act.

*How Did the Coast Guard Conduct This PARS?*

First, we announced the start of the study through a Notice of Study published in the **Federal Register** on January 18, 2002, (67 FR 2616). This notice identified potential study recommendations and solicited comments concerning these recommendations as well as answers to questions provided in the notice. Second, we considered previous studies, analyses of vessel traffic density, and agency and stakeholder experience in vessel traffic management, navigation, ship handling, and the effects of weather. This PARS recommendations are based mainly on

comments received to the docket and the results of the previous studies, analyses, and agency and stakeholder experience.

**Study Recommendations**

The PARS recommendations include the following:

1. Establish a Precautionary Area near the approaches to the Cape Fear River. A pilot transfer area will be located inside the precautionary area.

2. Establish a Traffic Separation Scheme (TSS) near the approaches to the Cape Fear River.

3. Establish offshore anchorage areas near the approaches to the Cape Fear River and Beaufort Inlet, NC.

**Next Steps**

A brief synopsis of how the PARS recommendations will proceed towards implementation follows:

1. Establishing a TSS will require approval by the International Maritime Organization (IMO). The addition of the TSS to the Code of Federal Regulations (CFR) will be accomplished through the rulemaking process.

2. The establishment of offshore anchorage areas will be accomplished through the rulemaking process.

3. Changes to aids to navigation resulting from the above actions will be accomplished through the following established procedures—notification of proposed changes in the Local Notice to Mariners with an opportunity for comment and notification of the final changes in the Local Notice to Mariners.

**Conclusion**

We appreciate the comments we received concerning the PARS. We will provide ample opportunity for additional comments on any recommended changes to existing routing or operational measures that require codification through notices of proposed rulemakings (NPRMs) published in the **Federal Register**.

Dated: March 31, 2004.

**Howard L. Hime,**

*Acting Director of Standards, Marine Safety, Security & Environmental Protection.*

[FR Doc. 04–7956 Filed 4–7–04; 8:45 am]

**BILLING CODE 4910–15–P**

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 147

**[FRL–7644–8]**

## State of Alabama: Underground Injection Control Program Revision; Proposed Response to Court Remand

**AGENCY:** Environmental Protection Agency.

**ACTION:** Proposed determination on remand of final rule; request for public comment.

**SUMMARY:** In this document, the Environmental Protection Agency (EPA) is requesting public comment on its proposed response to the Eleventh Circuit Court of Appeals' remand in *Legal Environmental Assistance Foundation, Inc.*, v. *United States Environmental Protection Agency*, 276 F.3d 1253 (11th Cir. 2001) (hereinafter *LEAF II*), directing EPA to determine whether Alabama's revised underground injection control (UIC) program covering hydraulic fracturing of coal bed seams to recover methane gas complies with the requirements for Class II wells. In *LEAF II*, the Eleventh Circuit Court affirmed EPA's decision to review Alabama's hydraulic fracturing program pursuant to the approval criteria in section 1425 of the Safe Drinking Water Act (SDWA), 42 U.S.C. 300h *et seq.*, instead of the approval criteria in section 1422 of the SDWA, and rejected LEAF's claim that EPA's approval of the program pursuant to section 1425 was arbitrary. However, the Court remanded the matter, in part, for EPA "to determine whether Alabama's revised UIC program complies with the requirements for Class II wells.'' After considering this issue, EPA has preliminarily determined that the hydraulic fracturing portion of the State's UIC program relating to coal bed methane production, which was approved under section 1425 of the SDWA, complies with the requirements for Class II wells within the context of section 1425's approval criteria. EPA is requesting comment on this proposed determination.

**DATES:** Comments on this proposed response to the Court remand must be in writing and either postmarked or received by the docket for this action by May 10, 2004.

**ADDRESSES:** Send written comments to: Larry Cole, U.S. Environmental Protection Agency, Region 4, Water Management Division, Ground Water and Drinking Water Branch, Sam Nunn Atlanta Federal Center, 61 Forsyth Street, SW., Atlanta, Georgia 30303. When submitting written comments, please submit an original and three copies of your comments and enclosures (including any references). Documents relevant to this action are available for inspection at this same address between 8 a.m. and 5 p.m., Monday through Friday, excluding legal holidays. A reasonable fee may be charged for copying.

**FOR FURTHER INFORMATION CONTACT:** General questions and questions on technical issues concerning today's document should be directed to Larry Cole at (404) 562–9474, or at the address above. Questions on legal issues concerning today's document should be addressed to Zylpha Pryor, Office of Environmental Accountability, U.S. Environmental Protection Agency—Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303, telephone (404) 562–9535.

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### I. Background Information

*A. Court Decisions*

On May 3, 1994, the Legal Environmental Assistance Foundation, Inc., (LEAF) submitted a petition to EPA to withdraw Alabama's UIC program, asserting that the State was not appropriately regulating injection activities associated with coal bed methane gas production wells. Following the Agency's May 5, 1995, denial of the petition, LEAF sought review of this decision by the United States Court of Appeals for the Eleventh Circuit. On August 7, 1997, in *LEAF* v. *EPA*, 118 F. 3d 1467 (11th Cir. 1997) (*LEAF I*), the Court held that hydraulic fracturing activities constitute underground injection under Part C of the SDWA and must be regulated by permit or rule. On February 18, 1999, the Eleventh Circuit directed EPA to implement the Court's August 1997 decision. The Court established a schedule for EPA to follow in determining whether, in light of the Court's ruling regarding hydraulic fracturing, EPA should withdraw approval of Alabama's UIC program. In a January 19, 2000, **Federal Register** (FR) final rule, EPA announced its determination that Alabama's UIC program regulating hydraulic fracturing associated with coal bed methane production was consistent with the requirements of the SDWA and the

*LEAF I* Court mandate. *See* 65 FR 2889 (January 19, 2000).

LEAF filed a petition for review of EPA's determination with the Eleventh Circuit Court, arguing that it should be set aside for three reasons. First, LEAF argued that the underground injection of hydraulic fracturing fluids to enhance the recovery of methane gas from coal beds is not underground injection for the secondary or tertiary recovery of natural gas under section 1425 of the SDWA. Second, LEAF contended that wells used for the injection of hydraulic fracturing fluids to enhance the recovery of methane gas from coal beds are Class II wells as defined in 40 CFR 144.6(b), and EPA's classification of hydraulic fracturing as a "Class II-like underground injection activity'' was not in accordance with law. Third, LEAF argued that, even if Alabama's revised UIC program was covered by the alternative approval procedure of section 1425, EPA's approval of the revised program was arbitrary and capricious. The Eleventh Circuit generally ruled in favor of EPA, holding that: (1) EPA's decision to approve Alabama's hydraulic fracturing program pursuant to section 1425 of the SDWA was a permissible construction of the statute; and (2) EPA was not arbitrary in determining that Alabama's UIC program complies with the section 1425 statutory approval requirements. *LEAF II*, 276 F.3d at 1260–61, 1265. However, the Court remanded, in part, for EPA to determine whether Alabama's revised program covering the hydraulic fracturing of coal beds to produce methane complies with the requirements for Class II wells. Id. at 1264. The purpose of this document is to announce EPA's preliminary determination regarding the remanded issue, and to request public comment on it. EPA is not soliciting comment on any other aspects of its January 2000 approval of Alabama's revised UIC program.

*B. Section 1425 of the SDWA*

Any State that seeks to acquire primary enforcement responsibility for the regulation of Class II wells may, at its option, apply for primacy for its Class II UIC program under the approval criteria in either section 1422 or section 1425 of the SDWA. Approval under either section is aimed at achieving the same fundamental objective of protecting underground sources of drinking water from endangerment by well injection. However, State program approvals under section 1422(b)(1) of the SDWA are required to meet a different legal standard than State program approvals under section 1425. Section 1425 was added as part of the 1980 amendments to the SDWA to offer States an approval alternative that was not necessarily tied to the detailed regulatory requirements for Class II wells found at 40 CFR Parts 124, 144, 145, and 146.

Approval under section 1422(b)(1)(A) requires that the State UIC program meet the requirements of regulations in effect under section 1421. Those regulations, which are found at 40 CFR Parts 124, 144, 145, and 146, are very detailed and specific. However, under the alternate section 1425 approval criteria, a State may instead demonstrate that the Class II portion of its UIC program meets the requirements of section 1421(b)(1)(A) through (D) and represents an "effective'' program to prevent injection which endangers drinking water sources. A State has more flexibility in developing a section 1425-approvable Class II program than if it were developing the same program for approval under section 1422. Similarly, EPA has more discretion to approve a Class II program under the section 1425 criteria, because that program does not have to "track'' or be "as stringent as'' each of the Class II-related requirements of 40 CFR parts 124, 144, 145, and 146. *See* 40 CFR 145.11(b)(1). If a State makes a satisfactory demonstration pursuant to section 1425 that its Class II program warrants approval, it has done all that is required to demonstrate that its program complies with the requirements for Class II wells.

**II. EPA's Response to Court Remand**

During the hydraulic fracturing process, fracturing fluids are injected through methane production wells to create fractures in the formation through which methane flows to the well and up to the surface. In its January 19, 2000, **Federal Register** final rule approving Alabama's UIC program revisions, EPA characterized hydraulic fracturing for the production of coal bed methane as a "Class II-like underground injection activity.'' In the final rule, EPA acknowledged that its classification scheme recognizes only five classes of wells. However, EPA stated that, since the injection of fracture fluids is often a one-time exercise of extremely limited duration and was ancillary to the well's principal function of producing methane, it did not seem entirely appropriate to ascribe full Class II status to that activity. EPA also based its Alabama well classification decision on the fact that the general UIC "well classification systems found in 40 CFR 144.6 and 146.5 do not expressly include hydraulic fracturing'' and "the various permitting, construction, and other requirements found in Parts 144 and 146 do not specifically address hydraulic fracturing.'' 65 FR at 2892. It is still the case today that EPA has not promulgated national regulations expressly and specifically designed to establish minimum requirements for State programs that regulate hydraulic fracturing of coal beds to enhance methane production.

The *LEAF II* Court found EPA's classification of Alabama's hydraulically fractured coal bed methane wells as "Class II-like'' to be inconsistent with the plain language of 40 CFR 144.6, which defines Class II injection wells. In its opinion, the Court held that, even though the injection of fracture fluids is often a one-time exercise of extremely limited duration, "wells used for the injection of hydraulic fracturing fluids fit squarely within the definition of Class II wells.'' *LEAF II*, 276 F.3d at 1263; *see also* 40 CFR 144.6(b)(2). In view of its finding that the wells are Class II wells, the Court remanded, in part, for EPA to determine whether Alabama's revised UIC program complies with the requirements for Class II wells.

In applying for approval of that part of its Class II UIC program regulating hydraulic fracturing of coal beds, Alabama could have sought primacy either under section 1422 or section 1425 approval criteria of the SDWA. Since Alabama chose to make its demonstration pursuant to section 1425, EPA appropriately evaluated that part of Alabama's Class II program regulating hydraulic fracturing of coal beds using the section 1425 alternative approval requirements.

To receive approval for its Class II program, or some component thereof, under the optional demonstration, section 1425 requires a State to show that its program meets the following five criteria: (1) Section 1421(b)(1)(A) provides that the State program must prohibit any underground injection which is not authorized by permit or rule; (2) section 1421(b)(1)(B) provides that the State program require that the applicant for a permit satisfy the State that the underground injection will not endanger drinking water sources and prohibits the State from promulgating any rule which authorizes underground injection which endangers drinking water sources; (3) section 1421(b)(1)(C) requires that the State program include inspection, monitoring, record keeping, and reporting requirements; (4) section 1421(b)(1)(D) provides that the State program must apply to underground injections by Federal agencies, as well as underground injections by any other person, whether or not occurring on

property owned or leased by the United States; and (5) the State program must represent "an effective program'' to prevent underground injection which endangers drinking water sources, in accordance with section 1425(a). If a State can successfully demonstrate that its Class II program satisfies all of these requirements, the program has met all the statutory requirements for approval. As previously discussed, under section 1425, that program, or a component thereof, does not have to demonstrate that it contains requirements as stringent as, or identical to, each of the specific Class II requirements found in Parts 144 and 146 of EPA's regulations. Instead, a finding that such a program, or component thereof, meets the Class II approval requirements of section 1425 means that such a program, by virtue of that finding, necessarily complies with all applicable statutory and regulatory requirements for Class II wells.

EPA's determination that Alabama's hydraulic fracturing program related to coal bed methane production complied with the section 1425 requirements for Class II program approval was explained in great detail in the January 19, 2000, **Federal Register** final rule. The *LEAF II* Court held that EPA's determination that Alabama's UIC program complies with the SDWA's statutory requirements was not arbitrary. *LEAF* v. *EPA,* 276 F.3d at 1265. EPA is not reopening that earlier approval decision or soliciting additional comment on it. EPA is only seeking comment on its proposed response to the *LEAF II* Court's question on remand.

In reviewing and approving Alabama's coal bed methane-related hydraulic fracturing program, EPA was cognizant of the various regulatory provisions in Parts 144 and 146 designed to prevent Class II injection wells from causing the movement of fluid containing any contaminant into an underground source of drinking water (USDW). EPA generally expects traditional State Class II programs, *i.e.*, those regulating the injection of fluids brought to the surface either in connection with conventional oil and gas production or for enhanced recovery or storage of oil and gas, to demonstrate their "effectiveness'' to prevent underground injection which endangers USDWs pursuant to Section 1425 by inclusion of statutory or regulatory provisions preventing fluid movement. EPA was concerned that according "full'' Class II status to Alabama's hydraulically-fractured methane production wells could have been misconstrued as requiring a strict application of those "no fluid movement'' provisions and could have unnecessarily impeded methane gas production in Alabama within the meaning of SDWA section 1421(b)(2) because Alabama's revised program allowed injection of fracturing fluids into USDWs, provided they did not cause a violation of any maximum contaminant level (MCL) or otherwise adversely affect the health of persons. *LEAF* v. *EPA,* F.3d at 1264 n.12; EPA brief at 30–31. EPA thus decided to characterize wells used to inject hydraulic fracturing fluids into Alabama's coal bed formations as "Class II-like,'' rather than Class II. However, this characterization of Alabama's hydraulically-fractured methane production wells, while designed to further ensure that regulation of those wells did not unnecessarily interfere with or impede methane gas production, was unnecessary for purposes of EPA's approval due, in part, to the unique attributes of hydraulic fracturing in Alabama, and because EPA did, in fact, make a substantive finding, which was upheld by the *LEAF II* Court, that Alabama's program does not endanger USDWs because, among other requirements, the injection must not cause a violation of any MCL or otherwise adversely affect the health of persons. EPA thus appropriately exercised the discretion and flexibility inherent in SDWA section 1425 to approve Alabama's coal bed methane-related hydraulic fracturing program allowing such movement where: (1) EPA's Class II regulations were not designed to, and do not specifically address the unique technical and temporal attributes of hydraulic fracturing, and (2) EPA determined pursuant to section 1425 that Alabama's program is effective at preventing endangerment of USDWs.

In sum, SDWA gives Alabama more flexibility in developing a section 1425-approvable Class II program for the hydraulic fracturing of coal beds to produce methane than if it were developing the same program for approval under the criteria in section 1422. Similarly, EPA has more discretion to approve Alabama's revised Class II program relating to coal bed methane production under the criteria in section 1425, because that program does not have to "track'' or be "as stringent as'' each of the Class II-related requirements of 40 CFR parts 124, 144, 145, and 146. *See* 40 CFR 145.11(b)(1). Because Alabama made a satisfactory demonstration pursuant to section 1425 that its coal bed methane-related hydraulic fracturing program warranted approval, it did all that was required to demonstrate that its program complies with the requirements for Class II wells.

Dated: April 5, 2004.

**Benjamin H. Grumbles,**

*Acting Assistant Administrator, Office of Water.*

[FR Doc. 04–7974 Filed 4–7–04; 8:45 am]

**BILLING CODE 6560–50–P**

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## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[OPP–2004–0025; FRL–7353–4]**

## Lambda-Cyhalothrin and an Isomer Gamma-Cyhalothrin; Tolerances for Residues

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** EPA is amending 40 CFR part 180 by promulgating a new tolerance expression for the isomer form of gamma-cyhalothrin. Gamma-cyhalothrin is the isolated active isomer of lambda-cyhalothrin under 40 CFR 180.438. Pytech Chemicals GmbH, 9330 Zionsville Rd., Indianapolis, IN 46268, requested this change in tolerance expression in support of the registration of a pesticide formulation enriched with the gamma isomer of lambda-cyhalothrin.

**DATES:** This regulation is effective April 8, 2004. Objections and requests for hearings, identified by docket ID number OPP–2004–0025, must be received on or before June 7, 2004.

**ADDRESSES:** Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**.

**FOR FURTHER INFORMATION CONTACT:** William G. Sproat, Jr.,Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 308–8587; e-mail address: *sproat.william@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

### I. General Information

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse,

nursery, and floriculture workers; farmers.

- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Get Copies of this Document and Other Related Information?*

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2004–0025. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

## II. Background and Statutory Findings

In the **Federal Register** of February 25, 2004 (69 FR 8654)(FRL–7345–5), EPA issued a notice pursuant to section 408(d)(3) of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4F6812) by Pytech Chemicals GmbH, 9330 Zionsville Rd., Indianapolis, IN 46268. That notice included a summary of the petition prepared by Pytech Chemicals GmbH, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.438 be amended by adding gamma-cyhalothrin, ((S)-a-cyano-3-phenoxybenzyl (Z)-(1R,3R)-3-(2-chloro-3,3,3- trifluoripropenyl)-2,2-dimethylcyclopropanecarboxylate) to the tolerance expression of lambda-cyhalothrin, ((S)-alpha-cyano-3-phenoxybenzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,1-dimethylcyclopropanecarboxylate and (R)-alpha-cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2, 2-dimethylcyclopropanecarboxylate). Gamma-cyhalothrin is a single, resolved isomer of the pyrethroid insecticide cyhalothrin, and as such shares physical, chemical, and biological properties with both cyhalothrin and lambda-cyhalothrin, which are mixtures of 4 and 2 isomers respectively. Gamma-cyhalothrin is the most insecticidally active isomer of cyhalothrin/lambda-cyhalothrin, and thus the technical gamma-cyhalothrin product may be considered a refined form of cyhalothrin/lambda-cyhalothrin in that it has been purified by removal of less active and inactive isomers. Thus, similar levels of insecticidal efficacy for gamma-cyhalothrin can be obtained with significantly reduced application rates as compared with either cyhalothrin or lambda-cyhalothrin.

The tolerance under 40 CFR 180.438 currently identifies lambda-cyhalothrin as a 1:1 mixture of two isomers and their epimers, one of which is the gamma isomer. The gamma isomer is present at 42% in this mixture. By contrast in the proposed tolerance expression the gamma isomer is present at 98% in the mixture. The petitioner requested this change in tolerance expression to support the registration of a pesticide formulation enriched with the gamma isomer of lambda-cyhalothrin.

EPA is also moving the dried hop cone food additive tolerance under 40 CFR 180.438(a)(3) to the table under 40 CFR 180.438(a)(1) since the Agency no longer establishes tolerances for pesticide residues under section 409 of FFDCA. The remainder of 40 CFR 180.438(a)(3) is being removed.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

## III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA. Aggregate risk assessment and determination of safety is discussed in this rule and the final rule on Lambda-cyhalothrin Tolerances (67 FR 60902, September 27, 2002) (FRL–7200–1).

*A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The toxicological evaluation of gamma-cyhalothrin can be accomplished by studies with gamma-cyhalothrin itself as well as by studies on lambda-cyhalothrin and/or cyhalothrin (the unpurified isomer compounds). Cyhalothrin and lambda-cyhalothrin have been reviewed by EPA for toxicity endpoint selection for the various exposure scenarios. Because gamma-cyhalothrin is a component of the other two mixed-isomer compounds, gamma-cyhalothrin essentially has been evaluated in the previous toxicological studies with cyhalothrin and lambda-cyhalothrin. The nature of the toxic effects caused by lambda-cyhalothrin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed are discussed in detail in the **Federal Register** of September 27, 2002 (67 FR 60902) (FRL–7200–1). The toxicological profile for cyhalothrin in the September 27, 2002 **Federal Register** remains current and can therefore be referenced as background information in support of this action.

Gamma-cyhalothrin is a single resolved isomer of cyhalothrin. In order to select toxicity endpoints for the purposes of risk assessment, bridging data on gamma-cyhalothrin were submitted so that the toxicity of gamma cyhalothrin could be compared with that of cyhalothrin and the data bases could be combined to form one complete data base for both chemicals. In the selection of toxicity endpoints, studies conducted with gamma-cyhalothrin were used whenever possible. The nature of the toxic effects of the data on gamma- cyhalothrin are discussed in Table 1 of this unit as well as the NOAEL and the LOAEL from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

| Guideline No. | Study Type | Results |
|---|---|---|
| 870.1200 | 21-Day Dermal Toxicity - Rabbit<br>Cyhalothrin<br>Lambda cyhalothrin<br>Gamma cyhalothrin | NOAEL: 100 mg/kg/day<br>LOAEL: 1,000 mg/kg/day (significant weight loss)<br>None |
| 870.3100 | 13-Week Dietary -Rat -<br>Cyhalothrin | NOAEL: 2.5 mg/kg/day<br>LOAEL: 12.5 mg/kg/day (decreased body weight gain in males). |
| 870.3100 | 13-Week Dietary - Rat<br>Lambda cyhalothrin | NOAEL: 2.5 mg/kg/day<br>LOAEL: 12.5 mg/kg/day (reduced body weight gain and food consumption in both sexes and food efficiency in females). |
| 870.3100 | 13-Week Dietary - Rat<br>Gamma cyhalothrin | NOAEL: male/female =3.4/4.2 mg/kg/day<br>LOAEL: male/female = 6.6/8.8 mg/kg/day (mortality in males, neuromuscular effects in both sexes, dermatitis, and gross and microscopic skin lesions in females). |
| 870.3150 | 26-Week Dietary - Dog<br>Cyhalothrin<br>Lambda cyhalothrin<br>Gamma cyhalothrin | NOAEL: 1.0 mg/kg/day<br>LOAEL: 2.5 mg/kg/day (increase in liquid feces. At 10.0 mg/kg/day, clinical signs of neurotoxicity).<br>None |
| None | 4-Week Dietary - Mouse<br>Cyhalothrin<br>Lambda cyhalothrin<br>Gamma cyhalothrin | NOAEL: 64.2/77.9 mg/kg/day<br>LOAEL: 309/294 mg/kg/day (mortality, clinical signs of toxicity, decreases in body weight gain and food consumption. changes in hematology and organ weights, minimal cetrilobular hepatocyte enlargement).<br>None |
| None | Chronic Toxicity - Dog<br>Lambda cyhalothrin<br>Cyhalothrin<br>Gamma cyhalothrin | NOAEL: 0.1 mg/kg/day<br>LOAEL: 0.5 mg/kg/day (clinical signs of neurotoxicity). Note: For one or two days of dosing, the NOEL is 0.5 mg/kg.<br>None |
| 870.3200 | 21-Day Dermal Toxicity - Rat<br>Lambda cyhalothrin<br>Cyhalothrin<br>Gamma cyhalothrin | NOAEL: 10 mg/kg/day<br>LOAEL: 50 mg/kg/day (clinical signs of toxicity, decreased body weight and body weight gain)<br>None |
| 870.3200 | 28-Day Dietary - Rat<br>Cyhalothrin | NOAEL: 2 mg/kg/day<br>LOAEL: 10 mg/kg/day (clinical signs of neurotoxicity). At higher doses, decreases in body weight gain and food consumption and changes in organ weights |
| 870.3200 | 28-Day Dietary - Rat<br>Cyhalothrin<br>Lambda cyhalothrin | NOAEL: 1.0 mg/kg/day<br>LOAEL: 2.0 mg/kg/day (decreases in mean body weight gain in females).<br>None |

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

| Guideline No. | Study Type | Results |
|---|---|---|
| 870.3200 | Gamma cyhalothrin | NOAEL: male/female = 4.2/4.5 mg/kg/day<br>LOAEL: male/female = 8.8/10.2 mg/kg/day. (decreased body weight, body weight gain, food consumption, clinical and biochemical effects). |
| 870.3200 | Gamma cyhalothrin | Maternal NOAEL: 0.5 mg/kg/day<br>Maternal LOAEL: 2.0 mg/kg/day (clinical signs, reduced body weight and body weight gain and food consumption).<br>Developmental NOAEL: 2.0 mg/kg/day<br>Developmental LOAEL: Not established |
| 870.3465 | 21-Day Inhalation Toxicity - Rat<br>Lambda cyhalothrin<br>Cyhalothrin<br>Gamma cyhalothrin | NOAEL: 0.08 mg/kg/day<br>LOAEL: 0.90 mg/kg/day (clinical signs of neurotoxicity, decreased body weight gains, increased incidence of punctate foci in cornea, slight reductions in cholesterol in females, slight changes in selected urinalysis parameters).<br>None |
| 870.3700 | Developmental Toxicity - Rat<br>Cyhalothrin<br>Lambda cyhalothrin | Maternal NOAEL: 10 mg/kg/day<br>Maternal LOAEL: 15 mg/kg/day (uncoordinated limbs, reduced body weight gain and food consumption).<br>Developmental NOAEL: 15 mg/kg/day<br>Developmental LOAEL: Not established<br>None |
| 870.3700 | Developmental Toxicity - Rabbit<br>Cyhalothrin<br>Lambda cyhalothrin<br>Gamma cyhalothrin | Maternal NOAEL: 10 mg/kg/day<br>Maternal LOAEL: 30mg/kg/day (reduced body weight gain and food consumption).<br>Developmental NOAEL: 30 mg/kg/day<br>Developmental LOAEL: Not established<br>None |
| 870.3800 | 3-Generation Reproduction - Rat<br>Cyhalothrin<br>Lambda cyhalothrin<br>Gamma cyhalothrin | Parental NOAEL: 1.5 mg/kg/day<br>Parental LOAEL: 5.0 mg/kg/day (decreased parental body weight and body weight gain during premating and gestation periods).<br>Reproductive NOAEL: 5.0 mg/kg/day<br>Reproductive LOAEL: Not established.<br>Offspring NOAEL: 1.5 mg/kg/day<br>Offspring LOAEL: 1.5 mg/kg/day (reduced pup weight and weight gain during lactation).<br>None |
| 870.4100 | Chronic Toxicity/Carcinogenicity - Rat<br>Cyhalothrin<br>Lambda cyhalothrin<br>Gamma cyhalothrin | NOAEL: 2.5 mg/kg/day<br>LOAEL: 12.5 mg/kg/day (decreases in mean body weight)<br>No evidence of carcinogenicity.<br>None |
| 870.4200 | Carcinogenicity - Mouse<br>Cyhalothrin<br>Lambda cyhalothrin<br>Gamma cyhalothrin | NOAEL: 15 mg/kg/day<br>LOAEL: 75 mg/kg/day (increased incidence of piloerection, hunched posture; decreased body weight gain in males).<br>No evidence of carcinogenicity.<br>None |
| 870.6200 | Sub Neurotoxicity - Rat<br>Lambda cyhalothrin<br>Cyhalothrin<br>Gamma cyhalothrin | NOAEL: 11.4 mg/kg/day<br>LOAEL: Not Established<br>None |
| 870.7485 | Metabolism and Pharmacokinetics<br>Lambda cyhalothrin<br>Cyhalothrin | In the rat, approximately 55% of the oral dose is absorbed. It is extensively metabolized when absorbed. After subcutaneous administration, the urinary/fecal excretion ration is 2.5:1.0. Over 50% of the dose remained in the carcass 7 days after a subcutaneous dose. Metabolism includes cleavage of the ester to cyclopropylcarboxylic acid and a phenoxybenzyl derivative. The distribution patterns and excretion rate in the multiple oral dose studies are similar to the single oral dose studies. There is accumulation of unchanged compound in the fat upon chronic administration. Otherwise, cyhalothrin is rapidly metabolized and excreted. Cyclopropyl carboxylic 3-4′-hydroxyphenoxy benzoic acid and a sulfate conjugate were identified in the urine. Cyhalothrin is taken up slowly by the fat andreleased slowly. It is rapidly released by blood, kidney, liver. |

These data indicate that bridging to the single resolved isomer is possible and endpoints for risk assessment may be from the gamma isomer toxicity data itself or in accordance with the Agency's "Draft Policy for Determining Toxicology Data Requirements for Enriched Isomer Technical Products'' (Revised April 1999) which states that

once we determine that the data can be bridged, toxicity endpoints can conservatively be estimated by assigning all toxic effects seen in the isomer mixture to the resolved isomer (in this case gamma-cyhalothrin).

It is noted that in the developmental toxicity study in the rat that the resolved gamma isomer is over an order of magnitude more toxic than in cyhalothrin. Since there were no effects on the fetus in either study and these studies are not used for toxicity endpoint selection, the impact of this difference is marginal.

*B. Toxicological Endpoints*

The dose at which the NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the LOAEL of concern identified is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

Three other types of safety or UFs may be used: "Traditional UFs;'' the "special FQPA safety factor;'' and the "default FQPA safety factor.'' By the term "traditional UFs,'' EPA is referring to those additional UFs used prior to FQPA passage to account for database deficiencies. These traditional UFs have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term "special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The "default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional UF or a special FQPA safety factor).

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (aRfD or cRfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any traditional UFs deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of safety factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand ($1 \times 10^{-5}$), one in a million ($1 \times 10^{-6}$), or one in ten million ($1 \times 10^{-7}$). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a "point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure ($MOE_{cancer}$ = point of departure/exposures) is calculated.

A summary of the toxicological endpoints for gamma cyhalothrin used for human risk assessment is shown in Table 2 of this unit. The toxicity studies submitted and reviewed were a battery of acute toxicity studies, 90–day feeding study in the rat, a developmental toxicity study in the rat, and a battery of mutagenicity studies. These studies taken together with those for cyhalothrin and lamba-cyhalothrin (i.e. a combination of studies) were used for hazard assessment of gamma-cyhalothrin for human health risk assessment.

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR GAMMA-CYHALOTHRIN FOR USE IN HUMAN RISK ASSESSMENT

| Exposure Scenario | Dose Used in Risk Assessment, UF | Special FQPA SF* and Level of Concern for Risk Assessment | Study and Toxicological Effects |
|---|---|---|---|
| Acute dietary general population including (infants and children) | Dose = 0.25<br>UF = 100<br>Acute RfD = 0.0025 milligrams(mg)/kilograms (kg) | FQPA SF = 1 X<br>aPAD acute RfD<br>FQPA SF = 0.0025 mg/kg/day | Chronic oral study in the dog (lambda-cyhalothrin)<br>Clinical signs of neurotoxicity (ataxia) observed from day 2, 3 to 7 hours post-dosing. |
| Chronic dietary (all populations) | NOAEL = 0.1<br>UF = 100<br>Chronic RfD = 0.001 mg/kg/day | FQPA SF = 1 X<br>cPAD = chronic RfD<br>FQPA SF = 0.001 mg/kg/day | Chronic oral study in the dog (lambda-cyhalothrin)<br>Gait abnormalities observed in two dogs. |
| Short-term<br>Incidental oral (1–30 days)<br>Intermediate-term<br>Incidental 0ral (1–6 months) | NOAEL = 0.1 mg/kg/day | Residential LOC for MOE = 100<br>Occupational = NA | Chronic oral study in the dog (lambda-cyhalothrin)<br>Gait abnormalities observed in two dogs. |

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR GAMMA-CYHALOTHRIN FOR USE IN HUMAN RISK ASSESSMENT—Continued

| Exposure Scenario | Dose Used in Risk Assessment, UF | Special FQPA SF* and Level of Concern for Risk Assessment | Study and Toxicological Effects |
|---|---|---|---|
| Short-term dermal (1 to 30 days)<br>Long-term dermal (< 6 months) | Dermal dose a = 5.0 mg/kg/day | Residential LOC for MOE = 100<br>Occupational LOC for MOE = 100 | 21–Day dermal toxicity study in the rat (lambda- cyhalothrin)<br>Clinical signs of neurotoxicity (observed from day 2) and decreased body weight and body weight gain. |
| Short-term inhalation (1 to 30 days)<br>Intermediate-term dermal (1 to 6 months)<br>Long-term dermal (< 6 months) | Inhalation dose a = 0.04 mg/kg/day | Residential LOC for MOE = 100<br>Occupational LOC for MOE = 100 | 21–Day inhalation study in rats (lambda-cyhalothrin)<br>Clinical signs of neurotoxicity, and systemic toxicity. |
| Cancer (oral, dermal, inhalation) | Classified as "Not likely to be Carcinogenic to Humans" | | |

Dose[a] = The values indicated above for acute dietary, dermal and inhalation exposure scenarios are the adjusted NOAELs (multiplied by a factor of ½ based on the purity of the lambda isomer compared to the enriched isomer gamma-cyhalothrin. This was not done for the chronic effect dose in the dog study since it was determined by the OPPTS Hazard Identification Assessment review Committee that the NOAEL was very conservative and based on marginal effects at the LOEL of 0.5 mg/kg/day.

UF = uncertainty factor, FQPA SF = special FQPA safety factor, NOAEL = no-observed-adverse-effect-level, LOAEL = lowest-observed-adverse-effect-level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern.

*C. Exposure Assessment*

Tolerances are established under 40 CFR 180.438 for residues of lambda-cyhalothrin on the same crops for which use is requested for the enriched isomer gamma-cyhalothrin. These tolerances for lambda-cyhalothrin will be adequate to cover residues of the enriched isomer based on the relative application rates and the results of the side-by-side field trials comparing residues from the two products. Based on the submitted comparison studies of gamma- and lambda-cyhalothrin for tomato (gamma - 0.018 ppm: lambda 0.038 ppm), sweet corn (gamma - 0.68 ppm: lambda - 1.55 ppm), broccoli (gamma - 0.042 ppm: lambda - 0.13 ppm), and cottonseed (gamma - 0.018: lambda - 0.058),EPA concludes that on average, residues from the gamma uses are not greater than half of the residues from lambda uses (the application rates for gamma-cyhalothrin are half of those of lambda-cyhalothrin for all field trials). Further, toxicological endpoints selected for gamma-cyhalothrin are not less than half of the lambda-cyhalothrin endpoints (i.e., gamma-cyhalothrin is not more than twice as toxic as lambda-cyhalothrin). Therefore, risks from the two products are expected to be similar. EPA's previous risk assessment on lambda-cyhalothrin (cited in 67 FR 60902, (FRL–7200–1)) is sufficient to cover gamma-cyhalothrin. Accordingly, a new aggregate risk assessment for gamma-cyhalothrin is not needed. Acute dietary exposure, chronic dietary exposure, cancer risk, and anticipated residues and percent crop treated (PCT) information, dietary exposure from drinking water, cumulative exposure to substances with a common mechanism of toxicity, and safety factors for infants and children are discussed in detail in the **Federal Register** of September 27, 2002 (67 FR 60902) (FRL–7200–1) and are not repeated here.

*D. Aggregate Risks and Determination of Safety*

Based on the toxicological endpoints selected for gamma-cyhalothrin, which are not less than half of those selected for lambda-cyhalothrin, and the residue data from the comparison studies, which showed that residues from gamma uses are, on average, no more than half of those of lambda-cyhalothrin, EPA concludes that the previous risk assessment on lambda-cyhalothrin sufficiently covers the gamma-cyhalothrin uses and no new aggregate risk assessment is needed for gamma-cyhalothrin.

## IV. Other Considerations

*A. Analytical Enforcement Methodology*

Adequate enforcement methods are available for determination of lambda-cyhalothrin residues in plant and animal commodities. (ICI) Method 81 (PRAM) 81) is used to determine the residues of lambda-cyhalothrin and its epimer in plant matrices and ICI Method 86 is used to determine residues of lambda-cyhalothrin and its epimer in animal matrices. Both methods have been validated by EPA as adequate enforcement methods for determination of parent lambda-cyhalothrin and its epimer in the respective matrices. ICI Method 96 is used to determine lambda-cyhalothrin metabolites in eggs, meat, milk, and poultry. The LOQ for all three methods is 0.01 ppm. Since gamma- and lambda-cyhalothrin differ only in the relative content of enantiomer and the enforcement methods do not use chiral columns, the lambda methods are applicable to gamma-cyhalothrin.

*B. International Residue Limits*

There are currently no Mexican, Canadian, or Codex MRLs (maximum residue limits) for gamma- or lambda-cyhalothrin; however, there are MRLs for cyhalothrin from which lambda-cyhalothrin is derived as an enriched isomer. A Codex MRLs of 0.2 part per million (ppm) has been established for pome fruits for cyhalothrin, which is inconsistent with the proposed U.S. lambda-cyhalothrin tolerance of 0.3 ppm for pome fruits. It is unclear if harmonization can be achieved because residues up to 0.25 ppm were found in the U.S. trials for apples. Codex MRLs were not established for the other crops presently under consideration.

*C. Magnitude of Residues*

The submitted residue comparison studies on broccoli, cottonseed, sweet corn, and tomato indicated that on average, residues from the gamma uses are not greater than half of the residues from lambda uses. The application rates for gamma-cyhalothrin are half of those

of lambda-cyhalothrin for all field trials. The analytical method validation for the determination of gamma- and lambda-cyhalothrin has also been submitted. This method determines the active isomer and its enantiomer as one peak and the two epimers as a separate peak. The two peaks are summed to give total residues.

## V. Conclusion

EPA concludes that the data on gamma-cyhalothrin in conjunction with that on lambda-cyhalothrin show that aggregate risks from dietary exposure is basically the same as lambda-cyhalothrin and that existing crop tolerances for lambda-cyhalothrin are adequate to account for the use of gamma-cyhalothrin on the same crops. Therefore, the tolerance expression under 40 CFR 180.438 is being amended to include the isomer gamma-cyhalothrin.

## VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to "object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

### *A. What Do I Need to Do to File an Objection or Request a Hearing?*

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2004–0025 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before June 7, 2004.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2004–0025, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

### *B. When Will the Agency Grant a Request for a Hearing?*

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

## VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, 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). This final rule does not contain any information collections subject to OMB approval under the

Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to 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 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on 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, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA 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.'' "Policies that have federalism implications'' is defined in the Executive Order 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.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any "tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' "Policies that have tribal implications'' is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, 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 in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

## VIII. Congressional Review Act

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 this final rule in the **Federal Register**. This final rule is not a "major rule'' as defined by 5 U.S.C. 804(2).

## List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 31, 2004.

**Lois Rossi,**

*Director, Registration Division, Office of Pesticide Programs.*

■ Therefore, 40 CFR chapter I is amended as follows:

## PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.438 is amended by:

■ a. Revising the section heading.

■ b. Removing "hop, dried cone'' from the table in paragraph (a)(3) and alphabetically adding it to the table in paragraph (a)(1).

■ c. Removing paragraph (a)(3).

■ d. Redesignating paragraph (a)(2) as new paragraph (a)(3).

■ e. Adding a new paragraph (a)(2).

The amendments read as follows:

### § 180.438 Lambda-cyhalothrin and an isomer gamma-cyhalothrin; tolerances for residues.

(a) * * *

(1) * * *

| Commodity | Parts per million |
|---|---|
| * * * | * * |
| Hop, dried cone | 10 |
| * * * | * * |

(2) Tolerances[1] are established for the combined residues of the pyrethroid [gamma-cyhalothrin (the isolated active isomer of lambda-cyhalothrin) ((*S*)-′-cyano-3-phenoxybenzyl (*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate)) and its epimer (*R*)-′-cyano-3-phenoxybenzyl (*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate in/on the following commodities

| Commodity | Parts per million |
|---|---|
| Alfalfa, forage | 5 |
| Alfalfa, hay | 6 |
| Almond, hulls | 1.5 |

| Commodity | Parts per million |
|---|---|
| Apple pomace, wet | 2.50 |
| Aspirated grain fractions | 2.0 |
| Avocados (imported) | 0.20 |
| Brassica, head and stem, subgroup | 0.4 |
| Canola, seed | 0.15 |
| Cattle, fat | 3 |
| Cattle, meat | 0.2 |
| Cattle, meat byproducts | 0.2 |
| Corn, grain (field and pop) | 0.05 |
| Corn, fodder | 1.0 |
| Corn, forage | 6.0 |
| Corn, grain flour | 0.15 |
| Corn, sweet, kernel plus cob with husks removed | 0.05 |
| Cottonseed | 0.05 |
| Dry bulb onion | 0.1 |
| Egg | 0.01 |
| Fruit, pome, group | 0.30 |
| Fruit, stone, group | 0.50 |
| Garlic | 0.10 |
| Goat, fat | 3.0 |
| Goat, meat | 0.2 |
| Goat, meat byproducts | 0.2 |
| Hog, fat | 3.0 |
| Hog, meat | 0.2 |
| Hog, meat byproducts | 0.2 |
| Horse, fat | 3.0 |
| Horse, meat | 0.2 |
| Horse, meat byproducts | 0.2 |
| Lettuce, head | 2.0 |
| Lettuce, leaf | 2.0 |
| Milk fat (reflecting 0.20 ppm in whole milk | 5.0 |
| Nut, tree, group | 0.05 |
| Pea and bean, dried shelled,(except soybean), subgroup | 0.10 |
| Pea and bean, succulent shelled, subgroup | 0.01 |
| Peanut | 0.05 |
| Peanut, hay | 3.0 |
| Poultry, fat | 0.03 |
| Poultry, meat | 0.01 |
| Poultry, meat byproducts | 0.01 |
| Rice, grain | 1.0 |
| Rice, hulls | 5.0 |
| Rice, straw | 1.8 |
| Sheep, fat | 3.0 |
| Sheep, meat | 0.2 |
| Sheep, meat byproducts | 0.2 |
| Sorghum, grain | 0.20 |
| Sorghum, grain, forage | 0.30 |
| Sorghum, grain, stover | 0.50 |
| Soybean | 0.01 |
| Sugarcane | 0.05 |
| Sunflower, forage | 0.20 |
| Sunflower, seed hulls | 0.50 |
| Sunflower, oil | 0.30 |
| Sunflowers, seed | 0.20 |
| Tomato | 0.10 |
| Tomato, pomace (dry or wet) | 6.0 |
| Vegetables, fruiting, group (except cucurbits) | 0.20 |
| Vegetables, legume, edible podded, subgroup | 0.20 |
| Wheat, grain | 0.05 |
| Wheat, forage | 2.0 |
| Wheat, hay | 2.0 |
| Wheat, straw | 2.0 |
| Wheat, bran | 2.0 |

[1] The analytical enforcement methods for lambda-cyhalothrin are applicable for determination of gamma-cyhalothrin residues in plant and animal commodities.

* * * * *

[FR Doc. 04–7979 Filed 4–7–04; 8:45 am]
BILLING CODE 6560–50–S

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 745

**[OPPT–2003–0061; FRL–7341–5]**

**RIN 2070–AD31**

## Lead; Notification Requirements for Lead-Based Paint Abatement Activities and Training

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** Under the authority of section 407 of the Toxic Substances Control Act (TSCA), as amended by the Residential Lead-Based Paint Hazard Reduction Act of 1992, also known as "Title X (ten),'' EPA is issuing this final rule to establish notification procedures for certified lead abatement professionals conducting lead-based paint abatement activities, and accredited training programs providing lead-based paint activities courses. Specifically, this rule establishes the procedures that must be used to provide notification to EPA prior to the commencement of lead-based paint abatement activities. This rule also establishes provisions that require accredited training programs to notify EPA under the following conditions: Prior to providing initial or refresher lead-based paint activities training courses; and following completion of lead-based paint activities training courses. These notification requirements are necessary to provide EPA compliance monitoring and enforcement personnel with information necessary to track lead-based paint abatement and training activities, and to prioritize compliance inspections. This rule will help to prevent lead poisoning in children under the age of 6 by supporting EPA's implementation of the mandate in Title X to ensure that lead professionals involved in inspecting, assessing or removing lead-based paint, dust or soil are trained and certified to conduct these activities. This rule applies only in States and Tribal areas that do not have authorized programs pursuant to 40 CFR 745.324.

**DATES:** This final rule is effective on May 10, 2004.

**FOR FURTHER INFORMATION CONTACT:** *For general information contact*: Barbara Cunningham, Director, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov*.

*For technical information contact*: Mike Wilson, National Program Chemicals Division (7404T), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 566–0521; e-mail address: *wilson.mike@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

### I. General Information

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you operate a training program required to be accredited under 40 CFR 745.225, or if you are a firm which must be certified to conduct lead-based paint abatement activities in accordance with 40 CFR 745.226. Specifically, the procedure for notification of the commencement of lead-based paint abatement activities applies to the certified firm conducting lead-based paint abatement activities. The procedure for notification of lead-based paint activities training courses applies to the training manager of an accredited training program. This rule applies only in States and Indian Tribes that do not have authorized programs pursuant to 40 CFR 745.324. For further information regarding the authorization status of States and Indian Tribes contact the National Lead Information Center (NLIC) at 1–800–424–LEAD(5323). Potentially affected categories and entities may include, but are not limited to:

- Lead abatement professionals (NAICS 562910); firms and supervisors engaged in lead-based paint activities
- Training programs (NAICS 611519); training programs providing training services in lead-based paint activities

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action applies to certain entities. To determine whether you or your business is affected by this action, you should carefully examine the applicability provisions in 40 CFR part 745. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Get Additional Information, Including Copies of this Document or Other Related Documents?*

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPPT–2003–0061 (legacy number OPPT–62165). The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the EPA Docket Center, Rm. B102–Reading Room, EPA West, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566–1744 and the telephone number for the OPPT Docket, which is located in EPA Docket Center, is (202) 566–0280.

2. *Electronic access*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at *http://www.epa.gov/*. To access this document, on the Home Page select "Laws and Regulations,'' "Regulations and Proposed Rules,'' and then look up the entry for this document under the"**Federal Register**--Environmental Documents.'' You can also go directly to the **Federal Register** listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 745 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr745_00.html*, a beta site currently under development. To access information about lead-based paint and the Lead Program, go directly to the Home Page at *http://www.epa.gov/lead*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available

docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search,'' then key in the appropriate docket ID number.

## II. Introduction

### *A. What is the Agency's Authority for Taking this Action?*

EPA is issuing this final rule under the authority of TSCA section 407, 15 U.S.C. 2687. Section 407 states that regulations of the Administrator under Subchapter IV of TSCA shall include such recordkeeping and reporting requirements as may be necessary to ensure effective implementation. EPA regulations under Subchapter IV of TSCA include lead-based paint activities regulations, which this final rule amends, codified at 40 CFR part 745, subpart L.

### *B. Why is the Agency Taking this Action?*

The requirements in this final rule provide EPA compliance monitoring and enforcement personnel with information necessary to track lead-based paint abatement and training activities, and to prioritize compliance inspections. The objective of the rule is to ensure that a workforce of qualified and properly trained firms and individuals can assist in the elimination of hazards associated with lead-based paint. Providing a quality workforce of this type will ensure that individuals and firms will conduct lead-based paint activities in a way that safeguards the environment and protects human health, specifically, the health of building occupants (especially children under 6 years of age) and the workers themselves.

### *C. How Does this Action Fit into EPA's Overall Lead Program?*

The Residential Lead-Based Paint Hazard Reduction Act of 1992 (Title X) amended TSCA by adding a new Title IV. Several sections of Title X directed EPA to promulgate regulations aimed at fulfilling the purposes of Title X. These include TSCA section 402, Lead-Based Paint Activities Training and Certification, which directs EPA to promulgate regulations to govern the training and certification of individuals engaged in lead-based paint activities, the accreditation of training programs, and the establishment of standards for conducting lead-based paint activities. TSCA section 404 requires that EPA establish procedures for States seeking to establish their own programs for lead-based paint activities. On August 29, 1996, EPA promulgated a final rule under TSCA sections 402 and 404 titled *Lead; Requirements for Lead-Based Paint Activities in Target Housing and Child-Occupied Facilities* (61 FR 45778). The rule is codified at 40 CFR part 745, subparts L and Q.

One of the standards EPA developed for performing lead-based paint activities, codified at 40 CFR 745.227(e)(4), requires notification to EPA prior to the commencement of lead-based paint abatement activities in a residential dwelling, or child-occupied facility, or as a result of a Federal, State, Tribal, or local order. However, 40 CFR 745.227(e)(4) did not detail specific notification procedures. This final rule includes such procedures.

This final rule also requires training programs accredited under 40 CFR 745.225 to notify EPA prior to providing initial and refresher lead-based paint activities courses and to provide certain information after the completion of a training course. Currently, accredited training programs are asked to voluntarily notify EPA prior to offering a lead-based paint activities course. To provide consistency in this reporting, this final rule clearly defines the information needed by the Agency and when it must be provided.

The notification requirements for lead-based paint abatement activities and training courses in this final rule will assist significantly in the implementation and enforcement of lead-based paint activities regulations codified at 40 CFR part 745, subpart L. The notification provisions will help to assure compliance by facilitating observation of abatement activities and training by EPA compliance monitoring and enforcement personnel.

### *D. Summary of Proposed Rule and Public Comments.*

On January 22, 2001, EPA issued a proposed rule (66 FR 7208) (FRL–6764–7) seeking to establish notification procedures, in those States and Federally recognized Tribal jurisdictions without authorized programs, for certified lead abatement professionals conducting lead-based paint abatement activities, and accredited training programs providing lead-based paint activities courses. Specifically, the proposal introduced procedures for providing notification to EPA prior to the commencement of lead-based paint abatement activities. The proposal also introduced provisions which would require accredited training programs to notify EPA under the following conditions: (1) Prior to providing lead-based paint activities training courses; and (2) following completion of lead-based paint activities training courses.

In response to the proposal, EPA received 11 comments. The largest number of responses was received from trainers and public educators (5 of the responses). Other commenters included government agencies (2 of the responses), a representative of a municipality, and a national organization representing demolition contractors. A summary of all comments received, and EPA's responses, may be found in the Response to Comments document which is available for public review in the TSCA Docket for this rulemaking (see Unit I.B.).

The majority of the comments raised concerns regarding the time periods allotted for notification of both lead-based paint abatement activities and associated training. Specific areas of concern included: (1) Time period for initial notification; (2) time period for notification of delayed start date; (3) time period for notification of cancellation or other significant changes; (4) emergency notification requirements; (5) which businesses must provide notification and who must sign the notification; and (6) purpose and use of information collected. Major comments are discussed in Unit III., and remaining comments are discussed in the Response to Comments document.

## III. Final Rule Provisions

### *A. What are the Requirements for Notification of Lead-based Paint Abatement Activities?*

This final rule requires firms certified under 40 CFR 745.226 to provide notification to the Agency prior to conducting lead-based paint abatement activities. The original notice must be received by the Agency at least 5 business days prior to the start of lead-based paint abatement activities. An abbreviated notification period is provided for lead-based paint abatement activities conducted in response to an elevated blood lead level (EBL) determination and/or a Federal, State, Tribal, or local emergency abatement order, where the firm is unable to comply with the standard notification period due to the necessity for an expeditious response to such event. If lead-based paint abatement activities are expected to begin on a date other than that specified in the original notice or if the other reported information changes, an updated notice is required. The notice must include the following:

1. Notification type (original, updated, cancellation).

2. Date when lead-based paint abatement activities will start.

3. Date when lead-based paint abatement activities will end (approximation using best professional judgement).

4. Firm's name, EPA certification number, address, telephone number.

5. Type of building (e.g., single family dwelling, multi-family dwelling, child-occupied facilities) on/in which abatement work will be performed.

6. Property name (if applicable).

7. Property address including apartment or unit number(s) (if applicable) for abatement work.

8. Documentation showing evidence of an EBL determination or a copy of the Federal/State/Tribal/local emergency abatement order, if using the abbreviated time period.

9. Name and EPA certification number of the project supervisor.

10. Approximate square footage/acreage to be abated.

11. Brief description of abatement activities to be performed.

12. Name, title, and signature of the representative of the certified firm who prepared the notification.

Notification must be accomplished using any of the following methods: written notification, or electronically using the Agency's Central Data Exchange (CDX). Written notification can be accomplished using either the sample form titled *Notification of Lead-Based Paint Abatement Activities* or similar form containing the required information. All written notifications must be delivered by U.S. Postal Service, fax, commercial delivery service, or hand delivery.

*B. What are the Requirements for Notification of Lead-based Paint Activities Training?*

This final rule requires training programs accredited under 40 CFR 745.225 to provide notification to the Agency prior to conducting lead-based paint activities courses. The original notice must be received by the Agency at least 7 business days prior to the start of a lead-based paint activities course. An updated notice is required if the starting date for a lead-based paint activities course is changed to a date other than that specified in the original notice or if the other reported information changes. The notice must include the following:

1. Notification type (original, update, cancellation).

2. Training program name, EPA accreditation number, address, and telephone number.

3. Course discipline, type (initial/refresher), and the language in which instruction will be given.

4. Date(s) and time(s) of training.

5. Training location(s) telephone number, and address.

6. Principal instructor's name.

7. Training manager's name and signature.

Training programs must also provide notice to the Agency following completion of a lead-based paint activities course. This notice must be provided to the Agency within 10 business days of course completion. This notice must include the following:

1. Training program name, EPA accreditation number, address, and telephone number.

2. Course discipline and type (initial/refresher).

3. Date(s) of training.

4. The following information for each student who took the course:

a. Name.

b. Address.

c. Date of birth.

d. Course completion certificate number.

e. Course test score.

f. Training manager's name and signature.

Notification must be accomplished using any of the following methods: Written notification, or electronically using the Agency's Central Data Exchange (CDX). Written notification of lead-based paint activities course schedules can be accomplished by using either the appropriate sample form provided by EPA or a similar form containing the required information. All written notifications must be delivered by U.S. Postal Service, fax, commercial delivery service, or hand delivery.

*C. What Changes Were Made in the Final Rule?*

In light of the public's comments, EPA has carefully reviewed the proposed rulemaking and has made certain modifications in the final rule. The following is a brief description of the most significant changes adopted in response to public comment on the proposal. Further information regarding comments received or EPA's response can be reviewed in the Response to Comments document available for public review in the public docket described in Unit I.B.1. With the exception of these and additional minor editorial changes, the final rule is as proposed on January 22, 2001. The following discussion describes the changes.

1. *Time period for initial abatement notification*. EPA received comments expressing concern that the proposed 10 business day initial notification may hamper some abatement processes, including the ability of lead abatement firms to respond quickly to work demands.

Upon review, EPA has modified the initial notification period. The final rule includes a 5 business day initial notification period for lead-based paint abatement activities. EPA believes that the 5 business day notification period adequately addresses the concerns of the commenters while providing EPA with enough time to enable enforcement and compliance assistance personnel to adequately oversee abatement activities. Specifically, a 5–day notification period provides EPA sufficient time to perform activities such as processing the notification, making a determination of whether a compliance inspection is needed, preparing a travel authorization, providing a pre-inspection notification, performing a preliminary compliance review, and completing travel arrangements.

2. *Time period for notification of delayed start date*. EPA received comments regarding the proposed requirement that, if the project start date was to be delayed, notification would be provided to EPA 2 business days prior to the original start date. A commenter pointed out that it would be impossible to provide notification to EPA 2 business days prior to the original start date if issues regarding commencement of work arose on the day that work begins (e.g., lack of access to the work site).

EPA agrees that circumstances can arise on the project start date which delay work. Therefore, the final rule requires that notification of delayed lead-based paint abatement start dates be received by EPA on or before the original start date.

3. *Time period for notification of cancellation or other significant changes*. EPA received comments regarding the proposed requirement that, where abatement activities are canceled or other significant changes occur, EPA be notified 2 business days prior to the original start date. The commenters pointed out that it is impossible to update EPA regarding significant changes to the abatement project 2 days before the start date when the changes occur during the project.

Upon further review EPA agrees that providing cancellation or updated information 2 business days prior to the original start date in some cases could prove impossible. Therefore, the final regulation requires that notification of cancellation of lead-based paint activities be received by EPA on or before the original start date. In addition, any other required information updates must be received by EPA on or before the original start date, and where work has begun, within 24 hours of the change.

4. *Certified supervisor's signature on the notification*. A commenter asked why a certified supervisor must sign an abatement notification.

EPA has an interest in verifying that the project will be overseen by a certified supervisor as required by the regulation; however, on re-examination in light of the commenter's question, EPA believes that the notification itself need not be signed by a certified supervisor. EPA has modified the requirement in the final rule to indicate that a representative of the firm may sign the notification document. EPA also added a requirement that the name and certification number of the supervisor overseeing the project be included in the notification.

5. *Time period for initial training notification*. EPA received a comment regarding the time period for initial training notification. The commenter expressed concern that a 10 business day notification could hamper the ability of firms and individuals in the lead-based paint abatement field to obtain training quickly.

EPA is concerned that the proposed 10 business day notification period could prevent individuals from obtaining timely lead-based paint activities training. The final rule is modified to include a 7 business day initial notification period for lead-based paint activities training. This notification period provides EPA time to perform activities such as: Processing the notification, making a determination of whether a compliance inspection is needed, preparing a travel authorization, providing a pre-inspection notification, performing a preliminary compliance review, and completing travel arrangements. This notification period differs from abatement because compliance personnel often observe training in its entirety which necessitates an early arrival, whereas they will routinely monitor only a portion of an abatement project.

6. *Student information*. EPA received a comment that a student's date of birth should be provided to EPA following training rather than their social security number. The commenter stated that trainees are often reluctant to provide valid social security numbers, and believes that a date of birth would be as reliable an indicator of the student's identity as their social security number.

EPA agrees that a student's date of birth in conjunction with other required information is a reliable indicator of the student's identity. Therefore, the final regulation eliminates the requirement that training programs provide student's social security numbers and instead requires that a student's date of birth be reported.

7. *Requirement to follow e-mail notification with written notification*. EPA received comments regarding the requirement to follow e-mail notification with written notification. The commenters indicated that e-mail notification should be sufficient, and that a follow-up written notification would be redundant and increase the paperwork burden of both government and industry.

EPA plans to use its Central Data Exchange (CDX) to receive electronic notification submitted to satisfy the requirements of this regulation. One of the basic purposes of the CDX system is to provide a method of electronic signature verification, which eliminates the need for a follow-up written notification after an e-mail notification is provided. Therefore, where a submission is provided electronically via the Agency's CDX system, follow-up written notice is not required.

8. *Ability to use other forms if information is the same*. EPA received comments regarding the use of forms, other than the sample forms developed by EPA, containing the information specified in the proposal. Both commenters suggest EPA minimize respondent burden by allowing the use of other forms as long as they provide the same information required under the EPA rule.

EPA agrees that allowing alternative forms can reduce respondent burden and agrees that other forms should be allowed to be used if they contain the information required by EPA. The final rule allows the use of alternative forms that contain the information required by EPA.

9. *Terminology*. EPA received a comment that the use of the terms "project start date'' and "original start date'' were confusing.

EPA agreed and introduced new terms and definitions for "start date'' and "start date provided to EPA'' which clarify these requirements. In addition, EPA removed the definition of "lead abatement professional'' because the term was not introduced in the regulatory text.

### *D. How Do I Obtain Notification Instructions and Sample Forms?*

Instructions and sample forms can be obtained from the National Lead Information Center at 1–800–424–LEAD(5323), or on the Internet at *http://www.epa.gov/lead*.

## IV. Statutory and Executive Order Reviews

### *A. Executive Order 12866*

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), it has been determined that this final rule is not a "significant regulatory action'' subject to review by the Office of Management and Budget (OMB) under Executive Order 12866, because this action does not meet any of the criteria for a "significant regulatory action'' under section 3(f) of Executive Order 12866.

The costs for the first year of implementation are estimated to be approximately $440,000, decreasing to an average annual estimated cost of approximately $395,000 in subsequent years. For additional information about these estimated costs, please refer to the document titled *Information Collection Request (ICR) Supporting Statement for a Proposed Addendum to EPA ICR No. 1715* titled *TSCA §402/404 Training and Certification, Accreditation, and Standards for Lead-Based Paint Activities* (hereinafter the ICR Addendum (EPA ICR No. 1715.03)). This document, identified as EPA ICR No. 1715.03, is an addendum to the existing ICR. A copy is available in the public docket described in Unit I.B.1.

### *B. Paperwork Reduction Act*

The information collection requirements contained in this final rule have been approved by OMB under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, and assigned OMB control number 2070–0155. A copy of the Information Collection Request (ICR) document (EPA ICR No. 1715.05) has been placed in the public docket described in Unit I.B.1.

The information requirements contained in this rule are not effective until promulgation and OMB approval, which is represented by a currently valid OMB control number. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information subject to OMB approval under the PRA unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in Title 40 of the CFR, after initial publication in the **Federal Register** and inclusion on the collection instruments, are maintained in a list at 40 CFR part 9.

The final rule contains the following information collection requirements subject to the PRA that impose paperwork burdens: (1) Reading and interpreting the final rule; (2) the notification of lead-based paint

abatement activities; (3) the notification of lead-based paint activities training courses; and (4) the notification following completion of lead-based paint activities training courses. The total paperwork burdens are estimated to be 21,254 total hours for the first year of implementation, and 19,048 hours annually in subsequent years.

Under the PRA, ''burden'' means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal Agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

*C. Regulatory Flexibility Act*

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), EPA hereby certifies that this action will not have a significant economic impact on a substantial number of small entities. The factual basis for EPA's determination, which is summarized here, is based on the small entity impact analysis prepared as part of the Regulatory Impact Analysis (RIA) for the 1996 Lead Abatement Training and Certification Final Rule (61 FR 45778). EPA assessed the potential small entity impacts of the notification requirement that was contained in the 1996 final rule as part of the economic analysis that was prepared for that rulemaking, a copy of which is available in the public docket described in Unit I.B.1. In addition, EPA has estimated the impacts of the procedural requirements contained in this rule, which are presented in the ICR Addendum (EPA ICR No. 1715.03).

In considering the potential small entity impacts of this final rule, EPA believes that its previous determination regarding the Lead Abatement Training and Certification Final Rule is not affected by the notification procedures contained in this final rule. Based on the estimated total costs of this final rule as presented in the ICR Addendum (EPA ICR No. 1715.03), EPA has determined that this rulemaking is not likely to result in a significant economic impact on a substantial number of small entities. In general, EPA strives to minimize potential adverse impacts on small entities when developing regulations to achieve the environmental and human health protection goals of the statute and EPA.

For the purpose of analyzing the potential impacts of this final rule on small entities, EPA used the definition for small entities that is found in section 601 of the RFA. Under section 601, "small entity'' is defined as: (1) A small business that meets Small Business Administration (SBA) size standards codified at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. The SBA size standards for the small businesses potentially affected by this final rule is 500 employees or less for lead abatement firms whose primary activity is classified as environmental remediation (NAICS code 562910), and revenues of $5 million or less for firms that are accredited to provide lead-based paint training (NAICS code 611519).

This rule only applies in those States and Tribes that do not have authorized programs pursuant to 40 CFR 745.324, and then only applies if that State or Tribe chooses to seek certification to perform lead abatement activities or accreditation to provide lead training. As such, small governmental jurisdictions are only impacted if there is not a State or Tribe authorized program and then only if the small governmental entity chooses to seek certification to perform lead abatement activities or accreditation to provide lead training on their own. To estimate potential impacts on small governments, EPA estimated that in the first year of implementation there could be approximately 15.36 abatement notifications per firm and 17.93 training provider notifications per provider. In subsequent years, the number of training provider notifications are expected to decrease to four each year per provider.

Small businesses are only impacted if there is not a State or Tribe authorized program in their State, and then only if they seek certification to perform lead abatement activities or accreditation to provide lead training. EPA estimates that there could be approximately 15.36 notifications per firm each year, and approximately 4,000 firms.

The estimated average cost per notification for abatement firms is approximately $5, with an estimated total cost per entity of approximately $75 annually. The estimated average cost per notification for training providers is approximately $32, with an estimated total cost per entity of approximately $298 in the first year and approximately $67 in subsequent years. EPA believes that the impact of these costs would be proportional for both small and large firms, and that the impacts may be slightly lower for small governmental jurisdictions that seek EPA certification as an abatement firm or EPA accreditation as a training provider due to lower wage rates and overhead expenses. Overall, EPA believes that these costs would not result in a significant economic impact on affected small entities.

Small non-profit organizations are only impacted if they seek certification to perform lead abatement activities or accreditation to provide lead training on their own. Although EPA believes that non-profit organizations may seek certification, EPA does not have sufficient information about these organizations or their intentions regarding certification or accreditation. Nevertheless, given the low costs for notification and the relatively small number of non-profit organizations, EPA does not believe that this affects EPA's determination that this rule is not expected to have a significant economic impact on a substantial number of small entities.

*D. Unfunded Mandates Reform Act*

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law No. 104–4), EPA has determined that this regulatory action does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any 1 year. This final rule applies only in States and Indian Tribes that do not have authorized programs pursuant to 40 CFR 745.324, and then only applies to those States and Indian Tribes who choose to seek certification to perform lead abatement activities or accreditation to provide lead training. As such, the rule will not impose an enforceable duty on any State, local or Tribal governments. Since, this final rule is estimated to cost approximately $439,573 in the first year of implementation, and $395,157 annually in subsequent years, it is not expected to result in expenditures by the private sector of $100 million or more in any given year. As a result, the UMRA requirements in sections 202, 204, and 205 do not apply to this final rule.

This rule contains no regulatory requirements that might significantly or uniquely affect small governments. Therefore, no action is needed under section 203 of the UMRA.

*E. Executive Order 13132*

Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), requires EPA 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.'' "Policies that have federalism implications'' is defined in the Executive Order 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.''

This final rule does not have federalism implications, because it 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. This final rule applies only in States that do not have authorized programs pursuant to 40 CFR 745.324, and then only applies to those States who choose to seek certification to perform lead abatement activities or accreditation to provide lead training.

Although section 6 of Executive Order 13132 does not apply to this rule, EPA consulted with the States at meetings of the Forum on State and Tribal Toxics Action and the annual EPA meeting with State Lead Program representatives.

*F. Executive Order 13175*

This rule does not significantly or uniquely affect the communities of Indian tribal governments, because this final rule applies only in Indian Tribes that do not have authorized programs pursuant to 40 CFR 745.324, and then only applies to those Indian Tribes who choose to seek certification to perform lead abatement activities or accreditation to provide lead training. Accordingly, the requirements of section 3(b) of Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 276755, May 19, 1998), do not apply to this rule. Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000), which took effect on January 6, 2001, revokes Executive Order 13084 as of that date. EPA developed this rulemaking, however, during the period when Executive Order 13084 was in effect; thus, EPA addressed tribal considerations under Executive Order 13084. For the same reasons stated for Executive Order 13084, the requirements of Executive Order 13175 do not apply to this rule either.

*G. Executive Order 13045*

Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), applies to any rule that (1) is economically significant as defined under OMB's guidance related to section 3(f)(1) of Executive Order 12866, and (2) addresses an environmental health or safety risk that EPA has reason to believe has a disproportionate effect on children. If the regulatory action meets both criteria, EPA must evaluate the environmental health or safety effects of the planned rule on children; and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by EPA.

This rule is not subject to Executive Order 13045 because it is not an "economically significant regulatory action'' as defined by Executive Order 12866 (see Unit IV.A.). Although this final rule is associated with EPA's overall lead-based paint management program which is designed to reduce health risks to children, this rule itself simply establishes an Agency notification procedure and does not directly address environmental health or safety risk. This final rule does, however, help to further EPA's efforts to prevent lead poisoning in children under the age of 6 by supporting EPA's implementation of the mandate in Title X, which requires that lead professionals involved in inspecting, assessing or removing lead-based paint, dust or soil be trained and certified to conduct these activities.

*H. Executive Order 13211*

This rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use.

*I. National Technology Transfer and Advancement Act*

This regulatory action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law No. 104–113, 12(d) (15 U.S.C. 272 note). Section 12(d) of NTTAA directs EPA to use voluntary consensus standards in its regulatory activities unless to do 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. The NTTAA requires EPA to provide Congress, through OMB, explanations when EPA decides not to use available and applicable voluntary consensus standards. EPA invites comment on the potential use of voluntary consensus standards in this rulemaking, and, specifically, invites the public to identify potentially applicable consensus standard(s) and to explain why such standard(s) should be used here.

*J. Executive Order 12898*

Pursuant to Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), EPA has considered environmental justice related issues with regard to the potential impacts of this action on the environmental and health conditions in low-income and minority communities. EPA's analysis has determined that this final action has no disproportionate impact on minority or low-income populations.

*K. Executive Order 12630*

EPA has complied with Executive Order 12630, entitled *Governmental Actions and Interference with Constitutionally Protected Property Rights* (53 FR 8859, March 15, 1988), by examining the takings implications of this rule in accordance with the Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings issued under the Executive Order.

*L. Executive Order 12988*

In issuing this final rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct, as required by section 3 of Executive Order 12988, entitled *Civil Justice Reform* (61 FR 4729, February 7, 1996).

**V. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, 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 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**. This rule is not a "major rule'' as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 745**

Environmental protection, Fees, Hazardous substances, Lead poisoning, Reporting and recordkeeping requirements.

Dated: March 31, 2004.

**Michael O. Leavitt,**

*Administrator.*

Therefore, 40 CFR chapter I is amended as follows:

## PART 745—[AMENDED]

■ 1. The authority citation for part 745 continues to read as follows:

**Authority:** 15 U.S.C. 2605, 2607, 2615, 2681–2692, and 42 U.S.C. 4852d.

■ 2. Section 745.223 is amended by alphabetically adding the following definitions to read as follows:

**§ 745.223 Definitions.**

* * * * *

*Business day* means Monday through Friday with the exception of Federal holidays.

* * * * *

*Lead-based paint activities courses* means initial and refresher training courses (worker, supervisor, inspector, risk assessor, project designer) provided by accredited training programs.

* * * * *

*Start date* means the first day of any lead-based paint activities training course or lead-based paint abatement activity.

*Start date provided to EPA* means the start date included in the original notification or the most recent start date provided to EPA in an updated notification.

* * * * *

*Training provider* means any organization or entity accredited under § 745.225 to offer lead-based paint activities courses.

* * * * *

■ 3. Section 745.225 is amended by adding paragraphs (c)(13) and (c)(14) and revising paragraph (e)(5)(vi) to read as follows:

**§ 745.225 Accreditation of training programs: target housing and child-occupied facilities.**

* * * * *

(c) * * *

(13) The training manager must provide notification of lead-based paint activities courses offered.

(i) The training manager must provide EPA with notification of all lead-based paint activities courses offered. The original notification must be received by EPA at least 7 business days prior to the start date of any lead-based paint activities course.

(ii) The training manager must provide EPA updated notification when lead-based paint activities courses will begin on a date other than the start date specified in the original notification, as follows:

(A) For lead-based paint activities courses beginning prior to the start date provided to EPA, an updated notification must be received by EPA at least 7 business days before the new start date.

(B) For lead-based paint activities courses beginning after the start date provided to EPA, an updated notification must be received by EPA at least 2 business days before the start date provided to EPA.

(iii) The training manager must update EPA of any change in location of lead-based paint activities courses at least 7 business days prior to the start date provided to EPA.

(iv) The training manager must update EPA regarding any course cancellations, or any other change to the original notification. Updated notifications must be received by EPA at least 2 business days prior to the start date provided to EPA.

(v) Each notification, including updates, must include the following:

(A) Notification type (original, update, cancellation).

(B) Training program name, EPA accreditation number, address, and telephone number.

(C) Course discipline, type (initial/refresher), and the language in which instruction will be given.

(D) Date(s) and time(s) of training.

(E) Training location(s) telephone number, and address.

(F) Principal instructor's name.

(G) Training manager's name and signature.

(vi) Notification must be accomplished using any of the following methods: Written notification, or electronically using the Agency's Central Data Exchange (CDX). Written notification of lead-based paint activities course schedules can be accomplished by using either the sample form titled "Lead-Based Paint Activities Training Course Schedule'' or a similar form containing the information required in paragraph (c)(13)(v) of this section. All written notifications must be delivered by U.S. Postal Service, fax, commercial delivery service, or hand delivery (persons submitting notification by U.S. Postal Service are reminded that they should allow 3 additional business days for delivery in order to ensure that EPA receives the notification by the required date). Instructions and sample forms can be obtained from the NLIC at 1–800–424–LEAD(5323), or on the Internet at *http://www.epa.gov/lead*.

(vii) Lead-based paint activities courses must not begin on a date, or at a location other than that specified in the original notification unless an updated notification identifying a new start date or location is submitted, in which case the course must begin on the new start date and/or location specified in the updated notification.

(viii) No training program shall provide lead-based paint activities courses without first notifying EPA of such activities in accordance with the requirements of this paragraph.

(14) The training manager must provide notification following completion of lead-based paint activities courses.

(i) The training manager must provide EPA notification after the completion of any lead-based paint activities course. This notice must be received by EPA no later than 10 business days following course completion.

(ii) The notification must include the following:

(A) Training program name, EPA accreditation number, address, and telephone number.

(B) Course discipline and type (initial/refresher).

(C) Date(s) of training.

(D) The following information for each student who took the course:

(*1*) Name.

(*2*) Address.

(*3*) Date of birth.

(*4*) Course completion certificate number.

(*5*) Course test score.

(E) Training manager's name and signature.

(iii) Notification must be accomplished using any of the following methods: Written notification, or electronically using the Agency's Central Data Exchange (CDX). Written notification following lead-based paint activities training courses can be accomplished by using either the sample form titled "Lead-Based Paint Activities Training Course Follow-up''

or a similar form containing the information required in paragraph (c)(14)(ii) of this section. All written notifications must be delivered by U.S. Postal Service, fax, commercial delivery service, or hand delivery (persons submitting notification by U.S. Postal Service are reminded that they should allow 3 additional business days for delivery in order to ensure that EPA receives the notification by the required date). Instructions and sample forms can be obtained from the NLIC at 1–800–424–LEAD(5323), or on the Internet at *http://www.epa.gov/lead*.

* * * * *

(e) * * *

(5) * * *

(vi) The requirements in paragraphs (c)(1) through (c)(5), and (c)(7) through (c)(14) of this section apply to refresher training providers.

* * * * *

■ 4. Section 745.227 is amended by revising paragraph (e)(4) to read as follows:

**§ 745.227 Work practice standards for conducting lead-based paint activities: target housing and child-occupied facilities.**

* * * * *

(e) * * *

(4) A certified firm must notify EPA of lead-based paint abatement activities as follows:

(i) Except as provided in paragraph (e)(4)(ii) of this section, EPA must be notified prior to conducting lead-based paint abatement activities. The original notification must be received by EPA at least 5 business days before the start date of any lead-based paint abatement activities.

(ii) Notification for lead-based paint abatement activities required in response to an elevated blood lead level (EBL) determination, or Federal, State, Tribal, or local emergency abatement order should be received by EPA as early as possible before, but must be received no later than the start date of the lead-based paint abatement activities. Should the start date and/or location provided to EPA change, an updated notification must be received by EPA on or before the start date provided to EPA. Documentation showing evidence of an EBL determination or a copy of the Federal/State/Tribal/local emergency abatement order must be included in the written notification to take advantage of this abbreviated notification period.

(iii) Except as provided in paragraph (e)(4)(ii) of this section, updated notification must be provided to EPA for lead-based paint abatement activities that will begin on a date other than the start date specified in the original notification, as follows:

(A) For lead-based paint abatement activities beginning prior to the start date provided to EPA an updated notification must be received by EPA at least 5 business days before the new start date included in the notification.

(B) For lead-based paint abatement activities beginning after the start date provided to EPA an updated notification must be received by EPA on or before the start date provided to EPA.

(iv) Except as provided in paragraph (e)(4)(ii) of this section, updated notification must be provided to EPA for any change in location of lead-based paint abatement activities at least 5 business days prior to the start date provided to EPA.

(v) Updated notification must be provided to EPA when lead-based paint abatement activities are canceled, or when there are other significant changes including, but not limited to, when the square footage or acreage to be abated changes by more than 20%. This updated notification must be received by EPA on or before the start date provided to EPA, or if work has already begun, within 24 hours of the change.

(vi) The following must be included in each notification:

(A) Notification type (original, updated, cancellation).

(B) Date when lead-based paint abatement activities will start.

(C) Date when lead-based paint abatement activities will end (approximation using best professional judgement).

(D) Firm's name, EPA certification number, address, telephone number.

(E) Type of building (e.g., single family dwelling, multi-family dwelling, child-occupied facilities) on/in which abatement work will be performed.

(F) Property name (if applicable).

(G) Property address including apartment or unit number(s) (if applicable) for abatement work.

(H) Documentation showing evidence of an EBL determination or a copy of the Federal/State/Tribal/local emergency abatement order, if using the abbreviated time period as described in paragraph (e)(4)(ii) of this section.

(I) Name and EPA certification number of the project supervisor.

(J) Approximate square footage/acreage to be abated.

(K) Brief description of abatement activities to be performed.

(L) Name, title, and signature of the representative of the certified firm who prepared the notification.

(vii) Notification must be accomplished using any of the following methods: Written notification, or electronically using the Agency's Central Data Exchange (CDX). Written notification can be accomplished using either the sample form titled "Notification of Lead-Based Paint Abatement Activities'' or similar form containing the information required in paragraph (e)(4)(vi) of this section. All written notifications must be delivered by U.S. Postal Service, fax, commercial delivery service, or hand delivery (persons submitting notification by U.S. Postal Service are reminded that they should allow 3 additional business days for delivery in order to ensure that EPA receives the notification by the required date). Instructions and sample forms can be obtained from the NLIC at 1–800–424–LEAD(5323), or on the Internet at *http://www.epa.gov/lead*.

(viii) Lead-based paint abatement activities shall not begin on a date, or at a location other than that specified in either an original or updated notification, in the event of changes to the original notification.

(ix) No firm or individual shall engage in lead-based paint abatement activities, as defined in § 745.223, prior to notifying EPA of such activities according to the requirements of this paragraph.

* * * * *

[FR Doc. 04–7980 Filed 4–7–04; 8:45 am]

BILLING CODE 6560–50–S

## DEPARTMENT OF TRANSPORTATION

### National Highway Traffic Safety Administration

### 49 CFR Part 571

**[Docket No. NHTSA 2004–17471]**

### Federal Motor Vehicle Safety Standards; Rearview Mirrors Correction

**AGENCY:** National Highway Traffic Safety Administration, DOT.

**ACTION:** Correcting amendment.

**SUMMARY:** On March 27, 1995, the National Highway Traffic Safety Administration (NHTSA) published a final rule amending the field of view requirements for System A mirrors on school buses, such that those mirrors will no longer be required to provide a view of the ground forward of the rear wheels (60 FR 15690). Previously, System A mirrors were required to provide a view of the area beneath those mirrors, a view that overlapped with the vehicle's System B mirrors, which are also required. The effective date of the amendment was April 26, 1995.

However, this new language was later inadvertently modified in two later, substantively unrelated amendments.

This document corrects NHTSA's inadvertent modification of the relevant regulatory language.

**DATES:** These amendments are effective May 10, 2004.

**FOR FURTHER INFORMATION CONTACT:** The following persons at the NHTSA, 400 Seventh Street, SW., Washington, DC 20590.

For non-legal issues, you may call Mr. Charles Hott, Office of Crash Avoidance Standards (Telephone: 202–366–0247) (Fax: 202–366–4329).

For legal issues, you may call Mr. Eric Stas, Office of Chief Counsel (Telephone: 202–366–2992) (Fax: 202–366–3820).

**SUPPLEMENTARY INFORMATION:** Federal Motor Vehicle Safety Standard (FMVSS) No. 111, *Rearview Mirrors*, specifies requirements for the performance and location of rearview mirrors on passenger cars, multipurpose passenger vehicles, trucks, buses, school buses, and motorcycles. The purpose of the standard is to reduce the number of deaths and injuries that occur when the driver of a motor vehicle does not have a clear and reasonably unobstructed view to the rear.

On March 27, 1995, the agency amended paragraphs S9.2(b)(1) and (2) of FMVSS No. 111 to change the field of view requirements of System A mirrors on school buses, which provide a view of the area beneath those mirrors, along both sides of the bus, and to the rear of the bus (60 FR 15690). Under the final rule, System A mirrors were no longer required to provide a view of the ground forward of the rear wheels, because this field of view overlaps with that provided by the bus's required System B mirrors, which provide a view of the area around the front of the school bus and near the rear wheels. The intention was to modify the standard's existing requirements such that school bus manufacturers would no longer have to install either an additional convex mirror, which creates a larger blind spot for the driver, or replace the existing convex mirror with a highly curved convex mirror that produces more distorted images.

In 1998, NHTSA published two final rules related to metric conversion that, in part, amended FMVSS No. 111, but which inadvertently resulted in unintended modification of the standard's field of view requirements for school buses. In the final rule for metric conversion, published in the **Federal Register** on May 27, 1998, language was mistakenly inserted under paragraphs S9.2(b)(1) and (2) of the standard that would require measurement from the mirror surface, rather than maintaining proper focus on measurement from the appropriate test cylinder (63 FR 28922). Subsequently, NHTSA published a final rule; response to petitions for reconsideration in the **Federal Register** on September 24, 1998 (63 FR 50995). In attempting to correct an unrelated error brought to the agency's attention, a modification intended for paragraph S9.3(b)(2) was inadvertently inserted at S9.2(b)(2).

In light of the above, NHTSA is publishing this correcting amendment to reinstate the appropriate regulatory language for field of view measurement for System A mirrors on school buses, consistent with both the March 27, 1995 final rule modifying FMVSS No. 111 and the 1998 final rules for metric conversion. We also are making the necessary correction to S9.3(b)(2).

This amendment to the final rule is effective 30 days after the date of publication in the **Federal Register**. Remedying this error on the part of the agency will not impose any additional substantive requirements or burdens on manufacturers. Therefore, NHTSA finds for good cause that any notice of proposed rulemaking and opportunity for comment on these amendments are not necessary.

**List of Subjects in 49 CFR Part 571**

Imports, Motor vehicle safety, Reporting and recordkeeping requirements, Tires.

## PART 571—FEDERAL MOTOR VEHICLE SAFETY STANDARDS

■ Accordingly, 49 CFR Part 571 is corrected by making the following correcting amendment:

■ 1. The authority citation for Part 571 of Title 49 continues to read as follows:

**Authority:** 49 U.S.C. 322, 30111, 30115, 30117, and 30166; delegation of authority at 49 CFR 1.50.

■ 2. Section 571.111 is amended by revising S9.2 and S9.3 to read as follows:

**§ 571.111 Standard No. 111; Rearview mirrors.**

* * * * *

S9.2. System A shall be located with stable supports so that the portion of the system on the bus's left side, and the portion on its right side, each:

(a) Includes at least one mirror of unit magnification with not less than 323 $cm^2$ of reflective surface; and

(b) Includes one or more mirrors which together provide, at the driver's eye location, a view of:

(1) For the mirror system on the right side of the bus, the entire top surface of cylinder N in Figure 2, and that area of the ground which extends rearward from cylinder N to a point not less than 61 meters from the mirror surface.

(2) For the mirror system on the left side of the bus, the entire top surface of cylinder M in Figure 2, and that area of the ground which extends rearward from cylinder M to a point not less than 61 meters from the mirror surface.

S9.3(a) For each of the cylinders A through P whose entire top surface is not directly visible from the driver's eye location, System B shall provide, at that location:

(1) A view of the entire top surface of that cylinder.

(2) A view of the ground that overlaps with the view of the ground provided by System A.

(b) Each mirror installed in compliance with S9.3(a) shall meet the following requirements:

(1) Each mirror shall have a projected area of at least 258 $cm^2$, as measured on a plane at a right angle to the mirror's axis.

(2) Each mirror shall be located such that the distance from the center point of the eye location of a 25th percentile adult female seated in the driver's seat to the center of the mirror shall be at least 95 cm.

(3) Each mirror shall have no discontinuities in the slope of the surface of the mirror.

(4) Each mirror shall be installed with a stable support.

(c) Each school bus which has a mirror installed in compliance with S9.3(a) that has an average radius of curvature of less than 889 mm, as determined under S12, shall have a label visible to the seated driver. The label shall be printed in a type face and color that are clear and conspicuous. The label shall state the following:

"USE CROSS VIEW MIRRORS TO VIEW PEDESTRIANS WHILE BUS IS STOPPED. DO NOT USE THESE MIRRORS TO VIEW TRAFFIC WHILE BUS IS MOVING. IMAGES IN SUCH MIRRORS DO NOT ACCURATELY SHOW ANOTHER VEHICLE'S LOCATION.''

* * * * *

Issued: April 2, 2004.

**Stephen R. Kratzke,**

*Associate Administrator for Rulemaking.*

[FR Doc. 04–7962 Filed 4–7–04; 8:45 am]

BILLING CODE 4910–59–P

**DEPARTMENT OF TRANSPORTATION**

**Surface Transportation Board**

**49 CFR Part 1104**

**[STB Ex Parte No. 651]**

## Electronic Filing Option for Certain Documents

**AGENCY:** Surface Transportation Board, Transportation.

**ACTION:** Final rule.

**SUMMARY:** The Surface Transportation Board (Board) is amending its regulations concerning filing of pleadings and other documents with the Board to give persons the option of filing certain types of pleadings and documents electronically instead of filing paper copies and to give persons the option of filing documents in formats other than WordPerfect.

**DATES:** These rules are effective on April 8, 2004.

**FOR FURTHER INFORMATION CONTACT:** John Sado, (202) 565–1661. (Federal Information Relay Service (FIRS) for the hearing impaired: 1–800–877–8339.)

**SUPPLEMENTARY INFORMATION:** The Board is amending its regulations at 49 CFR part 1104 as needed to add the option of electronically filing (e-filing) certain types of pleadings and documents. If the e-filing option is chosen, it will eliminate the need for filing paper copies of those types of pleadings and documents that are eligible for e-filing.

The Board's updated Web site, *http://www.stb.dot.gov,* has a link labeled "E-FILING''. Clicking on that link will open a series of prompts that will indicate what types of pleadings and documents are eligible for e-filing and will lead the e-filer, step-by-step, through the process of how to e-file. Formal filings, recordations, environmental comments, rail consumer complaints, FOIA requests and other correspondence may be submitted to the Board through the e-filing process. The e-filing process may *not* be used to file: (1) Initial filings in a proceeding; (2) filings requiring a fee (except recordations); or (3) large evidentiary filings (collectively, over 10 megabytes). Persons are not required to file electronically, but may choose the e-filing option at their discretion.

It should be noted that e-filing will not relieve a party of the obligation to serve other parties. Rather, e-filing pertains only to documents that are sent to the Board, and existing service requirements remain as to other parties. With respect to e-filings made with the Board, the service requirements of §1104.12(a) of the Board's rules may be met by simultaneously e-mailing a copy of the e-filed document to other parties if that means of service is acceptable to those other parties, or by simultaneous personal service of a paper copy of the document on the other parties, but if e-mail is not acceptable to the receiving party and personal service is not feasible, the service requirements may be met by service of a paper copy by first-class or express mail.

To e-file a formal filing or a recordation, the e-filer must first establish a login account. A login account can be obtained by clicking on the "Request Login Account'' button found on the e-filing page. The user will be prompted to provide the information required to establish an account. The user's e-mail address will be the "user name'' and the user will have the opportunity to choose a password.

E-filing is a file attachment process. Submissions are to be prepared in the same manner in which a filer would if filing on paper, except that extra copies will not be required. E-filings will be available for public viewing in the Board's Public Docket Room. They will also be on the Board's Web site, just as paper filings are on the Web site. When using e-filing for a formal filing, the e-filer must submit a document as a PDF-format document and also, if available, in the original document format. The document submitted must include the applicable docket number and the name and address of the person responsible for the filing. For purposes of e-filing, a typewritten name is considered the signature of the appropriate party if a signature is required by the Board's regulations. The original, handwritten signature must be maintained in the files of the filing party. E-filers will be able to indicate, as part of the e-filing process, if the filing is to be treated by the Board as confidential.

Documents received by e-filing before 5 p.m. eastern time on a business day will be considered filed on that day. Documents received by e-filing on a non-business day, or after 5 p.m. eastern time on a business day, will be considered filed on the next business day.

Additionally, the Board is revising its rules to delete a reference to the WordPerfect format for electronic submissions of textual material and thus to permit practitioners to file documents in formats other than WordPerfect.

Because these rule changes relate solely to the rules of agency practice and procedure, they will be issued as final rules without requesting public comment. *See* 5 U.S.C. 553(b)(3)(A). It should be noted that public comment in this matter is unnecessary, as the new rule will permit but not require e-filing, and will not affect any person's ability to review agency filings. See 5 U.S.C. 553(b)(3)(B). Moreover, good cause is found for making these rules effective on less than 30 days' notice under 5 U.S.C. 553(d) to give interested persons the option to use this new filing method, which will reduce paperwork and ease filing burdens on parties before the agency, as soon as possible.

The Board certifies that the rules will not have a significant impact on a substantial number of small entities. As noted, the e-filing option should streamline and simplify the process of filing certain pleadings and documents with the Board. If the e-filing option is chosen, it will eliminate the need for multiple paper copies and also eliminate the time and expense associated with the physical delivery of paper copies to the Board by mail, messenger or other delivery service, which should be beneficial to entities of all sizes. This action will not significantly affect either the quality of the human environment or the conservation of energy resources.

### List of Subjects in 49 CFR Part 1104

Administrative practice and procedure.

Decided: April 5, 2004.

**By the Board, Chairman Nober.**

*Vernon A. Williams, Secretary.*

■ For the reasons set forth in the preamble, part 1104 of title 49, chapter X, of the Code of Federal Regulations is amended as follows:

## PART 1104—FILINGS WITH THE BOARD—COPIES—VERIFICATION—SERVICE—PLEADINGS, GENERALLY

■ 1. The authority citation for part 1104 continues to read as follows:

**Authority:** 5 U.S.C. 553 and 559; 18 U.S.C. 1621; 21 U.S.C. 862; and 49 U.S.C. 721.

■ 2. Revise the heading for § 1104.1 and add new paragraph (e) to read as follows:

### § 1104.1 Address, identification, and electronic filing option.

* * * * *

(e) Persons filing pleadings and documents with the Board have the option of electronically filing (e-filing) certain types of pleadings and documents instead of filing paper copies. Details regarding the types of pleadings and documents eligible for e-filing, the procedures to be followed, and other pertinent information are available on the Board's Web site, *http://www.stb.dot.gov.* If the e-filing

option is chosen (for those pleadings and documents that are appropriate for e-filing, as determined by reference to the information on the Board's Web site), then the applicable requirements will be those specified on the Web site, and any requirements of 49 CFR part 1104 that are specifically applicable to filing of paper copies will not apply to the e-filed pleadings and documents (these requirements include, but are not limited to, number of copies, stapling or binding specifications, submission of compact disks or floppy diskettes for documents of 20 pages or more, signature "in ink,'' *etc.*). Persons are not required to e-file, and may continue to use the Board's processes for filing paper copies.

**§ 1104.2 [Amended]**

■ 3. Amend the first sentence in § 1104.2(a) by adding the words ", except electronic filings,'' after the word "Documents''.

**§ 1104.3 [Amended]**

■ 4. Amend § 1104.3 as follows:
■ A. In paragraph (a), in the first sentence, remove the words "of every pleading,'' and add in their place "of every paper pleading,''.
■ B. In paragraph (b), add the words "accompanying paper filings'' after the words "Electronic submissions''.
■ C. In paragraph (b)(1), remove the words "in WordPerfect 9.0 format or earlier releases''.
■ 5. Amend § 1104.6 by adding the following sentence at the end of the section:

**§ 1104.6 Timely filing required.**

* * * If the e-filing option is chosen (for those pleadings and documents that are appropriate for e-filing, as determined by reference to the information on the Board's Web site), then the e-filed pleading or document is timely filed if the e-filing process is completed before 5 p.m. eastern time on the due date.

■ 6. Amend §1104.12 by revising paragraph (a) to read as follows:

**§ 1104.12 Service of pleadings and papers.**

(a) *Generally.* Every document filed with the Board should include a certificate showing simultaneous service upon all parties to the proceeding. Service on the parties should be by the same method and class of service used in serving the Board, with charges, if any, prepaid. One copy should be served on each party. If service is made on the Board in person, and personal service on other parties is not feasible, service should be made by first-class or express mail. If a document is filed with the Board through the e-filing process, a copy of the e-filed document should be emailed to other parties if that means of service is acceptable to those other parties, or a paper copy of the document should be personally served on the other parties, but if email is not acceptable to the receiving party and personal service is not feasible, service of a paper copy should be by first-class or express mail. When a party is represented by a practitioner or attorney, service upon the practitioner is deemed to be service upon the party.

* * * * *

[FR Doc. 04–8074 Filed 4–7–04; 8:45 am]

BILLING CODE 4915–01–P

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## DEPARTMENT OF THE INTERIOR

## Fish and Wildlife Service

## 50 CFR Part 17

**RIN 1018–AG09**

## Endangered and Threatened Wildlife and Plants; Determination of Endangered Status and Prudency Determination for Designation of Critical Habitat for Two Plant Species From the Commonwealth of the Northern Mariana Islands

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Final rule.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), determine endangered status and critical habitat prudency pursuant to the Endangered Species Act of 1973, as amended (Act), for two plant species: *Nesogenes rotensis* (no common name) and *Osmoxylon mariannense* (no common name). *Nesogenes rotensis* and *Osmoxylon mariannense* are found only on the island of Rota in the U.S. Commonwealth of the Northern Mariana Islands (CNMI). Based on a public comment, we have re-examined the basis of recognition of *Tabernaemontana rotensis* as a distinct endemic species on Rota and the U.S. Territory of Guam, and are not listing this species as endangered. This rule implements the protection and recovery provisions afforded by the Act for these species.

**DATES:** This rule is effective May 10, 2004.

**FOR FURTHER INFORMATION CONTACT:** Gina M. Shultz, Acting Field Supervisor, the Pacific Islands Fish and Wildlife Office; telephone, 808/792–9400; facsimile, 808/792–9581.

**SUPPLEMENTARY INFORMATION:**

### Background

*Nesogenes rotensis, Osmoxylon mariannense,* and *Tabernaemontana rotensis* all occur on the island of Rota in the CNMI; Tabernaemontana rotensis is also found in the U.S. Territory of Guam.

We provided detailed physical descriptions for these species and their habitats for Guam and Rota in the proposed listing rule (65 FR 35025, June 1, 2000).

*Discussion of the Three Plant Species*

*Nesogenes rotensis*

Williams has observed *Nesogenes rotensis* in flower throughout the year; however, she has never observed it in fruit (Laura Williams, CNMI Division of Fish and Wildlife (DFW), pers. comm. 2004).

Biannual surveys for this species have been conducted since 2000. The species was observed in flower in February 2000, and a direct count was made on June 27, 2000 (L. Arriola, in litt. 2000). At that time there were 80 individuals within an approximate area of 960 $yd^2$ (800 $m^2$). In May and November 2001, direct counts made by staff from CNMI DFW identified 458 and 579 adult plants, respectively. No individuals of *Nesogenes rotensis* were observed in May or November of 2003 following supertyphoon Pongsona; however, 34 adults were observed in December 2003 (L. Williams, pers. comm. 2004).

*Osmoxylon mariannense*

In 2000, a survey conducted by biologists with the CNMI DFW identified six living, and five dead, individual trees on Rota (L. Arriola, in litt. 2000). A survey conducted in 2002 by Taisacan confirmed eight occurrences in this same vicinity, again with only one living mature tree in each. *Osmoxylon mariannense* individuals were defoliated during supertyphoon Pongsona; however, are leafing out and appear to be recovering (E. Taisacan, pers. comm. 2003).

*Tabernaemontana rotensis*

*Tabernaemontana rotensis* has been recognized as an endemic species on Guam and Rota by most who have studied the flora of the Marianas (Fosberg in Stone 1980, Raulerson pers. comm., Herbst pers. comm.) and is recognized as distinct by the government of Guam. Nevertheless, in an authoritative monographic work on the genus in the Old World (Leeuwenberg 1991), it was submerged in an expansive interpretation of the widespread species *T. pandacaqui*, which was originally described from the

Philippines, but that in Leeuwenberg's interpretation ranges from southern China to Australia and includes several dozen previously recognized species. Differences of this sort are not uncommon regarding species or groups of related species that have broad and discontinuous ranges. Prompted in part by a comment from the Air Force, we have re-examined the basis for recognition of *T. rotensis* as a distinct endemic species and now consider Leeuwenberg's treatment to be the most credible taxonomic interpretation of the native *Tabernaemontana* of Guam and Rota. Since we have no authority to list plants at a level below subspecies or variety, and there is no indication that *T. pandacaqui* is endangered or threatened throughout all or a significant portion of its range, we are not listing *T. rotensis*. Despite this determination, we recognize that native *Tabernaemontana* is an important natural resource and an element of the native biodiversity of these two islands. It is perfectly appropriate that local authorities seek to conserve this species, but under our current understanding of its taxonomy, it does not qualify for protection under the Act. If further information becomes available that supports recognition of an endemic taxon, we will reconsider the need to list.

*Previous Federal Action*

On June 1, 2000, we published the proposed rule to list as endangered three plant species from the Mariana Islands (65 FR 35025). In that proposed rule (beginning on page 35027), we included a detailed summary of the previous Federal actions completed prior to publication of the proposal. We now provide updated information on the actions that we have completed since publication of the proposed rule. Our final listing decision for *Nesogenes rotensis*, *Osmoxylon mariannense*, and *Tabernaemontana rotensis* was deferred due to lack of resources because the Service's Pacific Islands Office (where the proposed listing was initiated) staff were under court orders to designate critical habitat for 255 Hawaiian plants and four Hawaiian invertebrates. Pursuant to a settlement agreement approved by the U.S. District Court for the District of Hawaii on August 21, 2002, the Service must make a final decision on whether to list these species and submit this decision to the **Federal Register** by April 1, 2004 (*Center for Biological Diversity* v. *Norton*, Civil No. 99–00603 (D. Haw.)).

*Summary of Comments and Recommendations*

In our June 1, 2000, proposed rule and associated notifications, we requested that all interested parties submit comments, data, or other information that might contribute to the development of a final rule. A 60-day comment period closed on July 31, 2000. Appropriate CNMI and Government of Guam agencies, Federal agencies, and other interested parties were contacted and requested to comment. A legal notice announcing the publication of the listing proposal was published in the Marianas Variety newspaper on June 16, 2000, and the Pacific Daily News on June 23, 2000. During this period we received one request for a public hearing from the CNMI DFW. On October 30, 2000, we gave notice in the **Federal Register** (65 FR 64649) and the Marianas Variety of the public hearing to be held on the island of Rota and reopened the public comment period until November 29, 2000. On November 16, 2000, we held a public hearing at the Rota Resort, Rota.

We reopened the public comment period on January 9, 2004, because we believed that additional review was warranted at this time since three years had passed since publication of the proposed rule (69 FR 1560). In order to address any additional comments received in response to reopening the comment period and to meet the August 21, 2002, court order to submit to the **Federal Register** a final listing decision for these three plants no later than April 1, 2004, the comment period was open for 18 days, closing on January 26, 2004. The reopening of the comment period gave all interested parties additional time to consider the proposed rule's information and submit comments on the proposal.

During the comment periods, we received a total of 18 letters, facsimile transmissions, comment cards, and e-mails from public agencies and individuals. Eleven of these written communications were from various departments of the government of the CNMI and Guam, two were from the Air Force, and the remaining five were from non-governmental entities. Of the written comments, four reviewers supported the listing of *Nesogenes rotensis, Osmoxylon mariannense,* and *Tabernaemontana rotensis,* ten opposed the listing, three provided information on the species but remained neutral on the listing, and one recommended delaying the listing of *Tabernaemontana rotensis.* Five persons provided testimony at the public hearing held on November 16, 2000. We received oral comments from a representative from the Mayor's office on Rota and four representatives from the CNMI DLNR at this public hearing. Representatives of the Mayor's office and the CNMI DLNR also responded by letter or e-mail during the first comment period.

This final rule has been revised and updated to reflect the comments and information received during the comment periods. We address those substantive comments concerning the rule in the summary that follows.

*Peer Review*

Our Interagency Cooperative Policy for Peer Review in Endangered Species Act Activities published in the **Federal Register** (59 FR 34270) states that the Service will incorporate independent peer review in listing decisions during the public comment period in the following manner: (1) solicit the expert opinions of a minimum of three appropriate and independent specialists regarding pertinent scientific and commercial data and assumptions relating to the taxonomy, population models, and supportive biological and ecological information for species under consideration for listing; and (2) summarize in the final decision document the opinions of all independent peer reviewers received on the species under consideration. The purpose of such review is to ensure that listing decisions are based on scientifically sound data, assumptions and analyses, including input of appropriate experts and specialists.

In accordance with our policy, we sought the expert opinions of seven independent reviewers regarding the proposed rule. The purpose of such review is to ensure that our decisions are based on scientifically sound data, assumptions, and analyses. We invited these peer reviewers to comment, during the public comment periods, on the accuracy of the data used regarding the proposed listing of *Nesogenes rotensis, Osmoxylon mariannense,* and *Tabernaemontana rotensis* and conclusions drawn from these data. We received comments from four peer reviewers during the comment period. Three reviewers concur with our determination to list based upon available information on the species. One peer reviewer recommended a delay in the listing of *Tabernaemontana rotensis* pending the collection and analysis of an additional five years of data. All of the reviewers agreed that the proposed rule was based on scientifically sound data, assumptions, and analysis. These experts' comments are incorporated in the final rule and

summarized in the following responses to comments.

Issue 1: Biological Justification and Methodology

*Comment 1:* One peer reviewer recommended that as additional individuals of *Tabernaemontana rotensis* have been found since the time of the proposed listing we continue to gather information on population data and monitor select groups of individuals of to determine local trends in numbers, seedling survival rates, and causes of mortality in populations on the islands of Guam and Rota. Based on the analysis of this new information, the status of the species would then be re-assessed after five years. Other reviewers also suggested that, based on the detection of new individuals, *Tabernaemontana rotensis,* may be more widespread than originally believed. The peer reviewer also believed that we had failed to incorporate information on a significant population of *Tabernaemontana rotensis* which occurs on an upper terrace of Tagua Point.

*Our Response:* The Service collected, collated, and analyzed that new information on the newly documented individuals of *Tabernaemontana rotensis* and distribution on Guam and Rota since the publication of the proposed listing rule in 2000. This included field observations and information from persons with direct knowledge of the species. The new information was provided by knowledgeable private individuals, Territory of Guam and Commonwealth biologists, and the Air Force. However, we are not listing *T. rotensis* on the basis of taxonomy.

*Section 4(i) Comments Received From Commonwealth and Territorial Government Agencies*

Issue 1: Biological Justification and Methodology

*Comment 2:* The Guam Department of Agriculture (GDOA) and the Air Force provided additional information on the locations and population numbers of *Tabernaemontana rotensis*. Several reviewers, including the GDOA, CNMI DLNR, and the Air Force commented, however, that listing of one or more of the three species should be based on the results of comprehensive, island-wide surveys as it would be premature to list them absent the results of such survey efforts.

*Our Response:* As required by the Act (section 4(a)(1)) and its implementing regulations, we must list species as endangered or threatened based on the best available scientific and commercial information. We have determined that *Nesogenes rotensis* and *Osmoxylon mariannense* meet the definition of endangered. However, we are not listing *Tabernaemontana rotensis* on the basis of taxonomy.

As cited above in the response to Comment 1, since publication of the proposed listing in 2000, we have compiled new information on the numbers of individuals and distribution of *Nesogenes rotensis* and *Osmoxylon mariannense* and incorporated this information into the final rule. These two species have been the subject of searches conducted in the last 20 years on Rota by knowledgeable biologists and technicians, including staff from the CNMI DLNR and DFW. Biannual surveys for *Nesogenes rotensis* have been conducted on Rota since 2000 by biologists from the CNMI DFW to assess the health and status of the single known population at Poña Point Fishing Cliff; however, no surveys have been conducted for *Nesogenes rotensis* in other coastal habitat areas on Rota. *Nesogenes rotensis* is currently known from a single population of 34 individuals. Surveys between 1980 and 1995 on Rota located 20 individuals of *Osmoxylon mariannense* in the same limestone forest area that it had been reported from almost 50 years earlier (D. Grout and L. Mehrhoff, pers. comm.1997; L. Raulerson, pers. comm. 1998). Surveys conducted in 1997 and 1998 in the same area following several typhoons located only eight individuals (E. Taisacan and G. Hughes, pers. comm. 1998). In a survey conducted in 2000, CNMI DFW identified six living and five dead trees (L. Arriola, in litt. 2000). And in a 2002 survey, eight living trees were reported in the same vicinity (E. Taisacan, pers. comm. 2003).

*Comment 3:* The CNMI DLNR requested that, in addition to comprehensive, island-wide surveys, the following issues be considered prior to listing: species distribution, identification of destructive pests and diseases, propagation techniques, land ownership rights, public education and awareness, management plans for existing populations, and short- and long-term recovery plans for the species.

*Our Response:* As cited above in response to Comment 2, since publication of the proposed listing in 2000, we compiled new information on the numbers of individuals and the distributions of *Nesogenes rotensis* and *Osmoxylon mariannense,* and have incorporated this information into this final rule.

To date, no specific diseases have been identified for these species, and we are not aware of any research on destructive pests or diseases of these two species. Individuals of *Osmoxylon mariannense* have been reported to suffer defoliation by an unknown agent (L. Mehrhoff and C. Russell, pers. comm. 1997; E. Taisacan, pers. comm. 1997). Invertebrate pests, rats, or disease are suspected to be the cause for a lack of seedlings or juveniles of *Osmoxylon mariannense,* deleterious effects on the leaves, and the death of several mature individual trees (D. Grout, pers. comm. 1997).

We are aware of ongoing efforts by the CNMI DNLR to propagate *Osmoxylon mariannese* for outplanting on Rota (E. Taisacan, in litt. 2002). A summary of these efforts is provided in this final rule below under Factor 3. There is no species-specific management plan.

Currently, no Federal recovery plans exist for *Nesogenes rotensis* and *Osmoxylon mariannense* because such documents are prepared for species subsequent to their listing as endangered or threatened under the Act. Following the listing of *Nesogenes rotensis* and *Osmoxylon mariannese,* recovery plans will be completed pursuant to section 4(f)(1) of the Act for these three species. These plans will provide a framework for combining and coordinating Federal, State, and regional agency efforts for conservation of the species as well as establish recovery priorities and estimate the cost of tasks necessary to accomplish these priorities. They will also describe site-specific management actions necessary to achieve conservation and survival of these species.

*Comment 4:* The GDOA also commented that they did not feel that fire was a threat to *Tabernaemontana rotensis* because none of the trees occur in a fire-prone area, and fire is not known to occur in limestone forests on Guam or Rota. Rather, they point out that fires originate from human use of an area or vandalism. In addition, GDOA feels that few obvious threats to *Tabernaemontana rotensis* have been noted on Guam. Finally, GDOA suggests that clearings created by typhoons or humans might actually favor reproduction in this species and that the species, overall, appears to be quite hardy and resilient to adverse environmental and anthropogenic damage.

*Our Response:* The threat of fire is no longer an issue because we are not listing *T. rotensis* on the basis of taxonomy.

Issue 2: Effects of Listing

*Comment 5:* The CNMI DLNR commented that *Tabernaemontana rotensis* and *Osmoxylon mariannense*

are currently listed as endangered under CNMI public law and that stakeholders have taken the initiative, under local home rule, to protect the resources under their jurisdiction.

*Our Response*: Section 4 of the Act provides guidance regarding the listing of species. Listing decisions are based upon the best scientific and commercial data available and take into consideration those efforts, if any, being made by any State or foreign nation, or any political subdivision of a State or foreign nation, to protect such species, whether by predator control, protection of habitat and food supply, or other conservation practices, within any area under its jurisdiction. With Federal protection as listed species, Federal agencies all insure that these species are not jeopardized pursuant to section 7 actions and Federal monies may be made available for their conservation pursuant to section 6 of the Act. *Osmoxylon mariannense* and *Nesogenes rotensis* are endemic to Rota. *Osmoxylon mariannense* is included on the "List of Protected Wildlife and Plant Species in the CNMI'' (Table 3 of the 1999 revised DFW regulations implementing CNMI Public Law 2–51) for Rota; however, *Nesogenes rotensis* is not. Pursuant to these DFW regulations, protected species may not be hunted or harassed. These regulations do not, however, identify specific prohibitions regarding collection or possession of protected plant species or any requirements to analyze the effects of any proposed actions on such species. Cooperative efforts between the Service and the Rota DFW have resulted in the construction of fenced exclosures around several individuals of *Osmoxylon mariannense* on Rota. We are unaware of any other actions to protect the unfenced trees and to alleviate the threats posed by feral Sambal deer and pigs as well as invasive non-native plant species.

*Comment 6:* The Mayor of Rota commented that there are no Federal lands on Rota and asked if Federal protection would extend to private property.

*Our Response:* Federal protection of listed plants extends to private lands under two circumstances: (1) removal, cutting, digging up, damaging, or destroying endangered plants would constitute a violation of section 9 if conducted in knowing violation of State law or regulations or in violation of State criminal trespass law and (2) any activity that would be authorized, funded, or implemented by a Federal entity requires, pursuant to section 7(a) of the Act, that the Federal entity evaluate their actions with respect to any species that is proposed or listed as endangered or threatened, and with respect to its critical habitat if any is designated (50 CFR part 402). If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into consultation with the Service to ensure that its actions are not likely to jeopardize the continued existence of the species or destroy or adversely modify its critical habitat. Examples of Federal agency actions on private lands in the Commonwealth of the Northern Mariana Islands that may require consultation include the following: Army Corps of Engineers projects, such as the construction of roads, firebreaks, and bridges; various U.S. armed forces activities on the northern Mariana Islands, including combat and mobility training and construction; Natural Resources Conservation Service projects; Federal Emergency Management Agency activities; and U.S. Department of Housing and Urban Development projects. Conservation of these plant species may be consistent with some ongoing operations at these sites; however, the listing of these species in the CNMI could result in some restrictions on certain Federal activities and the use of certain lands.

*Comment 7:* The Air Force and another reviewer commented that the Service should accept the taxonomic inclusion of *Tabernaemontana rotensis* into *Tabernaemontana pandacaqui* based on Leeuwenburg (1991) as it is the only peer-reviewed study directly applicable on Guam.

*Our Response:* We have re-examined the basis for recognition of *T. rotensis*' as a distinct endemic species and now consider Leeuwenberg's treatment to be the most credible taxonomic interpretation of the native *Tabernaemontana* of Guam and Rota. Accordingly, we are not listing *T. rotensis*.

*Non-Government Comments*

*Comment 8:* One reviewer asked if the listing of *Nesogenes rotensis, Osmoxylon mariannense,* and *Tabernaemontana rotensis* would impede local recovery efforts with the need to obtain numerous Federal permits and extra paperwork that would be required by the Service policy regarding the propagation of listed species.

*Our Response:* Under the Act, the controlled propagation of animals and plants in certain situations is recognized as an essential tool for the conservation and recovery of listed species. In recognition of this, our "Policy Regarding Controlled Propagation of Species Listed Under the Act'' (65 FR 56916) addresses botanical facilities and others who may be involved in the propagation of listed species. The goals of this policy include coordinating recovery actions specific to controlled propagation activities; maximizing benefits to the listed species from controlled propagation efforts; assuring that appropriate recovery measures other than controlled propagation and other existing recovery priorities are considered in making controlled propagation decisions; and ensuring prudent use of funds. We have also made substantial efforts to avoid adverse impacts, economic or otherwise, in order that cooperative recovery partnership opportunities may be maintained or increased with qualified organizations and individuals. As such, no significant adverse impacts to persons or entities involved in the propagation of federally-listed plant species, including *Osmoxylon mariannense* and *Nesogenes rotensis*, are anticipated.

*Comment 9:* One reviewer commented that the Service should propose critical habitat for *Nesogenes rotensis, Osmoxylon mariannense,* and *Tabernaemontana rotensis* concurrent with the final rule to list the species.

*Our Response:* In this final rule, we find that critical habitat for *N. rotensis* and *O. mariannense* is prudent but not determinable at this time due to a lack of information regarding the physical and biological features or specific areas essential to the conservation of these three species. In accordance with section 4(b)(6)(C)(ii) of the Act, however, it is our intent, if funded, to gather this information and to propose critical habitat for these two plant species within one year of their listing. In the interim, we will protect the two plant species through the provisions provided pursuant to sections 7 and 9 of the Act. However, we are not listing *T. rotensis* on the basis of taxonomy.

*Comment 10:* One reviewer asked if the listing of *Nesogenes rotensis*, *Osmoxylon mariannense*, and *Tabernaemontana rotensis* would result in extra protection for these three species.

*Our Response:* This is discussed in Our Response to Comment 6. However, we are not listing *T. rotensis* on the basis of taxonomy.

*Summary of Factors Affecting the Species*

Section 4(a)(1) (16 U.S.C. 1531 *et seq.*) of the Act and regulations (50 CFR part 424) promulgated to implement the Act describe the procedures for adding species to the Federal lists. We may

determine a species to be endangered or threatened due to one or more of the five factors described in section 4(a)(1) of the Act. These factors and their application to *Nesogenes rotensis* and *Osmoxylon mariannense* are discussed in the following sections. The primary threats facing these two species are summarized in Table 1.

The only known population of *Nesogenes rotensis* at Poña Point Fishing Cliff occurs in an area adjacent to a trail that is subject to bonfires, collecting, trampling by fishermen and tourists, and potential expansion of the park's facilities. *Casuarina equisetifolia* (ironwood), a large-stature, fast-growing non-native tree, is colonizing the Poña Point Fishing Cliff area. Ironwoods can reach heights of up to 65 ft (20 m) and form monotypic stands that can shade out other plant species. Dominance by *Casuarina equisetifolia* takes up much of the available nutrients, and the species is believed to release allelopathic chemicals that prevent understory growth (Neal 1965; Smith 1985). Ironwoods presence constitutes a major threat to *Nesogenes rotensis* through degradation of suitable habitat. As such, given the current single population is comprised of only 34 individuals, *Nesogenes rotensis* is extremely vulnerable to other factors. For example, two typhoons have made landfall on Guam and Rota since this species was proposed for listing: typhoon Chataan in July 2002 and supertyphoon Pongsona in December 2002. While the species appears to be recovering from the effects of supertyphoon Pongsona, it remains extremely vulnerable during this recovery period (L. Williams, pers. comm. 2004).

TABLE 1.—SUMMARY OF PRIMARY THREATS TO *Nesogenes rotensis* AND *Osmoxylon mariannense*

| Species | Feral animals | Rodents | Non-native plants | Invertebrate pests | Development/ road work | Typhoons/ storms | Trampling/ collection | Vandalism | Limited numbers |
|---|---|---|---|---|---|---|---|---|---|
| *Nesogenes rotensis.* | Unknown | Unknown | Yes ..... | Unknown ..... | Yes ..... | Yes ..... | Yes ..... | Potential | Yes; 34 individuals. |
| *Osmoxylon mariannense.* | Yes ..... | Potential | Yes ..... | Potential ..... | Yes ..... | Yes ..... | Unknown .. | Potential | Yes; 8 individuals. |

The primary threat to *Osmoxylon mariannense* is degradation or disturbance of native forest habitat from a variety of factors including competition from invasive non-native species and feral ungulate activity. Rota has historically experienced typhoon disturbances that have opened the canopy of the sabana forest considerably, creating conditions favorable to invasive non-native shrubs and vines that compete with *Osmoxylon mariannense* (L. Mehrhoff, in litt. 1995). Feral pigs (*Sus scrofa*) and deer (*Cervus mariannus*) are abundant on Rota, and their browsing and trampling threaten unfenced individuals (G. Hughes, pers. comm. 1998; L. Williams, pers. comm. 2004). Predation of seeds that fall to the forest floor by insects, house mice (*Mus musculus*), and/or rats (*Rattus* spp.) is also a suspected cause of reduced or absent reproductive vigor. Since several individuals occur in close proximity to roadways, routine road maintenance and/or improvement also pose a threat to the species.

A. *The present or threatened destruction, modification, or curtailment of its habitat or range.* Native vegetation, including cloud limestone forest habitat for *Osmoxylon mariannense* and open coastal scrubland habitat for *Nesogenes rotensis* on Rota, has undergone extreme alteration due to past and present land use practices, including ranching, deliberate and unintentional non-native animal and plant introductions, agricultural, and military activities during World War II (Falanruw *et al.* 1989).

Rota was subject to extensive agricultural development (particularly cultivation of sugar cane in the lowland areas) by the Japanese prior to World War II. The island was not, however, invaded by allied forces during World War II. Rota retains less than 60 percent of its historic native forest (Falanruw *et al.* 1989). Continued loss of native forest is attributable to application of the Agricultural Homestead Act of 1990 that allows for the distribution of 2.5-ac (1-ha) parcels of public land to eligible participants. Land use plans have proposed that approximately 25 to 45 percent of Rota be designated private agricultural homestead land or as land likely to be converted to agricultural homesteads (Resources Northwest, Inc. 1997). In 2001, the Agricultural Homestead Act of 1990 was amended to allow agricultural homestead permitting on any public lands not required for government use or reserved for other purposes by any other provision of the law. Thus, individuals awaiting permits may choose many areas of Rota's public lands for agricultural homesteads, rather than areas planned and reserved specifically for those purposes (Pub. L. 12–53). Therefore, the potential for agricultural development continues to threaten the remaining limestone forests on Rota, which include habitat for *Osmoxylon mariannense.*

Throughout the Mariana Islands, goats, pigs, cattle, and deer have severely damaged forest vegetation by browsing on plants, causing habitat degradation and erosion (Kessler 1997; Marshall *et al.* 1995) that then retards forest growth and regeneration (Lemke 1992). Remaining habitat is threatened by fragmentation and degradation associated with resort development, agricultural activities, and road maintenance and construction (D. Grout and L. Mehrhoff, pers. comms. 1997). Individuals of *Osmoxylon mariannense* on Rota were almost lost during road-widening activities that occurred in the late 1990s (D. Grout and L. Mehrhoff, pers. comms. 1997). Coastal habitat is threatened by fragmentation and degradation associated with resort development, and potential beach park expansion and development of park facilities at the only known location of *Nesogenes rotensis.*

B. *Overutilization for commercial, recreational, scientific, or educational purposes.* At this time, overutilization of the two species is not known to be an important factor. Unrestricted scientific or horticultural collecting by interested individuals may significantly affect these species due to their extremely low numbers. The only population of *Nesogenes rotensis* is located in a public park and threatened by trampling by foot traffic and bonfires set by tourists and fishermen. Due to the small population size, reproductive vigor may also be depressed by a limited gene pool.

Propagation studies are ongoing only for *Osmoxylon mariannense* on Rota. Seeds were collected from wild individuals of *Osmoxylon mariannense* and planted in October 2001 and March 2002. From the October planting, approximately 150 individuals had germinated by November, and, as of March 2002, 11 are surviving in a

nursery. The seeds planted in March 2002, produced approximately 100 seedlings. Thirty-five of these individuals survived and are in good condition (Taisacan 2002).

C. *Disease and predation.* To date, no specific diseases have been identified for these species. Individuals of *Osmoxylon mariannense* have suffered defoliation by an unknown agent (E. Taisacan, pers. comm. 1997). Invertebrate pests, rats, or disease are suspected to have caused the defoliation due to the poor health of the leaves, the lack of seedlings or juveniles of *Osmoxylon mariannense,* and the death of several previously mapped older individual plants (D. Grout, pers. comm. 1997).

Feral ungulates threaten seedlings of *Osmoxylon mariannense* (G. Wiles, in litt. 1998; D. Janeke, pers. comm. 2003; L. Williams, pers. comm. 2004). Cooperative efforts between the Service and the Rota DFW have resulted in the construction of fenced exclosures around several individuals of *Osmoxylon mariannense.* The majority of individuals of *Osmoxylon mariannense* are not currently protected by fencing and are vulnerable to browsing or trampling by feral ungulates.

D. *The inadequacy of existing regulatory mechanisms. Osmoxylon mariannense* is on the list of protected species for the government of the CNMI but there are no specific prohibitions regarding collection or possession of protected plant species or requirement for the analysis of potential adverse effects associated with proposed projects. *Nesogenes rotensis* is not included on this list of protected species in the CNMI.

At the time of publication of the proposed rule, an island-wide multiple species habitat conservation plan for Rota was envisioned by the CNMI government and local Rota residents. This plan was to be prepared with technical assistance from the Service. The preparation of this plan has since been abandoned by the CNMI government in lieu of the development of a project-specific habitat conservation plan to address impacts to a single species, the Mariana crow (*Corvus kubaryi*) (Arlene Pangelinan, Service, pers. comm. 2003).

E. *Other natural or manmade factors affecting its continued existence.* The combination of storm disturbance and resultant competition from invasive, non-native plant species adversely affects the condition of habitat occupied by *Osmoxylon mariannense* (L. Williams, pers. comm. 2004). Rota has a long history of disturbances by tropical typhoons (Weir 1991). While native biota are adapted to these events, these typhoons, in combination with anthropogenic disturbances, and the relatively new presence of invasive species threaten the continued existence of *Nesogenes rotensis* and *Osmoxylon mariannense.* Within the past decade, frequent typhoons have made landfall on Rota, severely affecting the islands. Most recently, super typhoon Pongsona affected the Mariana Islands, particularly Guam and Rota, with winds of up to 184 mph. While *Nesogenes rotensis* and *Osmoxylon mariannense* are expected to have adapted to high winds, typhoons, and storm surge, their distribution and numbers have been reduced significantly due to human activities and this makes the remaining individuals particularly susceptible to extirpation or extinction from a natural disaster. Destruction of the sabana forest canopy by typhoons has adversely affected *Osmoxylon mariannense* by altering sub-canopy vegetation conditions over the long-term by opening up and drying out older, closed forest habitat (E. Taisacan, pers. comm. 1998; L. Williams, pers. comm. 2004). The single population of *Nesogenes rotensis* is extremely vulnerable to typhoons, storm surge, and high surf because its open scrubland habitat is located in a coastal area. *Osmoxylon mariannense* is threatened by competition from one or more invasive, non-native plant species including *Momordica charantia, Mikania scandens,* and *Passiflora suberosa.* In opened forest areas, various opportunistic, weedy vines such as *Momordica charantia, Momordica scandens,* and *Passiflora suberosa* cover the ground (Fosberg 1960; G. Hughes, pers. comm. 1998) and may alter conditions necessary for seed germination and seedling growth provided in closed-canopy, high-stature forests covered with mosses and various epiphytic species. *Casuarina equisetifolia* is becoming established in the coastal scrubland habitat at Pona Point Fishing Cliff and will likely spread and change the coastal scrubland into a forest habitat with no understory due to restriction of available sunlight, restriction of available nutrients, and possibly release of a chemical agent that prevents other plants from growing beneath it and, thereby, adversely affecting the single remaining population of *Nesogenes rotensis* (Smith 1985; L. Williams, pers. comm. 2004).

Small population size and limited distribution make these species particularly vulnerable to extinction from reduced reproductive vigor or random environmental events. On Rota, 8 individuals of *Osmoxylon mariannense,* and a single population of 34 individuals of *Nesogenes rotensis* are known. A single adverse environmental event or lack or decline of successful reproduction in *Nesogenes rotensis* or *Osmoxylon mariannense* could lead to the extinction of these two species. *Nesogenes rotensis* is found in the coastal zone where a single disturbance from storm surge could destroy a significant percentage of the individuals or the entire population. In addition, the continuing adverse impacts of trampling of *Nesogenes rotensis* by people and/or expansion of facilities at Pona Point could also destroy a significant percentage of the individuals or the entire population resulting in the extinction of this species.

We have carefully assessed the best scientific and commercial information available on the past, present, and future threats facing these species in determining the actions to take in this rule. Based on this evaluation, the appropriate action is to list *Nesogenes rotensis* and *Osmoxylon mariannense* as endangered. *Nesogenes rotensis* is endemic to the island of Rota and has one population with fewer than 34 individuals. *Osmoxylon mariannense* is endemic to the island of Rota and has eight occurrences, with only one living tree in each. These two species are threatened by one or more of the following: habitat degradation or destruction by feral ungulates; competition for space, light, water, and nutrients with invasive non-native plant species; road construction and maintenance activities; trampling by humans (*Nesogenes rotensis*); development; limited reproductive vigor; vandalism; natural disasters or random environmental events; and potentially disease or predation by insects, mice, or rats. Because these species are in danger of extinction throughout all or a significant portion of their ranges, they fit the definition of endangered as defined in the Act.

**Critical Habitat**

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12) require that, to the maximum extent prudent and determinable, the Secretary designate critical habitat at the time the species is determined to be endangered or threatened. Our implementing regulations (50 CFR 424.12(a)) state that critical habitat is not determinable if information sufficient to perform the required analyses of impacts of the designation is lacking, or if the biological needs of the species are not

sufficiently well known to permit identification of an area as suitable habitat.

We find that designation of critical habitat for *Nesogenes rotensis* and *Osmoxylon mariannense,* is not determinable at this time because we are unable to identify the physical and biological features essential to the conservation of these two species and we are unable to identify whether specific unoccupied areas are essential for their conservation. When a "not determinable'' finding is made, we must, within one year of the publication date of the final listing rule, designate critical habitat, unless the designation is found to be not prudent.

We will continue to protect these two species and their habitat through the recovery process and section 7 consultations to assist Federal agencies in avoiding jeopardizing these species.

*Available Conservation Measures*

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, development of recovery plans, requirements for Federal protection, and prohibitions against certain activities. Recognition through listing results in public awareness and encourages conservation actions by Federal, State, Tribal, and local agencies, non-governmental conservation organizations, and private individuals. The Act provides for possible land acquisition and cooperation with the States and requires that recovery actions be carried out for listed species. Recovery planning and implementation, the protection required by Federal agencies and the prohibitions against certain activities involving listed species are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Subsection 4(f) of the Act requires the Service to develop and implement plans for the conservation of endangered and threatened species ("recovery plans''). The recovery process involves halting or reversing the species' decline by addressing the threats to its survival. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems, thus allowing delisting.

Recovery planning, the foundation for species recovery, includes the development of a recovery outline as soon as a species is listed, and later, preparation of draft and final recovery plans, and revision of the plan as significant new information becomes available. The recovery outline—the first step in recovery planning—guides the immediate implementation of urgent recovery actions, and describes the process to be used to develop a recovery plan. The recovery plan identifies site-specific management actions that will achieve recovery of the species, measurable criteria that determine when a species may be downlisted or delisted, and methods for monitoring recovery progress. Recovery teams, consisting of species experts, Federal and State agencies, non-government organizations, and stakeholders, are often established to develop recovery plans. When completed, a copy of the recovery outline, draft recovery plan, or final recovery plan will be available from our Web site (*http://endangered.fws.gov*) or, if unavailable or inaccessible, from our office (see **FOR FURTHER INFORMATION CONTACT** section).

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, States, non-governmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (*e.g.*, restoration of vegetation), research, captive propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands. To achieve the recovery of these species requires cooperative conservation efforts on private lands as many occur primarily or solely on private lands.

The funding for recovery actions can come from a variety of sources, including Federal budgets, State programs, and cost share grants for non-Federal landowners, the academic community, and non-governmental organizations. Additionally, pursuant to section 6 of the Act, we would be able to grant funds to the CNMI for management actions that promote the protection and recovery of these two plant species. Information on the Service's grant programs that are available to aid species recovery can be found on our Web site at: *http://endangered.fws.gov/grants/index.html.* In the event that our internet connection is inaccessible, please check *www.grants.gov* or check with our grants contact at U.S. Fish and Wildlife Service, Ecological Services, 911 NE 11th Avenue, Portland, OR 97232–4181 (telephone 503/231–2063; FAX 503/231–6243).

For additional information on available conservation measures, refer to Summary of Factors Affecting the Species, B.

Please let us know if you are interested in participating in recovery efforts for *Nesogenes rotensis* and *Osmoxylon mariannense* (see **FOR FURTHER INFORMATION CONTACT** section). Additionally, we invite you to submit any further information on these species whenever it becomes available or other information you may have for species' recovery planning purposes (see **FOR FURTHER INFORMATION CONTACT** section).

Section 7(a) of the Act, as amended, requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened, and with respect to its critical habitat if any is being designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species or destroy or adversely modify its critical habitat if any has been designated. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into formal consultation with us.

Federal agency actions that may require consultation for *Nesogenes rotensis* and *Osmoxylon mariannense* include, but are not limited to: Army Corps of Engineers projects, such as the construction of roads, firebreaks, and bridges; various U.S. armed forces activities on the northern Mariana Islands, such as combat and mobility training, and construction; Natural Resources Conservation Service projects; Federal Emergency Management Agency activities; and U.S. Department of Housing and Urban Development projects. Federal actions not affecting the two species, as well as actions on non-Federal lands that are not federally funded or permitted, would not require section 7 consultation.

The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to all endangered plants. All prohibitions of section 9(a)(2) of the Act implemented at 50 CFR 17.61 for endangered plants would apply. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to import or export, transport in interstate or foreign commerce in the course of a commercial activity, sell or offer for sale these two species in interstate or foreign

commerce, or to remove the species from areas under Federal jurisdiction. In addition, for plants listed as endangered, the Act prohibits the malicious damage or destruction in areas under Federal jurisdiction and the removal, cutting, digging up, damaging, or destroying of such endangered plants in knowing violation of any State, Commonwealth, or Territory law or regulation, or in the course of any violation of State, Commonwealth, or Territory criminal trespass law. Certain exceptions to the prohibitions apply to any employee or agent of the Service, any other Federal land management agency, or a State conservation agency (50 CFR 17.61(c)(2)–(4)).

The Act and 50 CFR 17.62 and 17.63 also provide for the issuance of permits to carry out otherwise prohibited activities involving endangered plant species under certain circumstances. Such permits are available for scientific purposes, to enhance the propagation or survival of the species. We anticipate that the only permits that would be sought or issued would be in association with recovery efforts as these two species are not common in cultivation or the wild.

It is our policy, published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify, to the maximum extent practicable at the time a species is listed, those activities that are likely to constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effects of the listing on proposed and ongoing activities within a species' range.

We believe the following activities could potentially result in a violation of section 9; however, possible violations are not limited to these actions alone: collection (including scientific collection absent authorization by the Service), damage, or destruction of *Nesogenes rotensis* or *Osmoxylon mariannense* on non-Federal lands if conducted in knowing violation of CNMI law or regulations, including CNMI criminal trespass law. In addition, possible violations include importing or exporting these species, and selling or shipping specimens in interstate or foreign commerce in the course of commercial activity.

We will review other activities not identified above on a case-by-case basis to determine whether they may be likely to result in a violation of section 9 of the Act. We do not consider these lists to be exhaustive and provide them as information to the public. You should direct questions regarding whether specific activities would constitute a violation of section 9 to the Field Supervisor of the Pacific Islands Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT** section).

You may request copies of the regulations regarding listed plants and address questions about prohibitions and permits to the U.S. Fish and Wildlife Service, Ecological Services, Permits Branch, 911 NE 11th Avenue, Portland OR 97232–4181 (telephone 503/231–2063; FAX 503/231–6243).

*National Environmental Policy Act*

We have determined that environmental assessments and environmental impact statements, as defined in the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted pursuant to section 4(a) of the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

*Civil Justice Reform*

In accordance with Executive Order 12988, the Department of the Interior's Office of the Solicitor has determined that this rule does not unduly burden the judicial system and does meet the requirements of sections 3(a) and 3(b)(2) of the Order. We have listed *Nesogenes rotensis* and *Osmoxylon mariannense* as endangered species in accordance with the provisions of the Endangered Species Act.

*Paperwork Reduction Act*

This rule does not contain any new collections of information that require approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This rule will not impose record keeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The existing OMB control number is 1018–0094 and expires July 31, 2004.

*References Cited*

A complete list of all references cited in this rulemaking is available upon request from the Pacific Islands Fish and Wildlife Office (See **FOR FURTHER INFORMATION CONTACT** section.)

*Author*

The primary authors of this final rule are the staff of the Fish and Wildlife Service (see **FOR FURTHER INFORMATION CONTACT** section).

**List of Subjects in 50 CFR Part 17**

Endangered and threatened species, Exports, Imports, Reporting and record-keeping requirements, Transportation.

**Regulation Promulgation**

■ Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

## PART 17—[AMENDED]

■ 1. The authority citation for part 17 continues to read as follows:

**Authority:** 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

■ 2. Section 17.12(h) is amended by adding the following, in alphabetical order under FLOWERING PLANTS, to the List of Endangered and Threatened Plants:

**§ 17.12 Endangered and threatened plants.**

* * * * *

(h) * * *

| Species | | Historic range | Family | Status | When listed | Critical habitat | Special rules |
|---|---|---|---|---|---|---|---|
| Scientific name | Common name | | | | | | |
| FLOWERING PLANTS | | | | | | | |
| * | * | * | * | * | * | * | |
| *Nesogenes rotensis* ..... | None ..... | Western Pacific Ocean—U.S.A. (Commonwealth of the Northern Mariana Islands). | Verbenaceae—Verbena family. | E | 742 | NA | NA |

| Species | | Historic range | Family | Status | When listed | Critical habitat | Special rules |
|---|---|---|---|---|---|---|---|
| Scientific name | Common name | | | | | | |
| * | * | * | * | * | * | * | * |
| *Osmoxylon mariannense.* | None | Western Pacific Ocean—U.S.A. (Commonwealth of the Northern Mariana Islands). | Araliaceae—Ginseng family. | E | 742 | NA | NA |
| * | * | * | * | * | * | * | * |

Dated: April 1, 2004.

**Marshall Jones,**

*Deputy Director, Fish and Wildlife Service.*

[FR Doc. 04–7934 Filed 4–7–04; 8:45 am]

**BILLING CODE 4310–55–P**

# Proposed Rules

Federal Register
Vol. 69, No. 68
Thursday, April 8, 2004

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 TRANSPORTATION

### Federal Aviation Administration

### 14 CFR Part 71

**[Docket No. FAA–2003–16457; Airspace Docket No. 03–ASO–4]**

**RIN 2120–AA66**

### Proposed Revision of Federal Airway V–521

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Proposed rule; withdrawal.

**SUMMARY:** This action withdraws the notice of proposed rulemaking (NPRM) published in the **Federal Register** on January 14, 2004 (69 FR 2091). In that notice the FAA proposed to revise a segment of Very High Frequency Omnidirectional Range (VOR) Federal Airway 521 (V–521), between the Lee County Very High Frequency Omnidirectional Range/Tactical Air Navigation (VORTAC), and the RINSE intersection. The change was proposed to support the development of a new Standard Terminal Arrival Route (STAR) to serve the Southwest Florida International Airport and the Page Field Airport at Fort Myers, FL. However, after an internal review, the FAA has decided not to implement the planned STAR, therefore, the proposed revision of V–521 is being withdrawn upon publication of this action.

**EFFECTIVE DATE:** 0901 UTC, April 8, 2004.

**FOR FURTHER INFORMATION CONTACT:** Paul Gallant, Airspace and Rules, Office of System Operations and Safety, ATO–R, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8783.

**SUPPLEMENTARY INFORMATION:** On January 14, 2004, an NPRM was published in the **Federal Register** (69 FR 2091) proposing to amend Title 14 Code of Federal Regulations (14 CFR) part 71 (part 71) to revise a segment of V–521 between the Lee County VORTAC and the RINSE intersection. The change was proposed to support the development of a new STAR to serve the Southwest Florida International Airport and Page Field Airport at Fort Myers, FL. These changes were planned as part of an airspace redesign effort to enhance the management of air traffic operations into and out of southwest Florida.

After an internal review of the plan, the FAA has decided not to implement the planned STAR. Consequently, the proposed revision to V–521 is being withdrawn upon publication of this action.

#### List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

#### The Withdrawal

In consideration of the foregoing, the NPRM, Docket No. FAA–2003–16457/ Airspace Docket No. 03–ASO–4, as published in the **Federal Register** on January 14, 2004 (69 FR 2091), is hereby withdrawn.

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

* * * * *

Issued in Washington, DC, on April 1, 2004.

**Reginald C. Matthews,**

*Manager, Airspace and Rules Division.*

[FR Doc. 04–7958 Filed 4–7–04; 8:45 am]

**BILLING CODE 4910–13–P**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 54

**[GN Docket No. 04–54; FCC 04–55]**

### Deployment of Advanced Telecommunications Capability to All Americans in a Reasonable and Timely Fashion, and Possible Steps To Accelerate Such Deployment

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice of Inquiry; solicitation of comments.

**SUMMARY:** In this document, the Commission seeks comment on various market, investment, and technological trends in order for the Commission to analyze and assess whether infrastructure capable of supporting advanced services is being made available to all Americans in a reasonable and timely fashion.

**DATES:** Comments are due on or before May 10, 2004. Reply comments are due on or before May 24, 2004.

**ADDRESSES:** Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554. *See* **SUPPLEMENTARY INFORMATION** for further filing instructions.

**FOR FURTHER INFORMATION CONTACT:** Regina M. Brown, Attorney, Wireline Competition Bureau, Telecommunications Access Policy Division, (202) 418–7400, TTY (202) 418–0484.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's *Notice of Inquiry*, GN Docket No. 04–54, released March 17, 2004. The full text of this document is available for public inspection during regular business hours in the FCC Reference Center, Room CY–A257, 445 12th Street, SW., Washington, DC 20554.

#### I. Introduction

1. In this *Notice of Inquiry* (Notice), the Commission begins its fourth inquiry under section 706 of the Telecommunications Act of 1996 (the 1996 Act) into "whether advanced telecommunications capability is being deployed to all Americans in a reasonable and timely fashion.'' We seek comment on various market, investment, and technological trends in order for the Commission to analyze and assess whether infrastructure capable of supporting advanced services is being made available to all Americans in a reasonable and timely fashion.

2. In section 706, Congress directed the Commission and the states to encourage the deployment of advanced telecommunications capability to all Americans. In conjunction with this objective, Congress instructed this Commission to conduct regular inquiries concerning the availability of advanced telecommunications capability. In so doing, Congress recognized that the availability of infrastructure capable of transmitting broadband or advanced services was critical to the future of our nation. Advanced services already play a vital role, and will continue to do so throughout the 21st century, in the

nation's economy and the life of its people. Many U.S. companies, both large and small, now depend on advanced services to run various facets of their businesses, including tracking inventory, monitoring consumer relations, and forecasting product sales. Moreover, advanced services have created new jobs, while enabling skilled employees to work more effectively in their current jobs. Advanced services have also created greater flexibility and opportunity in the workplace, particularly in the increased use of telecommuting by employees who remain connected to their jobs despite distance and other factors.

3. In addition to their benefits to the economy, advanced services have a dramatic impact on everyday citizens. Advanced services improve the educational opportunities of children and adults everywhere. High-speed connections to the Internet allow children in rural areas from Alaska to Florida to access the same information as schoolchildren in urban areas. Moreover, distance learning provides more choices for children and adults to access educational materials of distant learning institutions.

4. Telemedicine networks made possible by advanced services save lives and improve the standard of healthcare in sparsely-populated, rural areas. These services bring the skills and knowledge of specialized doctors and other medical professionals to people that would otherwise have to travel long distances to reach them. Advanced services also permit rural healthcare providers to utilize the latest medical information, which, in turn, improves the general provision of healthcare in areas of the country that have traditionally been underserved.

5. Applications that require advanced telecommunications capability will continue to grow exponentially. Only a few years ago, applications and services that we take for granted today were unheard of by a vast segment of the population. These developments are expected to reduce the cost of communication and to spur innovation and individualization on a previously unthinkable scale. For example, companies are developing services and applications making use of Internet Protocol (IP), including Voice over IP (VoIP), which are delivered over broadband connections. This new communications environment could provide each consumer with a highly customized, low-cost choice of services delivered in the manner of his or her choosing. Therefore, monitoring the progress of deployment of advanced telecommunications platforms and determining if steps can or should be taken to further encourage this growth is one of the Commission's most important duties. We strongly encourage commenters to provide data and new ideas on how to conduct this and future section 706 inquiries. We also invite the Federal-State Joint Conference on Advanced Telecommunications Services (Joint Conference) to submit any information that it deems appropriate into this docket.

## II. Issues for Inquiry

6. At the outset, we solicit information consistent with the framework utilized in past reports: (i) How should we define advanced telecommunications capability? (ii) is advanced telecommunications capability being deployed to all Americans? (iii) is the current level of deployment reasonable and timely? and (iv) what actions, if any, can be taken to accelerate deployment? We intend, however, to extend our analysis beyond the framework of our previous 706 reports to examine additional questions of potential interest to policymakers. In particular, we seek to develop a more rigorous analysis of the availability of advanced telecommunications capability in different market segments and areas of varying densities. Moreover, we seek to develop a better understanding of the economic considerations that support the deployment of advanced telecommunications capability. We hope to analyze available information relating to consumer adoption and usage of services requiring advanced telecommunications capability. We also intend to examine trends in other nations and how our deployment of advanced telecommunications capability affects our role in a global economy. We welcome any additional information that commenters believe would further public understanding and dialogue on these critical issues.

### A. What Is "Advanced Telecommunications Capability"?

7. We seek comment on how we should define "advanced telecommunications capability'' for purposes of this inquiry. Since 1999, the Commission has used the terms "advanced telecommunications capability'' as "high-speed, switched, broadband telecommunications capability,'' but did not specify what speed should be encompassed within these terms. In the past, the Commission used the terms "advanced telecommunications capability'' and "advanced services'' to describe services and facilities with an upstream (customer-to-provider) and downstream (provider-to-customer) transmission speed of more than 200 kilobits per second (kbps). The Commission also used the term "high-speed'' to describe services and facilities with over 200 kbps capability in at least one direction. Given the rapid technological changes in the marketplace, we seek comment on the need to alter the definitional framework utilized in prior inquiries. Has technology or the marketplace evolved such that we should redefine the term "advanced services'' to be speeds higher than 200 kbps in one or both directions? Have consumer expectations with respect to bandwidth needs changed since prior reports? What sources of information currently exist regarding the deployment of advanced telecommunications capability under alternative definitions? We note that we intend to seek comment in a separate proceeding on whether to amend our existing FCC Form 477 reporting program to gather more detailed information about the provision of services at speeds higher than 200 kbps. Are there reasons other than the status of technological development that support modifying the definition? Are any other attributes, besides speed in which a particular quantity of information can be transmitted, relevant to the definition of advanced telecommunications capability?

8. In a report to Congress released after our last 706 inquiry, the General Accounting Office (GAO) recommended that the Commission "should develop a strategy for periodically evaluating whether existing informal and experimental methods of data collection are providing the information needed to monitor the essential characteristics and trends of the Internet backbone market and the potential effects of the convergence of communications services.'' The GAO also recommended that "if a more formal data collection program is deemed appropriate, [the Commission] should exercise its authority to establish such a program.'' We seek comment on the GAO's recommendations, and whether our existing methods of data collection relating to the Internet backbone are sufficient.

### B. Is Advanced Telecommunications Capability Being Deployed to All Americans?

9. We seek comment on whether advanced telecommunications capability is being deployed to all Americans. In particular, we seek comment on three general areas in order to facilitate our analysis: (1) The availability of advanced

telecommunications capability and whether it has changed since the *Third Report*, 66 FR 44636, August 24, 2001; (2) the economics underlying investment in advanced infrastructure and service deployment; and (3) various advances in advanced services technology.

10. *Availability.* As previously noted, the Commission began gathering data about the provision of high-speed and advanced services to end users in 2000. Our current data collection program requires any facilities-based provider that has at least 250 high-speed service lines or wireless channels in service in a state to report basic information about its service offerings and customers twice yearly. Each filer provides data on the total number of lines or wireless channels by technology (*i.e.*, service provided on coaxial cables, wireline telephone lines, fixed wireless, or satellite). For each "technology subtotal,'' providers report additional detail concerning the percentage of lines that are connected to residential and small business users, the percentage of lines that provide service at more than 200 kbps in both directions, and the number of lines that provide speeds exceeding 2 Mbps.

11. From this data, we obtain a verifiable count of how much service within specified parameters is being delivered by those service providers that responded. Given the association between subscription and deployment, such data collection provides a means to assess the pace at which advanced telecommunications capabilities are being made available in different parts of the country and across different demographic groups. Moreover, we will shortly propose to revise our current FCC Form 477 to obtain more detailed understanding of the provision of services with greater bandwidth than 200 kbps and the availability of the broadband technologies that have achieved the greatest mass market acceptance to date, cable modems and DSL connections, which should facilitate future 706 inquiries.

12. We recognize that altering our current Form 477 reporting framework could provide additional information that would be useful in analyzing the state of deployment of advanced telecommunications capabilities. Obtaining more detailed information about services at speeds higher than 200 kbps could become a valuable tool to assist us in future section 706 inquiries. At the same time, we encourage commenters in this proceeding to provide us with more detailed information about the provision of services today at speeds higher than 200 kbps.

13. We recognize that providers are not currently required to report the number or type of high-speed service subscribers in each zip code, but only to report the zip codes in which they had at least one high-speed service subscriber. As a result, we cannot determine from our data the extent to which high-speed services in a given zip code indicates that high-speed services are widely available, or whether they are restricted to certain types of customers located in limited areas. The zip code data depicts areas where at least one customer receives high-speed services in the last mile to the customer premises. This data provides the Commission with one tool for our analysis of whether advanced telecommunications capability is being made available to all Americans. We also note that we will shortly propose to require providers to indicate which technologies are being used to provide connections in a given zip code, which should enable more accurate mapping in the future of where specific technologies are in use, and we will seek comment on whether to require providers to indicate the number of subscribers in a given zip code.

14. We now have semi-annual data about subscribership to high-speed and advanced services dating from December 1999 through June 2003. These data represent a significant time series for analysis and discussion. Now that the Commission has several years of data, we are particularly interested in analyzing the trends that have developed over time. These data show a continued, steady increase in both residential and small business high-speed lines since our last 706 report. Cable modem and ADSL continue to be the market leading technologies, at present. We request comment on what conclusions we should draw from these data.

15. We welcome additional data from external sources that will enable us to make informed judgments about whether advanced telecommunications capability is being made available to consumers in a reasonable and timely manner. We request objective, empirical data from companies, think tanks, governments, analysts, consumer groups, and others. We especially welcome data organized in ways that will enable us to measure investment, availability, and subscription for different technologies, companies, areas, and types of consumers. Additionally, we seek information relating to the price points and actual speeds at which high-speed and advanced services are being made available to consumers, and information relating to product tiering. We also seek data that would shed additional light on the extent to which consumers have a choice of competing providers of advanced or high-speed services. In addition, we seek comment on whether there are other ways of analyzing our existing FCC Form 477 data.

16. *Economics of Network Investment and Service Deployment.* In the *Third Report*, the Commission observed that carriers continued to invest in the high-speed and advanced services sector in a substantial way, resulting in increased availability of high-speed and advanced services for consumers across the nation. The Commission took note, however, that investment trends had generally slowed and gone through a period of transition since the *Second Report*, 65 FR 11059, March 1, 2000. Despite these trends, the Commission concluded that investment in infrastructure for most high-speed and advanced services markets remained strong, and that the market would continue to expand and availability to increase.

17. We seek comment on current investment trends and the extent to which they may reflect the availability of high-speed and advanced services. We seek comment on the relationship between the pace of investment, consumer demand, and general market expectations. We also seek comment on whether providers of high-speed and advanced services have access to sufficient levels of capital to fund infrastructure build-out and whether additional steps should be taken to accelerate deployment.

18. We seek to develop a greater understanding of the economics underlying deployment of advanced telecommunications capability and services that utilize that capability. How do the economics change over time as certain levels of deployment and/or penetration are achieved? Do the economics of deploying advanced telecommunications capability reduce availability in some communities? What role could universal service play in ensuring that deployment is reasonable and timely for all Americans? How do providers differentiate their product among different consumer groups? What strategies, tactics, plans, organization, and operational structures do firms utilize to deliver technology and related services to consumers?

19. We note that some companies offer tiered service schemes, which permit both entry level and more sophisticated, higher bandwidth services to be delivered over the same

infrastructure. To what extent could the availability of different product tiers affect penetration in today's marketplace? To what extent should the existence of product tiering affect our assessment of whether advanced telecommunications capability is being deployed on a reasonable and timely basis?

20. *Trends in Developing Technologies.* In prior reports, the Commission looked closely at the various technologies currently capable of providing high-speed and advanced services as well as those technologies that are likely to emerge in the near future. In particular, the *Third Report* described in detail several "last mile'' technologies of high-speed systems: (1) Cable modem service; (2) digital subscriber line (DSL, especially asymmetric DSL or ADSL); (3) other Local Exchange Carrier (LEC)-provided wireline services; (4) terrestrial fixed wireless service; and (5) satellite service. The Commission determined that competition among providers within certain technologies is emerging and that there is potential for several different technological options for providing high-speed and advanced services.

21. We seek comment as to any new developments in this area. Are there new technologies that are now being used to provide high-speed or advanced services, or likely to be used in the near future, such as Wi-Fi or Wi-Max, or broadband over power lines? If so, how widely have these new technologies been deployed and what percentage of customers utilize such services? What is the role of mobile wireless technologies? To what extent may some of these developments improve the speed and range of services offered to consumers? Are these technological developments likely to be particularly beneficial to specific groups of customers, such as rural customers or customers with disabilities? Have there been any other changes in the industry that affect the Commission's conclusions in the *Third Report*?

22. We note that the Commission's Form 477 data collection program captures the marketplace presence of broadband services that utilize new and innovative technologies once consumer up-take of the services reaches a certain level. Our data collection does not, however, directly monitor the development of new technologies with likely, or possible, application to advanced services. Nor does our data collection program directly monitor the development of innovative applications that utilize advanced telecommunications capability. We therefore invite parties to bring to our attention technologies that might be used by current or potential providers to deliver new advanced services to consumers. In addition, we are interested in technologies that might be used directly by consumers, *e.g.*, within the consumer's premises, to lower the cost or difficulty of installing or using advanced services. We also are interested in technologies that might enable new broadband applications of interest to consumers.

**C. Is Deployment Reasonable and Timely?**

23. Once we have gathered information on the deployment of advanced telecommunications capability, section 706 requires that we determine whether such capability is being deployed to all Americans "in a reasonable and timely fashion.'' We generally seek comment on whether advanced telecommunications capability is being deployed to all Americans in a reasonable and timely fashion and ask commenters to describe the empirical basis for their conclusions.

24. In determining whether deployment is reasonable and timely, the Commission examined in the *Second* and *Third Reports* various aspects of the deployment of, and market for, advanced services. In particular, it examined the availability of high-speed and advanced services, focusing both on how it has changed since prior reports and how it was projected to change in the future. Second, it examined investment in the infrastructure to support advanced services. Third, it reviewed trends in the alternatives available to consumers of advanced services, assessing both the number of providers offering service through a particular technology and the different technological options available to consumers. We request comment on whether to modify our analytical framework in this inquiry, and welcome suggestions of additional or alternative criteria. Are there other areas of inquiry that would be informative for the Commission to explore?

25. In the *Third Report,* the Commission specifically considered the availability of advanced services for several groups of consumers, including businesses, residential consumers, rural communities, elementary and secondary schools, individuals living on tribal lands, and persons with disabilities. Should we separately examine these specific categories in this inquiry? Are there other types of consumers or geographic areas, such as insular areas, that are likely to experience broadband deployment at a different pace such that we should also monitor the rate of deployment to those customers and areas?

26. We specifically seek comment on the status of deployment of high-speed and advanced services to consumers living in rural areas. Our data collection shows that subscription to advanced services in sparsely populated zip codes has grown, and the gap in reported lines in service between densely and sparsely populated zip codes has shrunk. For example, in June 2003, 68.5% of the most sparsely populated zip codes had high-speed subscribers, compared to 36.8% two years earlier. Moreover, over the last two years, the gap between the most densely populated zip codes and most sparsely populated zip codes had shrunk from 61.3 percentage points to 30.4 percentage points, largely due to increases in the number of most sparsely populated zip codes with subscribers. What are some of the reasons for this reduction in the gap between the most densely populated and the most sparsely populated zip codes? To what extent is the gap in subscribership among more densely and more sparsely populated areas due to the fact that many smaller providers operating in rural areas may fall below the current reporting threshold for our Form 477 data collection program? Do consumers in rural areas enjoy choices among technologies and tiers of high-speed services comparable to those available to consumers in urban areas? Are high-speed services available to consumers in rural areas at rates comparable to those rates charged in urban areas?

27. We note that the National Exchange Carrier Association (NECA) recently published a study that concluded that technological advances among small, mostly rural local telephone companies between 2001 and 2003 were greater than expected. In fact, the number of NECA companies currently deploying DSL services increased from 557 in 2001 to 814 in 2003. According to the NECA report, 78.95% of member companies' access lines now are equipped for DSL. NECA concluded that rural telephone companies are meeting the growing consumer demand for advanced services in spite of the hurdles they must overcome, including the lack of economies of scale that large, non-rural companies are afforded. What lessons can be learned from the steps taken by some NECA members to encourage deployment in less-developed areas? Are there steps that the Commission should take that would encourage further deployment in rural areas?

28. We also seek focused comment on the deployment of advanced telecommunications capability to low income individuals. We note that, as of June 2003, 98.5% of the highest income zip codes reported high-speed lines, and 78.3% of the lowest income zip codes reported high-speed lines. By comparison, as of June 2001, 96.4% of the highest income zip codes reported high-speed lines, and 59.1% of the lowest income zip codes reported high-speed lines. As a result, over the last two years, the gap between the highest income zip codes and the lowest income ones shrunk from 37.3 to 20.2 percentage points, primarily due to increases in the number of low-income zip codes with subscribers. Why has the gap between the highest income zip codes and the lowest income zip codes decreased over the past two years? Have any specific developments occurred that account for these changes? To what extent are firms marketing lower priced tiers of services to lower income individuals?

29. In addition, we seek comment on the availability of advanced telecommunications capability to individuals living on tribal lands and in the U.S. territories. In June 2003, high-speed services were available in 86.9% of zip codes that contain tribal territories, up from 71.3% in June 2001. At this time, service providers report high-speed lines in Puerto Rico and the Virgin Islands, but no service providers report high-speed lines in the Pacific Insular Islands. Does the information from our data collection program adequately capture the availability of high-speed or advanced services in these areas? In areas where services are being made available, are they being deployed to all consumers, or just a limited number of consumers? What types of unique challenges are there to the deployment of advanced services in tribal areas or U.S. territories? Are these challenges similar or distinguishable from those encountered by consumers living in rural areas of the nation? What types of technology are being used to provide advanced services on tribal lands? What types of technology are most widely deployed on tribal lands and why? Are there certain types of technological developments that may be especially promising for future deployment in tribal areas or the U.S. territories?

30. We also seek specific comment on the deployment of advanced telecommunications capability to elementary and secondary schools and classrooms. The U.S. Department of Education publishes on an annual basis various statistics relating to Internet access in U.S. public schools and classrooms. Among other things, the most recent study documents the steady increase in number of schools with Internet access, and the number of instructional classrooms with Internet access. For instance, in 2002, 99% of public schools had access to the Internet, compared to 14% in 1996. Moreover, in 2002, 92% of public school classrooms had access to the Internet, compared to 14% in 1996. In 2002, 94% of public schools reported using broadband connections for Internet access, compared to 80% in 2000 and 85% in 2001. Do these figures support a conclusion that advanced telecommunications capability is being deployed to elementary and secondary schools and classrooms on a reasonable and timely basis? Are there any other sources of information that would provide insight into whether the deployment of advanced telecommunications services to elementary and secondary schools and classrooms is occurring on a reasonable and timely basis?

31. To what extent do persons with disabilities have access to advanced telecommunications? Have there been recent developments in adaptive technologies that improve the capacity of persons with disabilities to access advanced telecommunications? Does the availability of video relay services through the Telecommunications Relay Service Fund play a role in promoting demand for and access to high-speed services among persons with disabilities? To what extent does income, employment, or other factors among persons with disabilities influence their ability to access advanced or high-speed services? How should the Commission evaluate the "availability'' of advanced telecommunications services for persons with disabilities, given the unique challenges that persons with disabilities may encounter in accessing advanced services? Are advanced services being made available to medically underserved rural communities?

### D. What Actions Can Accelerate Deployment?

32. Pursuant to the 1996 Act, "the Commission and each State commission * * * shall encourage the deployment on a reasonable and timely basis of advanced telecommunications capability to all Americans * * * by utilizing * * * price cap regulation, regulatory forbearance, measures that promote competition in the local telecommunications market, or other regulating methods that remove barriers to infrastructure investment.'' The *Third Report* described several examples of these and other activities that the Commission, other governmental entities, private groups and individuals have undertaken to promote competition and speed the deployment of advanced services. These included Commission proceedings to establish a regulatory framework for broadband services, promote investment through increased opportunities for broadband competition, reform our universal service system, and encourage the efficient use of spectrum. We note that the Congressional Budget Office recently published a report that analyzed the development of the residential broadband market to assess whether structural features or regulatory obstacles impede its further rapid growth, and concluded that federal intervention was not warranted at this time. To the extent commenters advocate that we should undertake additional actions to encourage the deployment of advanced telecommunications capability, they should set forth those proposals with specificity.

33. We also note that if we find that advanced telecommunications capability is not being deployed in a reasonable and timely manner, we are to "take immediate action to accelerate deployment of such capability by removing barriers to infrastructure investment and promoting competition in the telecommunications market.'' Are there groups of Americans for whom the pace of deployment justifies action under section 706 to remove barriers to infrastructure investment or to promote competition? If so, what would those specific actions entail, and what would the costs and benefits of those actions be?

34. In the *Third Report,* the Commission expressed concern about the difficulty some companies have faced in securing access to the rights-of-way necessary to deploy advanced telecommunications infrastructure in a timely manner. Based on its commitment to ensuring that rights-of-way issues are resolved in a fair and expeditious manner, the Commission announced that it intended to explore solutions through a dialogue with industry and state and local colleagues, in order to remove barriers that may hinder investment in infrastructure for advanced or high-speed services. On October 16, 2002, the Commission hosted a public Rights-of-Way Forum. The Rights-of-Way Forum focused on exploring the Commission's role in facilitating discussion, identifying model principles and practices, and developing consensus positions among

local authorities, state regulators, and the industry. We invite comment regarding the record developed at the Commission's Rights-of-Way Forum.

35. We note that several other organizations, such as the National Association of Regulatory Utility Commissioners (NARUC) and the National Telecommunications and Information Administration (NTIA) have also initiated discussions regarding rights-of-way issues. For example, during the July 2002 NARUC conference, a study committee released a white paper that urged the Commission to include a section in the 706 report that discusses barriers to "deployment of broadband networks associated with abusive rights-of-way practices of federal, state and local units of government and steps that need to be taken to abate those practices.'' The NARUC study committee on rights-of-way issues also recommended the development of a set of national broadband principles and put forth model rights-of-way access rules. In addition, the NTIA launched a States and Local Rights-of-Way Resources Website, which is designed to foster an exchange of ideas to improve the management and use of rights-of-way. Further, the Commission's Intergovernmental Advisory Committee, formerly known as the Local State Government Advisory Committee (LSGAC), provides guidance to the Commission on issues of importance to state, local and tribal governments, including public rights-of-way matters.

36. We seek comment on the types of best practices that could help create reliable and reasonable expectations regarding management of the public rights-of-way that may help remove barriers to investment in advanced telecommunications services. We also seek comment on methods of facilitating resolution of rights-of-way disputes. Are the Commission's current rules effective in resolving rights-of-way disputes and promoting competition? We also ask commenters to discuss the distinction between federal and state responsibilities regarding the use of the public rights-of-way. We note that several states have adopted specific rules and regulations concerning the administration of the public rights-of-way. We request commenters to discuss their experiences in states where rights-of-way rules have been enacted. In addition, we seek comment on the types of practices used by municipalities or communities to encourage the deployment of advanced telecommunications capabilities. For example, we ask commenters to discuss efforts by municipalities or communities to provide advanced telecommunications capabilities to end-user customers or to aggregate demand to encourage private sector deployment.

### E. What are Patterns of Consumer Adoption and Usage of Services Utilizing Advanced Telecommunications Capability?

37. We seek information about how and why consumers, both individuals and businesses, adopt and use services utilizing advanced telecommunications capability. We seek to develop a better understanding of the specific applications and services that utilize advanced platforms. If the application or service existed prior to the advent of advanced infrastructure capable of transmitting information at higher speeds, how has it benefited by the deployment of such infrastructure? To what degree, if any, could these applications and services be improved if advanced infrastructure was more ubiquitous? Are there certain economies of scale that could be achieved if broadband was used by more individuals or businesses? Would the same be true if advanced telecommunications capability was deployed in more places?

38. We also seek information about consumers of advanced services. What types of entities, *e.g.*, businesses or individuals, purchase advanced services? How integral have advanced services become to these consumers? To what degree do businesses and individuals rely on advanced services to conduct business, sell products, or accomplish specific tasks? We also hope to examine how other individuals or businesses that interact with the consumers of advanced services are indirectly affected by the use of advanced services. For example, do customers of businesses that utilize advanced services enjoy lower prices, greater choices, or faster service? Moreover, what applications and services used by such individuals require access to advanced services themselves? We request that commenters not only discuss specific, current services and applications, but possible future ones as well.

### F. Does Deployment of Advanced Telecommunications Capability in the United States Impact Our Role in the International Arena?

39. The United States was recently ranked 11th worldwide in broadband use in a recent report by the International Telecommunications Union. According to another study, the number of broadband subscribers per inhabitant is said to be higher in South Korea, Canada, Japan, Iceland, Sweden, Denmark, Belgium, and the Netherlands than in the U.S. We ask parties to comment on the potential reasons for relatively high broadband penetration rates in some foreign nations. To the extent that these factors are different for different countries, we ask that parties identify specific actions (or inactions) taken to promote broadband deployment. It has been reported that several foreign governments provide direct investment in the deployment of advanced services. We note that the European Union is seeking widespread broadband access in all of its fifteen member nations by next year. What other factors have contributed to the higher utilization of advanced services in other countries? Are there lessons that we could learn from the experiences of other countries? Based on these experiences, are there actions that the Commission should take to accelerate the deployment of advanced telecommunications capability? Are higher levels of penetration in other nations indicative of broader availability of advanced telecommunications capability? Given that usage of advanced services may be more ubiquitous throughout the populations in a number of countries than in the United States, we wish to understand the factors that have contributed to this apparent discrepancy, including methodological or design flaws in existing studies that may have over- or under-estimated the extent of broadband use in particular countries.

40. How does our deployment of advanced infrastructure vis-à-vis other nations affect the ability of our citizens to participate in a global economy? Are domestic jobs and industries more likely to move to other countries where the advanced services deployment and/or penetration is higher? What effect, if any, do any trends in this area have on international trade and the U.S. economic position in the global economy? Commenters should not only focus on the present impact but also on what the effect will be for the foreseeable future.

## III. Procedural Matters

41. We invite comment on the issues and questions set forth in the Notice contained herein. Pursuant to applicable procedures set forth in sections 1.415 and 1.419 of the Commission's rules, interested parties may file comments as follows: comments are due on or before May 10, 2004, and reply comments are due on or before May 24, 2004. All filings should refer to GN Docket No. 04–54. Comments may be filed using the Commission's Electronic Comment

Filing System (ECFS) or by filing paper copies. *See Electronic Filing of Documents in Rulemaking Proceedings*, 63 FR 24121, May 1, 1998.

42. Comments filed through ECFS can be sent as an electronic file via the Internet to *http://www.fcc.gov/e-file/ecfs.html.* Generally, only one copy of an electronic submission must be filed. In completing the transmittal screen, commenters should include their full name, Postal Service mailing address, and the applicable docket number, which in this instance is GN Docket No. 04–54. Parties may also submit an electronic comment by Internet e-mail. To receive filing instructions for e-mail comments, commenters should send an e-mail to *ecfs@fcc.gov,* and should include the following words in the body of the message: Get form <your e-mail address>. A sample form and directions will be sent in reply.

43. Parties that choose to file by paper must file an original and four copies of each filing. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although we continue to experience delays in receiving U.S. Postal Service mail). The Commission's contractor, Natek, Inc., will receive hand-delivered or messenger-delivered paper filings for the Commission's Secretary at a new location in downtown Washington, DC. The address is 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002. The filing hours at this location will be 8 a.m. to 7 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building.

44. Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743. U.S. Postal Service first-class mail, Express Mail, and Priority Mail should be addressed to 445 12th Street, SW., Washington, DC 20554. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

| If you are sending this type of document or using this delivery method * * * | It should be addressed for delivery to * * * |
|---|---|
| Hand-delivered or messenger-delivered paper filings for the Commission's Secretary. | 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002 (8 to 7 p.m.) |
| Other messenger-delivered documents, including documents sent by overnight mail (other than United States Postal Service Express Mail and Priority Mail). | 9300 East Hampton Drive, Capitol Heights, MD 20743 (8 a.m. to 5:30 p.m.) |
| United States Postal Service first-class mail, Express Mail, and Priority Mail. | 445 12th Street, SW., Washington, DC 20554 |

45. Parties who choose to file by paper should also submit their comments on diskette. These diskettes, plus one paper copy, should be submitted to: Sheryl Todd, Telecommunications Access Policy Division, Wireline Competition Bureau, Federal Communications, at the filing window at 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002. Such a submission should be on a 3.5-inch diskette formatted in an IBM compatible format using Word or compatible software. The diskette should be accompanied by a cover letter and should be submitted in "read only'' mode. The diskette should be clearly labeled with the commenter's name, proceeding (including the docket number, in this case GN Docket No. 04–54, type of pleading (comment or reply comment), date of submission, and the name of the electronic file on the diskette. The label should also include the following phrase "Disk Copy—Not an Original.'' Each diskette should contain only one party's pleadings, preferably in a single electronic file. In addition, commenters must send diskette copies to the Commission's copy contractor, Qualex International, Portals II, 445 12th Street, SW., Room CYB402, Washington, DC 20554 (see alternative addresses above for delivery by hand or messenger).

46. Regardless of whether parties choose to file electronically or by paper, parties should also file one copy of any documents filed in this docket with the Commission's copy contractor, Qualex International, Portals II, 445 12th Street SW., CY–B402, Washington, DC 20554 (see alternative addresses above for delivery by hand or messenger) (telephone 202–863–2893; facsimile 202–863–2898) or via e-mail at *qualexint@aol.com.*

47. The full text of this document is available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554. This document may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone (202) 863–2893, facsimile (202) 863–2898, or via e-mail *qualexint@aol.com.*

48. Comments and reply comments must include a short and concise summary of the substantive arguments raised in the pleading. Comments and reply comments must also comply with § 1.49 and all other applicable sections of the Commission's rules. We direct all interested parties to include the name of the filing party and the date of the filing on each page of their comments and reply comments. All parties are encouraged to utilize a table of contents, regardless of the length of their submission. We also strongly encourage parties to track the organization set forth in the Notice in order to facilitate our internal review process.

49. We note that there are many other proceedings now underway at the Commission that include issues that could affect a company's, or class of companies' incentive and ability to deploy advanced telecommunications capability. If commenters wish to refer to their filing in another proceeding, they must provide in their comments in this proceeding a complete recitation of the pertinent information and also attach a copy of the filing to which they refer.

50. Subject to the provisions of 47 CFR 1.1203 concerning "Sunshine Period'' prohibitions, this proceeding is exempt from ex parte restraints and disclosure requirements, pursuant to 47 CFR 1.1204(b)(1). Because many of the matters on which we request comment in this Notice may call on parties to disclose proprietary information such as market research and business plans, we suggest that parties consult 47 CFR 0.459 about the submission of confidential information.

## IV. Further Information

51. Alternative formats (computer diskette, large print, audio recording, and Braille) are available to persons with disabilities by contacting Brian Millin at (202) 418–7426 voice, (202) 418–7365 TTY, or *bmillin@fcc.gov.* This Notice can also be downloaded in Microsoft Word and ASCII formats at *http://www.fcc.gov/ccb/universal_service/highcost.*

## V. Ordering Clause

52. Pursuant to the authority contained in section 706 of the

Telecommunications Act of 1996, this *Notice of Inquiry* is adopted.

Federal Communications Commission.

**Marlene H. Dortch,**

*Secretary.*

[FR Doc. 04–7531 Filed 4–7–04; 8:45 am]

**BILLING CODE 6712–01–P**

## DEPARTMENT OF THE INTERIOR

## Fish and Wildlife Service

## 50 CFR Part 17

**RIN 1018–AI72**

## Endangered and Threatened Wildlife and Plants; Reopening of the Public Comment Period for the Determination of Distinct Vertebrate Population Segment for the California Gnatcatcher (*Polioptila californica*)

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Proposed rule; reopening of public comment period.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), announce the reopening of the public comment period for the proposed determination of a distinct vertebrate population segment for the California gnatcatcher (*Polioptila californica*). The comment period will provide the public, and Federal, State, and local agencies and Tribes with an opportunity to submit written comments on the proposal. Comments previously submitted for this proposal need not be resubmitted as they have already been incorporated into the public record and will be fully considered in any final decision.

**DATES:** The original comment period closed on June 23, 2003. The public comment period for this proposal is now reopened, and we will accept comments and information until 5 p.m. May 24, 2004. Any comments received after the closing date may not be considered in the final decisions on these actions.

**ADDRESSES:** Written comments and materials may be submitted to us by any one of the following methods:

1. You may submit written comments and information to the Field Supervisor, Carlsbad Fish and Wildlife Office, 6010 Hidden Valley Road, Carlsbad, CA 92009.

2. You may hand-deliver written comments and information to our Carlsbad Fish and Wildlife Office at the above address, or fax your comments to 760/431–9618.

Comments and materials received, as well as supporting documentation used in preparation of the proposed determination of distinct vertebrate population segment for the California gnatcatcher, will be available for public inspection, by appointment, during normal business hours at the above address.

**FOR FURTHER INFORMATION CONTACT:** Jim Bartel, Field Supervisor, Carlsbad Fish and Wildlife Office, at the above address (telephone 760/431–9440; facsimile 760/431–9618).

**SUPPLEMENTARY INFORMATION:**

### Public Comments Solicited

We solicit comments or suggestions from the public, other concerned governmental agencies, Tribes, the scientific community, industry, or any other interested parties concerning our proposed determination of distinct vertebrate population segment for the California gnatcatcher, and on the taxonomic status of the gnatcatcher.

With respect to our consideration of listing of the California gnatcatcher species north of the international border as a distinct vertebrate population segment (DPS), we are particularly soliciting comments on the following:

(1) Do the recent genetic findings referenced in this report justify a review of the taxonomy of the California gnatcatcher?

(2) Is there any other new information that we should consider in this context?

In our consideration of the U.S. population of the California gnatcatcher as a DPS, we have presented a proposed five factor analysis of the status of the U.S. population. With respect to this analysis, we are particularly soliciting information on the following:

(1) Existing populations of the California gnatcatcher, including the coastal California gnatcatcher subspecies, within its range in the United States;

(2) Existing populations of the California gnatcatcher, including the coastal California gnatcatcher subspecies, in Mexico;

(3) Information on the regulatory authorities available for the protection of the California gnatcatcher in Mexico;

(4) Information on the adequacy of regulatory authorities available to protect coastal California gnatcatcher habitat in California absent the application of the Act;

(5) Ways in which the California gnatcatcher exists in the U.S. or throughout the range of the coastal California gnatcatcher subspecies, in an ecological setting that is unusual or unique compared to the California gnatcatcher generally; and

(6) Any other information that we should consider in our review of the species' taxonomy.

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 address, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold a respondent's identity, 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 comments. However, we will not consider anonymous comments. To the extent consistent with applicable law, 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 inspection in their entirety. Comments received will be available for public inspection, by appointment, during normal business hours at the above address.

### Background

On April 24, 2003, we published a proposed rule in the **Federal Register** (68 FR 20228) to designate critical habitat for the coastal California gnatcatcher subspecies and propose our determination of a distinct vertebrate population segment for the California gnatcatcher. In today's **Federal Register**, we also reopened the comment period on the proposed designation of critical habitat. By this notice we are reopening the comment period on the proposed determination of the DPS for the California gnatcatcher. We intend to proceed to finalize these two rulemakings separately.

A recent scientific paper (Zink, R.M., G.F. Barrowclough, J. L. Atwood, and R.C. Blackwell-Rago. 2000. Genetics, taxonomy, and conservation of the threatened California gnatcatcher. Conservation Biology 14(5):1394–1405) presents results of genetic research on the California gnatcatcher and calls into question the status of the coastal California gnatcatcher as a separate subspecies. This paper presents a contradictory view to previously published taxonomic reviews of the species. However, Atwood's research supported the original listing of the gnatcatcher. Zink *et al.* (2000) analyzed the genetic structure of California gnatcatcher populations throughout the range by looking for variation in the mitochondrial DNA (mtDNA) control region and three mtDNA genes. Their analysis found genetic structuring

inconsistent with that of a geographically distinct subspecies. The authors presented their data as evidence that the species is expanding its range from a southern Baja California, Mexico, refugium northward into the southern coastal regions of California. The authors argue that morphological variations previously described in taxonomic treatments were not genetically based, and therefore, subspecific divisions of the species are not supported by the genetic studies conducted by the researchers.

Zink *et al.* (2000) present important new information concerning genetic variability within the California gnatcatcher. Given the uncertainty regarding California gnatcatcher taxonomy that this paper introduces, we have initiated an evaluation to determine whether populations of the California gnatcatcher (*Polioptila californica*) species in the United States meet the definition of a DPS pursuant to our 1996 joint U.S. Fish and Wildlife Service and National Marine Fisheries Service Policy Regarding the Recognition of Distinct Vertebrate Populations (61 FR 4722).

We are reopening the comment period to allow all interested parties to comment on these issues.

## References Cited

A complete list of all references cited herein, as well as others used in the development of the proposed DPS, are available upon request from the Carlsbad Fish and Wildlife Office (see **ADDRESSES** section).

## Author

The primary authors of this notice are the staff of the Carlsbad Fish and Wildlife Office (see **ADDRESSES** section).

## Authority

The authority for this action is the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*).

Dated: March 26, 2004.

**Craig Manson,**

*Assistant Secretary for Fish and Wildlife and Parks.*

[FR Doc. 04–7993 Filed 4–7–04; 8:45 am]

**BILLING CODE 4310–55–P**

**DEPARTMENT OF THE INTERIOR**

**Fish and Wildlife Service**

**50 CFR Part 17**

**RIN 1018–AI71 and 1018–AI72**

# Endangered and Threatened Wildlife and Plants; Notice of the Availability of Draft Economic Analyses, and of a Public Hearing for the Proposed Designations of Critical Habitat for the Coastal California Gnatcatcher (*Polioptila californica californica*) and the San Diego Fairy Shrimp (*Branchinecta sandiegonensis*)

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Proposed rules; notice of availability of draft economic analyses, reopening of public comment periods, and notice of public hearings.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service) announce the availability of a draft economic analysis of the proposed designation of critical habitat for the coastal California gnatcatcher (*Polioptila californica californica*), the availability of a draft economic analysis of the proposed critical habitat designation for the San Diego fairy shrimp, and the reopening of the public comment periods on the proposed rules to designate critical habitat for the coastal California gnatcatcher and the San Diego fairy shrimp. The comment period will provide the public, Federal, State, and local agencies, and Tribes with an opportunity to submit written comments on these two proposals and their respective draft economic analyses. Comments previously submitted for these proposed rules need not be resubmitted as they have already been incorporated into the public record and will be fully considered in any final decision.

We are also announcing that public hearings will be held on both proposed rules and their respective draft economic analyses.

**DATES:** The public comment period for these two proposed rules is now reopened, and we will accept comments and information until 5 p.m. May 10, 2004. Any comments received after the closing date may not be considered in the final decisions on these actions.

The public hearings will take place on April 29, 2004, from 1 p.m. to 3 p.m. and from 6 p.m. to 8 p.m. in Carlsbad, California. Both public hearings will address both proposed rules.

**ADDRESSES:** The public hearings will be held at the Carlsbad Fish and Wildlife Office, 6010 Hidden Valley Road, Carlsbad, California.

Written comments and materials may be submitted to us by any one of the following methods:

1. You may submit written comments and information to the Field Supervisor, Carlsbad Fish and Wildlife Office, 6010 Hidden Valley Road, Carlsbad, CA 92009.

2. You may hand-deliver written comments and information to our Carlsbad Fish and Wildlife Office at the above address, or fax your comments to 760/431–9618.

Comments and materials received, as well as supporting documentation used in preparation of the proposed critical habitat rules for the coastal California gnatcatcher and San Diego fairy shrimp, will be available for public inspection, by appointment, during normal business hours at the above address. You may obtain copies of the draft economic analyses for the coastal California gnatcatcher and San Diego fairy shrimp by contacting the Carlsbad Fish and Wildlife Office at the above address.

**FOR FURTHER INFORMATION CONTACT:** Jim Bartel, Field Supervisor, Carlsbad Fish and Wildlife Office, at the above address (telephone 760/431–9440; facsimile 760/431–9618).

**SUPPLEMENTARY INFORMATION:**

## Public Comments Solicited

We solicit comments or suggestions from the public, other concerned governmental agencies, Tribes, the scientific community, industry, or any other interested parties concerning our proposed designation of critical habitat and/or the draft economic analysis of the proposed designation of critical habitat for both the coastal California gnatcatcher and San Diego fairy shrimp. With regard to the proposed rules and draft economic analyses for the coastal California gnatcatcher and San Diego fairy shrimp, we particularly seek comments concerning:

(1) Specific information on the amount and distribution of the gnatcatcher and its habitat, and which habitat is essential to the conservation of this species and why; and

(2) Whether habitat currently preserved in various conservation areas within the range of the coastal California gnatcatcher is sufficient for the conservation of the species;

(3) The reasons why any habitat should or should not be determined to be critical habitat for the coastal California gnatcatcher or the San Diego fairy shrimp as provided by section 4 of the Act, including whether the benefits of designation will outweigh any threats

to these species resulting from designation;

(4) Land use designations and current or planned activities in the subject areas and their possible impacts on areas proposed as critical habitat for these two species;

(5) Any foreseeable economic, national security, or other impacts resulting from the proposed designation of critical habitat for the coastal California gnatcatcher or San Diego fairy shrimp, in particular, any impacts on small entities or families;

(6) Do both economic analyses adequately address the likely effects and resulting costs arising from the California Environmental Quality Act and other State laws as a result of the proposed critical habitat designations;

(7) Whether both economic analyses make appropriate assumptions regarding current practices and likely regulatory changes imposed as a result of the designation of critical habitat for the coastal California gnatcatcher and the San Diego fairy shrimp;

(8) Any economic or other impacts associated with designating critical habitat on reserve, preserve, or other conservation lands within the boundaries of approved habitat conservation plans (HCP) that have been developed through cooperative, voluntary partnerships;

(9) The benefits of including or excluding military lands covered by an Integrated Natural Resource Management Plan and Tribal lands, NCCP lands, HCP lands, or any other lands covered by an adequate management plan;

(10) Do the analyses adequately address the indirect effects, *e.g.,* property tax losses due to reduced home construction, losses to local business due to reduced construction activity;

(11) Whether the economic analyses appropriately identify land and water use regulatory controls that could result from the proposed critical habitat designations for these species;

(12) Do the analyses accurately define and capture opportunity costs;

(13) Whether the economic analyses correctly assess the effect on regional costs (*e.g.,* housing costs) associated with land use controls that could arise from the designation of critical habitat for these species;

(14) Do the analyses adequately address the likelihood of "stigma effects'' and costs associated with the proposed designations;

(15) Whether the designation of critical habitat for either the coastal California gnatcatcher or San Diego fairy shrimp will result in disproportionate economic or other impacts to specific areas that should be evaluated for possible exclusion from the final designations;

(16) The economic analyses should identify all costs related to the designation of critical habitat for the coastal California gnatcatcher and San Diego fairy shrimp. Those designations were intended to take place at the time these species were listed. As a result, the assumptions in the economic analyses should be consistent with the Service's listing regulations. Do these analyses achieve that consistency? And

(17) Whether our approach to critical habitat designation could be improved or modified in any way to provide for greater public participation and understanding, or to assist us in accommodating public concern and comments.

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 address, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold a respondent's identity, 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 comments. However, we will not consider anonymous comments. To the extent consistent with applicable law, 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 inspection in their entirety. Comments received will be available for public inspection, by appointment, during normal business hours at the above address.

## Background

On April 24, 2003, we published a proposed rule in the **Federal Register** (68 FR 20228) to designate critical habitat for the coastal California gnatcatcher on approximately 495,795 acres (ac) (200,595 hectares (ha)) of land in Ventura, Los Angeles, Orange, Riverside, San Bernardino, and San Diego counties. The original comment period on the coastal California gnatcatcher proposed critical habitat rule closed on June 23, 2003.

We published a proposed rule in the April 22, 2003, edition of the **Federal Register** (68 FR 19888) to designate critical habitat for the San Diego fairy shrimp on approximately 6,098 ac (2,468 ha) of land in Orange and San Diego counties. The original comment period on the San Diego fairy shrimp proposed critical habitat rule also closed on June 23, 2003.

Critical habitat receives protection from destruction or adverse modification through required consultation under section 7 of the Endangered Species Act of 1973, as amended (Act), with regard to actions carried out, funded, or authorized by a Federal agency. Section 4(b)(2) of the Act requires that we designate or revise critical habitat on the basis of the best scientific and commercial data available, after taking into consideration economic and any other relevant impacts of specifying any particular area as critical habitat. Based upon the April 24, 2003, proposed rule to designate critical habitat for coastal California gnatcatcher, we have prepared a draft economic analysis of the proposed critical habitat designation. The economic analysis estimates that the proposed designation may result in a potential economic cost, resulting from section 7 of the Act, of approximately $915 million through the year 2025, with an estimated annualized cost of $114 million. Unit 10 of the proposed designation lies entirely within the proposed planning area of the Western Riverside County MSHCP. Based on very large projected growth estimates and other factors, the economic analysis suggests that approximately $460 million of the total $915 million estimated costs through 2025 occur in this unit.

We have also prepared a draft economic analysis of the April 22, 2003, proposed rule to designate critical habitat for the San Diego fairy shrimp. The draft analysis of this proposed designation estimates that potential economic costs associated with section 7 of the Act range up to $54.6 million over the next 20 years.

Section 4(b)(5)(E) of the Act (16 U.S.C. 1531 *et seq.*) requires that a public hearing be held if it is requested within 45 days of the publication of a proposed rule. In response to a request from the Natural Resources Defense Council, and a separate request from Citizens Against Recreational Eviction, we will conduct public hearings on the date and at the address described in the **DATES** and **ADDRESSES** sections above.

Anyone wishing to make an oral statement for the record is encouraged to provide a written copy of their statement and present it to us at the hearings. In the event there is a large attendance, the time allotted for oral statements may be limited. Oral and written statements receive equal consideration. There are no limits on the length of written comments submitted to us. If you have any

questions concerning the public hearings, please contact the Carlsbad Fish and Wildlife Office (*see* **ADDRESSES** section). This notice is being published in the **Federal Register** to provide the public and interested parties with a minimum of 15 days notification about the public hearings.

Persons needing reasonable accommodations in order to attend and participate in the public hearings should contact Patti Carroll at 503/231–2080 as soon as possible. In order to allow sufficient time to process requests, please call no later than one week before the hearing date. Information regarding this proposal is available in alternative formats upon requests.

We are reopening the comment period to allow all interested parties to comment simultaneously on the proposed rules for the coastal California gnatcatcher and San Diego fairy shrimp, potential exclusions and the draft economic analyses. The draft analyses are available by contacting the Carlsbad Fish and Wildlife Office as identified in the **ADDRESSES** section above.

## References Cited

A complete list of all references cited herein, as well as others used in the development of the proposed critical habitat designations and the draft economic analyses of the proposed critical habitat designations for the coastal California gnatcatcher and San Diego fairy shrimp, are available upon request from the Carlsbad Fish and Wildlife Office (*see* **ADDRESSES** section).

## Author

The primary authors of this notice are the staff of the Carlsbad Fish and Wildlife Office (*see* **ADDRESSES** section).

## Authority

The authority for this action is the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*).

Dated: March 30, 2004.

**Paul Hoffman,**

*Acting Assistant Secretary for Fish and Wildlife and Parks.*

[FR Doc. 04–7992 Filed 4–7–04; 8:45 am]

**BILLING CODE 4310–55–P**

# Notices

Federal Register

Vol. 69, No. 68

Thursday, April 8, 2004

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

## DEPARTMENT OF AGRICULTURE

### Natural Resources Conservation Service

### Notice of Availability Mancos Valley Salinity Control Project Plan and Environmental Assessment (EA), and Finding of No Significant Impact (FONSI)

**AGENCY:** Natural Resources Conservation Service, USDA.

**ACTION:** Notice.

**SUMMARY:** The Natural Resources Conservation Service (NRCS), has prepared a plan and environmental assessment consistent with the Environmental Policy Act of 1969, as amended. Funding for salinity control projects is available through the Environmental Quality Incentives Program which is covered by a programmatic EA. The Mancos Valley plan and EA were developed to more specifically evaluate the effects associated with this type of water quality activity. Upon review of the information in the Mancos Valley EA, the State Conservationist, NRCS, Colorado made a Finding of No Significant Impact (FONSI) and the determination was made that no environmental impact statement is required to support the Mancos Valley Plan. Pursuant to section 102(2)(c) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Regulations (40 CFR part 1500); and the Natural Resources Conservation Service Regulations (7 CFR part 650); the Natural Resources Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for the Mancos Valley Salinity Control Project, Montezuma County, Colorado. Written comments regarding this action may be submitted to: USDA/NRCS; Allen Green, State Conservationist, Room E200C, 655 Parfet St., Lakewood, Colorado 80215–5517. Comments must received no later than 30 days after this notice is published.

**FOR FURTHER INFORMATION CONTACT:** Allen Green, State Conservationist, Natural Resources Conservation Service, 655 Parfet St., Lakewood, CO 80215–5517; telephone (720) 544–2802.

**SUPPLEMENTARY INFORMATION:** The environmental assessment of this Federally assisted action documents that the project will not cause significant local, regional, state, or national impacts on the human environment. The findings of Allen Green, State Conservationist, indicate that the preparation and review of an environmental impact statement is not needed for this project.

The project purpose is to reduce salt loading to the Mancos River which is a tributary to the Colorado River. Excessive loading is the result of seepage from delivery ditch systems and inefficient irrigation application methods and procedures. The planned works of improvement include on-farm underground irrigation pipelines; on-farm concrete irrigation ditches; sprinkler irrigation systems; off-farm delivery system pipelines; polyacrylamide treatment of delivery ditches; structures for water control; and wildlife habitat development. These enduring practices are accompanied by facilitating management practices such as Irrigation Water Management, Wildlife Habitat Management Wetland, and Wildlife Habitat Management Upland.

This Notice of a Finding of No Significant Impact (FONSI) has been forwarded to the Environmental Protection Agency and to various, Federal, State, and local agencies and interested parties. Copies of the FONSI and Plan/Environmental Assessment are available by request from Allen Green, Colorado State Conservationist. Basic data developed during the environmental evaluation are on file and may be reviewed by contacting Allen Green, Colorado State Conservationist, or copies of the plan and environmental assessment, and FONSI can be obtained from Mr. Timothy Oulette, District Conservationist, NRCS, USDA, 628 West 5th Street, Cortez, CO 81321–4045; telephone: (970) 565–9045; extension 3. or Mr. Frank Riggle, Assistant State Conservationist, Water Resources, NRCS, USDA, 655 Parfet St., Room E200C, Lakewood, CO 80215–5517; telephone (720) 544–2804.

No administrative action on implementation of this project will be taken until 30 days after the date of this notice is published.

(This activity is listed in the Catalog of Federal Domestic Assistance under No. 10.902, Soil and Water Conservation and Environmental Quality Incentive Program 10.912.)

**Allen Green,**

*State Conservationist.*

[FR Doc. 04–7928 Filed 4–7–04; 8:45 am]

BILLING CODE 3410–06–P

## DEPARTMENT OF AGRICULTURE

### Natural Resources Conservation Service

### Notice of Proposed Change to the Natural Resources Conservation Service's National Handbook of Conservation Practices

**AGENCY:** Natural Resources Conservation Service, USDA.

**ACTION:** Notice of availability of proposed changes in the NRCS National Handbook of Conservation Practices, Section IV of the New York State Field Office Technical Guide (FOTG) for review and comment.

**SUMMARY:** It is the intention of NRCS to issue two revised conservation practice standards in its National Handbook of Conservation Practices. These standards are:

Animal Mortality Facility (NY316)
Composting Facility (NY317)

**DATES:** Comments will be received for a 30-day period commencing with the date of this publication.

**FOR FURTHER INFORMATION CONTACT:** Inquire in writing to Paul W. Webb, State Resource Conservationist, Natural Resources Conservation Service (NRCS), 441 S. Salina Street, Fifth Floor, Suite 354, Syracuse, New York 13202–2450. A copy of this standard is available from the above individual.

**SUPPLEMENTARY INFORMATION:** Section 343 of the Federal Agricultural Improvement and Reform Act of 1996 states that revisions made after enactment of the law to NRCS State Technical Guides used to carry out highly erodible land and wetland

provisions of the law shall be made available for public review and comment. For the next 30 days the NRCS will receive comments relative to the proposed changes. Following that period, a determination will be made to the NRCS regarding disposition of those comments and final determination of change will be made.

Dated: March 26, 2004.

**Paul W. Webb,**

*State Resource Conservationist, Natural Resources Conservation Service, Syracuse, NY.*

[FR Doc. 04–7929 Filed 4–7–04; 8:45 am]

**BILLING CODE 3410–06–P**

## DEPARTMENT OF COMMERCE

### Foreign-Trade Zones Board

**[Docket 13–2004]**

### Foreign-Trade Zone 29—Louisville, KY, Area; Application for Expansion

An application has been submitted to the Foreign-Trade Zones (FTZ) Board (the Board), by the Louisville and Jefferson County Riverport Authority, grantee of Foreign-Trade Zone 29, Louisville, Kentucky, requesting authority to expand FTZ 29–Site 4 to include an additional area within the Louisville Customs port of entry. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on March 29, 2004.

FTZ 29 was approved on May 26, 1977 (Board Order 118, 42 FR 29323, 6/8/77) and expanded on January 31, 1989 (Board Order 429, 54 FR 5992, 2/7/89); December 15, 1997 (Board Order 941, 62 FR 67044, 12/23/97); July 17, 1998 (Board Order 995, 63 FR 40878, 7/31/98); December 11, 2000 (Board Order 1133, 65 FR 79802, 12/20/00); January 15, 2002 (Board Order 1204, 67 FR 4391, 1/30/02); and, November 20, 2003 (Board Order 1305, 68 FR 67400, 12/2/03). The zone project currently consists of the following sites in the Louisville, Kentucky, area: *Site 1* (1,674 acres)—1,668 acres within the Riverport Industrial complex and 6 acres at 3401 Jewell Avenue, Louisville; *Site 2* (593 acres)—located at the junction of Gene Snyder Freeway and La Grange Road, eastern Jefferson County; *Site 3* (142 acres)—United States Naval Ordnance facility, 5403 Southside Drive, Louisville; *Site 4* (2,311 acres)—consisting of the Louisville International Airport and three other airport-related parcels; *Site 5* (70 acres)—Marathon Ashland Petroleum LLC Tank Farm and pipelines, 4510 Algonquin Parkway along the Ohio River, Louisville; *Site 6* (316 acres)—Cedar Grove Business Park, on Highway 480, near Interstate 65, Bullitt County; *Site 7* (273 acres)—Henderson County Riverport Authority facilities, 6200 Riverport Road, Henderson; and, *Site 8* (182 acres)—Owensboro Riverport Authority facilities, 2300 Harbor Road, Owensboro.

The applicant is now requesting authority to expand existing Site 4 to include an additional parcel at the Louisville Metro Commerce Center, 1900 Outer Loop Road in Louisville (101 acres, Proposed Site 4–Parcel E). The site is owned by Enterprise Industrial Park LLC. No specific manufacturing requests are being made at this time. Such requests would be made to the Board on a case-by-case basis.

In accordance with the Board's regulations, a member of the FTZ Staff has been designated examiner to investigate the application and report to the Board.

Public comment on the application is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at one of the following addresses:

1. *Submissions via Express/Package Delivery Services:* Foreign-Trade Zones Board, U.S. Department of Commerce, Franklin Court Building—Suite 4100W, 1099—14th St. NW., Washington, DC 20005; or

2. *Submissions via the U.S. Postal Service:* Foreign-Trade Zones Board, U.S. Department of Commerce, FCB—Suite 4100W, 1401 Constitution Ave. NW., Washington, DC 20230.

The closing period for their receipt is June 7, 2004. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to June 22, 2004).

A copy of the application and accompanying exhibits will be available for public inspection at the Office of the Foreign-Trade Zones Board's Executive Secretary at the first address listed above, and at the U.S. Department of Commerce, Export Assistance Center, Gene Snyder Courthouse Building, 601 West Broadway, Room 634B, Louisville, Kentucky 40402.

Dated: March 29, 2004.

**Dennis Puccinelli,**

*Executive Secretary.*

[FR Doc. 04–8017 Filed 4–7–04; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

### Foreign Trade Zones Board

**[Docket 2–2004]**

### Foreign-Trade Zone—Galveston, Texas; Correction

The **Federal Register** notice (69 FR 5315, 2/4/04), describing the expansion of Foreign-Trade Zone 36, located in the Galveston, Texas, area, is corrected as follows:

Paragraph 3, Sentence 1, should read "The applicant is now requesting authority to reorganize Site 1 to add 4 parcels (112 acres) and to combine the existing parcels of 3.99 acres (Site 1, Tract 2) and 1.14 acres (Site 1, Tract 3) into Site 1, Tract 1. The applicant is requesting the removal of one tract (tract 1, 2.67 acres) from Site 1. Site 1, Tract 2, will be reorganized and will add 45 acres. The applicant is requesting the addition of 96 acres (1 tract) to Site 2.'' Sites 1 and 2 are listed as Sites A and B in the original application. The application otherwise remains unchanged.

Comments on the change may be submitted to the Foreign-Trade Zones Board, U.S. Department of Commerce, FCB–Suite 4100W, 1401 Constitution Avenue, NW., Washington, DC 20230, by April 30, 2004.

Dated: March 31, 2004.

**Dennis Puccinelli,**

*Executive Secretary.*

[FR Doc. 04–8018 Filed 4–7–04; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–570–853]**

### Bulk Aspirin From the People's Republic of China: Preliminary Results of 2002/2003 Antidumping Duty Administrative Review and Notice of Intent To Revoke Order in Part

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**SUMMARY:** In response to requests from interested parties, the Department of Commerce is conducting an administrative review of the antidumping duty order on bulk aspirin from the People's Republic of China with respect to Shandong Xinhua Pharmaceutical Co., Ltd. This review covers sales of bulk aspirin to the United States during the period July 1, 2002, through June 30, 2003.

We preliminarily find that, during the period of review, Shandong Xinhua

Pharmaceutical Co., Ltd. has not made sales below normal value. We also preliminarily find that the antidumping duty order with respect to Shandong Xinhua Pharmaceutical Co., Ltd. should be revoked. If these preliminary results are adopted in our final results of this administrative review, we will instruct the U.S. Customs and Border Protection not to assess antidumping duties. We invite interested parties to comment on these preliminary results. We will issue the final results no later than 120 days from the date of publication of this notice.

**EFFECTIVE DATE:** April 8, 2004.

**FOR FURTHER INFORMATION CONTACT:** Julie Santoboni or Scott Holland, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–4194, or (202) 482–1279, respectively.

**SUPPLEMENTARY INFORMATION:**

## Background

On July 11, 2000, the Department of Commerce ("the Department") published an antidumping order on bulk aspirin from the People's Republic of China ("PRC"). *See Notice of Antidumping Duty Order: Bulk Aspirin from the People's Republic of China*, 65 FR 42673 (July 11, 2000) ("*Bulk Aspirin Order*"). On July 2, 2003, the Department published in the **Federal Register** a notice of the opportunity to request an administrative review in the above-cited segment of the antidumping duty proceeding (*see* 68 FR 39511). We received a timely filed request for review of Jilin Henghe Pharmaceutical Company Ltd. ("Jilin") and Shandong Xinhua Pharmaceutical Co., Ltd. ("Shandong") from Rhodia, Inc. ("the petitioner"). We also received a timely filed request for review from Shandong. Shandong also requested that the Department revoke the antidumping duty order with regard to its sales of subject merchandise, in accordance with 19 CFR 351.222(b). On August 22, 2003, we initiated an administrative review of Jilin and Shandong. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part*, 68 FR 50750 (August 22, 2003). The period of this review ("POR") is July 1, 2002, through June 30, 2003.

We issued antidumping questionnaires to Jilin and Shandong on September 15, 2003. We received responses to the questionnaires from Shandong on October 16 and November 7, 2003, and Jilin on October 30 and November 7, 2003.

On November 12, 2003, the Department invited interested parties to comment on surrogate country selection and to provide publicly available information for valuing the factors of production. We received responses from Jilin and Shandong on December 10, 2003 and January 9, 2004, respectively.

On January 5, 2004, the petitioner withdrew its request for review of Jilin. Although this withdrawal was received by the Department after the regulatory deadline of November 20, 2003, 19 CFR 351.213(d)(1) permits the Department to extend the deadline if "it is reasonable to do so." Because the petitioner was the only party to request the review, we found it is reasonable to extend the deadline to withdraw the review request. On February 3, 2004, in accordance with 19 CFR 351.213(d)(1), we rescinded the administrative review with respect to Jilin. *See Bulk Aspirin from the People's Republic of China: Notice of Partial Rescission of Antidumping Duty Administrative Review*, 69 FR 5126 (February 3, 2004).

We issued supplemental questionnaires to Shandong in January and February 2004, and received responses from Shandong in January, February and March 2004. In January 2004, Perrigo Company, an interested party, responded to certain supplemental questions issued to Shandong. The Department verified the sales and factors of production responses submitted by Shandong during March 2004.

## Scope of the Order

The product covered by this review is bulk acetylsalicylic acid, commonly referred to as bulk aspirin, whether or not in pharmaceutical or compound form, not put up in dosage form (tablet, capsule, powders or similar form for direct human consumption). Bulk aspirin may be imported in two forms, as pure ortho-acetylsalicylic acid or as mixed ortho-acetylsalicylic acid. Pure ortho-acetylsalicylic acid can be either in crystal form or granulated into a fine powder (pharmaceutical form). This product has the chemical formula $C_9H_8O_4$. It is defined by the official monograph of the United States Pharmacopoeia 23 ("USP"). It is currently classifiable under the *Harmonized Tariff Schedule of the United States* ("HTSUS") subheading 2918.22.1000.

Mixed ortho-acetylsalicylic acid consists of ortho-acetylsalicylic acid combined with other inactive substances such as starch, lactose, cellulose, or coloring materials and/or other active substances. The presence of other active substances must be in concentrations less than that specified for particular nonprescription drug combinations of aspirin and active substances as published in the *Handbook of Nonprescription Drugs*, eighth edition, American Pharmaceutical Association. This product is currently classifiable under HTSUS subheading 3003.90.0000.

Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise under review is dispositive.

## Verification

As provided in section 782(i) of the Tariff Act of 1930, as amended ("the Act"), during March 2004, we verified the information provided by Shandong in the PRC using standard verification procedures, including on-site inspection of the manufacturer's facilities, examination of relevant sales, cost and financial records, and selection of original documentation containing relevant information. The Department will report its findings from the Shandong sales and factors-of-production verifications at a later date.

## Separate Rates

It is the Department's standard policy to assign all exporters of the merchandise subject to review in nonmarket economy ("NME") countries a single rate unless an exporter can demonstrate an absence of government control, both in law and in fact, with respect to exports. To establish whether an exporter is sufficiently independent of government control to be entitled to a separate rate, the Department analyzes the exporter in light of the criteria established in the *Final Determination of Sales at Less Than Fair Value: Sparklers from the People's Republic of China*, 56 FR 20588 (May 6, 1991) ("*Sparklers*"), as amplified in the *Notice of Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the People's Republic of China*, 59 FR 22585 (May 2, 1994) ("*Silicon Carbide*").

## Absence of *De Jure* Control

Evidence supporting, though not requiring, a finding of *de jure* absence of government control over export activities includes: (1) An absence of restrictive stipulations associated with an individual exporter's business and export licenses; (2) any legislative enactments decentralizing control of companies; and (3) any other formal measures by the government decentralizing control of companies. *See Sparklers,* 56 FR at 20589.

**Absence of *De Facto* Control**

A *de facto* analysis of absence of government control over exports is based on four factors—whether the respondent: (1) Sets its own export prices independently of the government and other exporters; (2) retains the proceeds from its export sales and makes independent decisions regarding the disposition of profits or financing of losses; (3) has the authority to negotiate and sign contracts and other agreements; and (4) has autonomy from the government regarding the selection of management. *See Silicon Carbide*, 59 FR at 22587; *see also Sparklers,* 56 FR at 20589.

In the *Notice of Final Determination of Sales at Less Than Fair Value: Bulk Aspirin from the People's Republic of China*, 65 FR 33805 (May 25, 2000) ("LTFV Investigation''), we determined that there was an absence of both *de jure* and *de facto* government control of Shandong's export activities and determined that Shandong warranted a company-specific dumping margin. Shandong responded to the Department's request for information regarding separate rates during the POR. Specifically, Shandong provided the company's business license and information on its ownership, management, and business and financial practices. We examined this information at verification. We find that the evidence on the record is consistent with the *LTFV Investigation* and Shandong continues to demonstrate an absence of government control, both in law and in fact, with respect to its exports, in accordance with the criteria identified in *Sparklers* and *Silicon Carbide*.

**Intent To Revoke**

On July 30, 2003, Shandong requested the revocation of the antidumping duty order covering bulk aspirin from the PRC as it pertains to its sales. Under section 751(d)(1) of the Act, the Department "may revoke, in whole or in part'' an antidumping duty order upon completion of a review. Although Congress has not specified the procedures that the Department must follow in revoking an order, the Department has developed a procedure for revocation that is set forth under 19 CFR 351.222. Under section 351.222(b), the Department may revoke an antidumping duty order in part if it concludes that (i) an exporter or producer has sold the merchandise at not less than normal value for a period of at least three consecutive years, (ii) the exporter or producer has agreed in writing to its immediate reinstatement in the order if the Secretary concludes that the exporter or producer, subsequent to the revocation, sold the subject merchandise at less than normal value, and (iii) the continued application of the antidumping duty order is no longer necessary to offset dumping. Section 351.222(b)(3) states that, in the case of an exporter that is not the producer of subject merchandise, the Department normally will revoke an order in part under section 351.222(b)(2) only with respect to subject merchandise produced or supplied by those companies that supplied the exporter during the time period that formed the basis for revocation.

A request for revocation of an order in part must address three elements. The company requesting the revocation must do so in writing and submit the following statements with the request: (1) The company's certification that it sold the subject merchandise at not less than normal value during the current review period and that, in the future, it will not sell at less than normal value; (2) the company's certification that, during each of the consecutive years forming the basis of the request, it sold the subject merchandise to the United States in commercial quantities; and (3) the agreement to reinstatement in the order if the Department concludes that the company, subsequent to revocation, has sold the subject merchandise at less than normal value. *See* 19 CFR 351.222(e)(1).

We preliminarily find that the request from Shandong meets all of the criteria under 19 CFR 351.222(e)(1). Shandong's revocation request includes the necessary certifications in accordance with 351.222(e). Shandong has also agreed in writing to the immediate reinstatement in the order, as long as any exporter or producer is subject to the order, if the Department concludes that Shandong, subsequent to the revocation, sold the subject merchandise at less than normal value. With regard to the criteria of section 351.222(b)(2), our preliminary margin calculations show that Shandong sold bulk aspirin at not less than normal value during the current review period. *See Dumping Margins* below. In addition, it sold bulk aspirin at not less than normal value in the two previous administrative reviews in which it was involved. *See Notice of Amended Final Results of Antidumping Duty Administrative Review: Bulk Aspirin from the People's Republic of China*, 68 FR 12036 (March 13, 2003), covering the period July 6, 2000, through June 30, 2001, and *Notice of Amended Final Results of Antidumping Duty Administrative Review: Bulk Aspirin from the People's Republic of China*, 68 FR 54890 (September 19, 2003), covering the period July 1, 2001, through June 30, 2002. Based on our examination of the sales data submitted by Shandong, we preliminarily find that Shandong sold the subject merchandise in the United States in commercial quantities in each of the consecutive years cited by Shandong to support its request for revocation. *See Preliminary Results Calculation Memorandum* for Shandong, dated April 1, 2004, which is in the Department's Central Records Unit ("CRU''), Room B–099. Also, we preliminarily find that application of the antidumping order to Shandong is no longer warranted for the following reasons: (1) The company had zero or *de minimis* margins for a period of at least three consecutive years; (2) the company has agreed to immediate reinstatement of the order if the Department finds that it has resumed making sales at less than fair value; and (3) the continued application of the order is not otherwise necessary to offset dumping.

Therefore, we preliminarily find that Shandong qualifies for revocation of the order on bulk aspirin from the PRC pursuant to 19 CFR 351.222(b)(2) and that the order with respect to merchandise produced and exported by Shandong should be revoked. If these preliminary findings are affirmed in our final results, we will revoke the order in part with respect to bulk aspirin from the PRC produced and exported by Shandong. In accordance with 19 CFR 351.222(f)(3), we will terminate the suspension of liquidation for bulk aspirin produced and exported by Shandong that was entered, or withdrawn from warehouse, for consumption on or after July 1, 2003, and will instruct the U.S. Customs and Border Protection ("CBP'') to refund any cash deposits for such entries.

**Export Price and Constructed Export Price**

For certain sales made by Shandong to the United States, we used constructed export price ("CEP'') in accordance with section 772(b) of the Act, because the first sale to an unaffiliated purchaser occurred after importation of the merchandise into the United States. For other sales made by Shandong, we used export price ("EP''), in accordance with section 772(a) of the Act, because the subject merchandise was sold outside the United States to unaffiliated purchasers in the United States prior to importation into the United States and constructed export

price methodology was not otherwise indicated.

We calculated EP based on the FOB prices to unaffiliated purchasers. We calculated CEP based on delivered prices from Shandong's U.S. subsidiary to unaffiliated customers. In accordance with section 772(c) of the Act, as appropriate, we deducted from the starting price foreign inland freight, international freight, marine insurance, U.S. inland freight, U.S. customs duties, and U.S. warehousing expenses. We valued the deductions for foreign inland freight using surrogate data based on Indian freight costs. We selected India as the surrogate country for the reasons explained in the "*Normal Value*" section of this notice, below.

Where Shandong used a market-economy shipper for more than an insignificant portion of its sales and paid for the shipping in a market-economy currency, we used the average price paid by Shandong to value international freight for all of its sales. *See Tapered Roller Bearings from the People's Republic of China; Notice of Preliminary Results of 2000–2001 Review, Partial Rescission of Review, and Notice of Intent to Revoke Order, in Part,* 67 FR 45451, 45453 (July 9, 2002). Where Shandong used a market-economy marine insurance provider for more than an insignificant portion of its sales and paid for the insurance in a market-economy currency, we used the average price for marine insurance paid by Shandong for all of its sales.

In accordance with section 772(d)(1) of the Act, for CEP sales, we made deductions for the following selling expenses that related to economic activity in the United States: credit expenses, indirect selling expenses, and direct selling expenses. Since Shandong did not have U.S. dollar-denominated borrowings during the POR, we calculated credit expenses using the short-term interest rate during the POR, as stated by the Federal Reserve Board. In accordance with section 772(d)(3) of the Act, we deducted from the starting price an amount for profit.

**Normal Value**

Section 773(c)(1) of the Act provides that the Department shall determine the normal value ("NV") using a factors-of-production methodology if: (1) The merchandise is exported from a NME country; and (2) the information does not permit the calculation of NV using home-market prices, third-country prices, or constructed value ("CV") under section 773(a) of the Act.

The Department has treated the PRC as a NME country in all previous antidumping cases. In accordance with section 771(18)(C)(i) of the Act, any determination that a foreign country is a NME country shall remain in effect until revoked by the administering authority. The parties in this proceeding have not contested such treatment in this review. Therefore, we treated the PRC as a NME country for purposes of this review and calculated NV by valuing the factors of production in a surrogate country.

Section 773(c)(4) of the Act requires the Department to value the NME producer's factors of production, to the extent possible, in one or more market economy countries that: (1) Are at a level of economic development comparable to that of the NME, and (2) are significant producers of comparable merchandise. The Department has determined that India, Pakistan, Indonesia, Sri Lanka, and the Philippines are countries comparable to the PRC in terms of overall economic development. For a further discussion of our surrogate selection, *see* Memorandum from Ron Lorentzen, Office of Policy, to Susan Kuhbach, Director, AD/CVD Enforcement, Office 1, "Antidumping Administrative Review of Bulk Aspirin from the People's Republic of China: Request for a List of Surrogate Countries," dated October 31, 2003, which is on file in the Department's CRU. According to the available information on the record, we determined that India is a significant producer of comparable merchandise. None of the interested parties contested the selection of India as the surrogate country. Accordingly, we calculated NV using Indian values for the PRC producer's factors of production.

We obtained and relied upon publicly available information wherever possible. In many instances, we used the *Monthly Statistics of the Foreign Trade of India; Volume II Imports* ("*MSFTI*" ) to value factors of production, energy inputs and packing materials. Consistent with the *Final Determination of Sales at Less than Fair Value: Certain Automotive Replacement Glass Windshields From the People's Republic of China,* 67 FR 6482 (February 12, 2002) and accompanying Issues and Decision Memorandum, we excluded import data reported in the *MSFTI* for Korea, Thailand and Indonesia in our surrogate value calculations. In addition to the *MSFTI* data, we used Indian domestic prices from *Indian Chemical Weekly* ("*ICW*") to value certain chemical inputs. *See* Memorandum from Team to Susan Kuhbach, Director, AD/CVD Enforcement, Office 1, "Factors of Production Valuation for the Preliminary Results," dated April 1, 2004 ("*FOP Memo*").

**Factors of Production**

In accordance with section 773(c) of the Act, we calculated NV based on factors of production reported by the respondent. To calculate NV, the reported unit factor quantities were multiplied by either price quotes or publicly available Indian surrogate values.

In selecting the surrogate values, we considered the quality, specificity, and contemporaneity of the data. As appropriate, we adjusted input prices to make them delivered prices. For the distances reported, we added to Indian CIF surrogate values a surrogate freight cost using the reported distances from the PRC port to the PRC factory, or from the domestic supplier to the factory. This adjustment is in accordance with the United States Court of Appeals for the Federal Circuit's decision in *Sigma Corp.* v. *United States,* 117 F. 3d 1401, 1407–1408 (Fed. Cir. 1997). For those values not contemporaneous with the POR, we adjusted for inflation using the appropriate wholesale or producer price index published in the International Monetary Fund's *International Financial Statistics.*

*Material Inputs:* We valued these inputs from *MSFTI, ICW,* or price quotes, as appropriate. *See FOP Memo.*

*Labor:* We valued labor using the method described in 19 CFR 351.408(c)(3).

*Energy:* We calculated the surrogate value for electricity based on electricity rate data reported by the International Energy Agency ("IEA"), 4th quarter 2002. For coal, we used import values from the *MSFTI.* We based the value of fuel oil on prices reported by the IEA, 4th quarter 2002. We valued water using the Second Water Utilities Data Book, Asian and Pacific Region, October 1997, adjusted for inflation.

*Factory Overhead, SG&A, and Profit:* We based our calculation of factory overhead and SG&A on the 2001–2002 financial data of Alta Laboratories Ltd. ("Alta"), an Indian producer of identical merchandise. Because Alta did not realize a profit during the financial period, we relied on the financial data of two other Indian producers of comparable merchandise, Andhra Sugars Ltd. ("Andhra"), and Gujarat Organics Ltd. ("Gujarat") for 2002–2003 and 2001–2002, respectively.

*Packing Materials:* For packing materials we used import values from the *MSFTI.*

*Inland Freight Rates:* To value truck freight rates, we used an average of trucking rates quoted in ICW. For rail

freight, we based our calculation on 1999 price quotes from Indian rail freight transporters, adjusted for inflation.

**Preliminary Results of the Review**

We preliminary find that the following dumping margin exists for the period July 1, 2002, through June 30, 2003:

| Exporter/manufacturer | Weighted-average margin percentage |
|---|---|
| Shandong Xinhua Pharmaceutical Co., Ltd | 0.00 |

**Assessment Rates**

Pursuant to 19 CFR 351.212(b), the Department calculates an assessment rate for each importer of the subject merchandise for each respondent. Upon issuance of the final results of this administrative review, if any importer-specific assessment rates calculated in the final results are above *de minimis* (*i.e.*, at or above 0.5 percent), the Department will issue appraisement instructions directly to CBP to assess antidumping duties on appropriate entries. To determine whether the duty assessment rates covering the period were *de minimis*, in accordance with the requirement set forth in 19 CFR 351.106(c)(1), we calculate importer (or customer)-specific *ad valorem* rates by aggregating the dumping margins calculated for all U.S. sales to that importer (or customer) and dividing this amount by the total value of the sales to that importer (or customer). Where an importer (or customer)-specific *ad valorem* rate is greater than *de minimis*, we calculate a per unit assessment rate by aggregating the dumping margins calculated for all U.S. sales to that importer (or customer) and dividing this amount by the total quantity sold to that importer (or customer).

All other entries of the subject merchandise during the POR will be liquidated at the antidumping duty rate in place at the time of entry.

The Department will issue appropriate assessment instructions directly to CBP within 15 days of publication of the final results of this review.

**Cash Deposit Rates**

The following deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of bulk aspirin from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(1) of the Act: (1) Because Shandong has a zero margin, no cash deposit shall be required; (2) for a company previously found to be entitled to a separate rate and for which no review was requested, the cash deposit rate will be the rate established in the most recent review of that company; (3) for all other PRC exporters of subject merchandise, the rate will be the PRC country-wide rate, which is 144.02 percent; and (4) for non-PRC exporters of subject merchandise from the PRC, the cash deposit rate will be the rate applicable to the PRC exporter that supplied that exporter. Because Jilin is no longer covered by the antidumping duty order, no cash deposit is required for entries manufactured and exported by Jilin.

These requirements, when imposed, shall remain in effect until publication of the final results of the next administrative review.

**Public Comment**

Any interested party may request a hearing within 30 days of publication of this notice. A hearing, if requested, will be held 37 days after the publication of this notice, or the first business day thereafter. Interested parties may submit case briefs within 30 days of the date of publication of this notice. Rebuttal briefs, which must be limited to issues raised in the case briefs, may be filed not later than 35 days after the date of publication of this notice. The Department will issue the final results of this administrative review, which will include the results of its analysis of issues raised in any such comments, within 120 days of publication of the preliminary results.

**Notification to Importers**

This notice also serves as a preliminary 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 the subsequent assessment of double antidumping duties.

This administrative review and notice are in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: April 1, 2004.

**Jeffrey A. May,**

*Acting Assistant Secretary for Import Administration.*

[FR Doc. 04–8019 Filed 4–7–04; 8:45 am]

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## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–549–813]**

### Notice of Preliminary Results and Preliminary Determination To Revoke Order in Part: Canned Pineapple Fruit From Thailand

**AGENCY:** Import Administration, International Trade Administration, U.S. Department of Commerce.

**SUMMARY:** In response to requests by producers/exporters of subject merchandise and by the petitioners [1], the Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on canned pineapple fruit (CPF) from Thailand. This review covers four producers/exporters of the subject merchandise.

We preliminarily determine that for one producer/exporter, Vita Food Factory (1989) Co., Ltd., sales have been made below normal value (NV). If these preliminary results are adopted in our final results, we will instruct Customs and Border Protection (CBP) to assess antidumping duties based on the difference between the export price (EP) or the constructed export price (CEP), as applicable, and the NV.

**EFFECTIVE DATE:** April 8, 2004.

**FOR FURTHER INFORMATION CONTACT:** Marin Weaver or Charles Riggle, at (202) 482–2336 or (202) 482–0650, respectively; AD/CVD Enforcement Office 5, Group II, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

**SUPPLEMENTARY INFORMATION:**

**Case History**

On July 18, 1995, the Department issued an antidumping duty order on CPF from Thailand. *See Notice of Antidumping Duty Order and Amended Final Determination: Canned Pineapple Fruit From Thailand,* 60 FR 36775 (July 18, 1995). On July 2, 2003, we published in the **Federal Register** the notice of opportunity to request the eighth administrative review of this order. *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review,* 68 FR 39511 (July 2, 2003).

In accordance with § 351.213(b)(2) of the Department's regulations, the following producers/exporters made

[1] The petitioners are Maui Pineapple Company and the International Longshoremen's and Warehousemen's Union.

timely requests that the Department conduct an administrative review for the period from July 1, 2002, through June 30, 2003: Dole Food Company, Inc., Dole Packaged Foods Company, and Dole Thailand, Ltd. (collectively, Dole); Kuiburi Fruit Canning Co., Ltd. (Kuiburi); the Thai Pineapple Public Co., Ltd. (TIPCO); Vita Food Factory (1989) Co. Ltd. (Vita).

In addition, on July 30, 2003, the petitioners, in accordance with § 351.213(b)(1) of the Department's regulations, submitted a timely request that the Department conduct a review of Malee Sampran Public Co., Ltd. (Malee), Prachuab Fruit Canning Co. (Praft), Siam Fruit Canning (1988) Co., Ltd. (SIFCO), and the Thai Pineapple Canning Industry Corp., Ltd. (TPC), as well as for Dole, Kuiburi, TIPCO, and Vita. On August 27, 2003, the petitioners withdrew their review requests for TPC, Praft, SIFCO, and Malee.

On August 22, 2003, we published the notice of initiation of this antidumping duty administrative review, covering the period July 1, 2002, through June 30, 2003. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocation in Part,* 68 FR 50750 (August 22, 2003).

**Scope of the Review**

The product covered by this order is CPF, defined as pineapple processed and/or prepared into various product forms, including rings, pieces, chunks, tidbits, and crushed pineapple, that is packed and cooked in metal cans with either pineapple juice or sugar syrup added. CPF is currently classifiable under subheadings 2008.20.0010 and 2008.20.0090 of the Harmonized Tariff Schedule of the United States (HTSUS). HTSUS 2008.20.0010 covers CPF packed in a sugar-based syrup; HTSUS 2008.20.0090 covers CPF packed without added sugar (*i.e.,* juice-packed). Although these HTSUS subheadings are provided for convenience and for customs purposes, the written description of the scope is dispositive.

**Verification**

As provided in sections 782(i)(2) of the Act, in February and March 2004 we verified information provided by Dole, Kuiburi, and TIPCO. We used standard verification procedures, including on-site inspection of the respondent producers' facilities and examination of relevant sales and financial records.

**Product Comparisons**

We compared the EP or the CEP, as applicable, to the NV, as described in the *Export Price and Constructed Export Price* and *Normal Value* sections of this notice. We first attempted to compare contemporaneous sales in the U.S. and comparison markets of products that were identical with respect to the following characteristics: Weight, form, variety, and grade. Where we were unable to compare sales of identical merchandise, we compared products sold in the United States with the most similar merchandise sold in the comparison markets based on the characteristics listed above, in that order of priority. Where there were no appropriate comparison market sales of comparable merchandise, we compared the merchandise sold in the United States to constructed value (CV), in accordance with section 773(a)(4) of the Act. For all respondents, we based the date of sale on the date of the invoice.

**Export Price and Constructed Export Price**

For the price to the United States, we used, as appropriate, EP or CEP as defined in sections 772(a) and 772(b) of the Act, respectively. Section 772(a) of the Act defines EP as the price at which the subject merchandise is first sold (or agreed to be sold) before the date of importation by the producer or exporter of the subject merchandise outside the United States to an unaffiliated purchaser in the United States, or to an unaffiliated purchaser for exportation to the United States. Section 772(b) of the Act defines CEP as the price at which the subject merchandise is first sold (or agreed to be sold) inside the United States before or after the date of importation, by or for the account of the producer or exporter of the merchandise, or by a seller affiliated with the producer or exporter, to an unaffiliated purchaser, as adjusted under subsections 772(c) and (d) of the Act.

For all respondents, we calculated EP and CEP, as appropriate, using as a starting price the packed prices charged to the first unaffiliated customer in the United States.

In accordance with section 772(c)(2) of the Act, we calculated the EP and CEP by deducting movement expenses and export taxes and duties from the starting price, where appropriate. Section 772(d)(1) of the Act provides for additional adjustments to CEP. Accordingly, for CEP sales we also reduced the starting price by direct and indirect selling expenses incurred in the United States and an amount for profit.

We determined the EP or CEP for each company as follows:

*TIPCO*

For TIPCO's U.S. sales, the merchandise was sold either directly by TIPCO or indirectly through its U.S. affiliate, TIPCO Marketing Co. (TMC), to the first unaffiliated purchaser in the United States prior to importation. We calculated an EP for all of TIPCO's sales because CEP was not otherwise warranted based on the facts of record. Although TMC is a company legally incorporated in the United States, the company does not have either business premises or employees in the United States. TIPCO employees based in Bangkok conduct all of TMC's activities out of TIPCO's Bangkok headquarters, including invoicing, paperwork processing, receipt of payment, and arranging for customs and brokerage. Accordingly, as the merchandise was sold before importation by TMC outside the United States, we have determined these sales to be EP transactions. *See Canned Pineapple Fruit from Thailand: Final Results of Antidumpting Duty Administrative Review,* 66 FR 52744 (October 17, 2001) and accompanying Decision Memo at TIPCO Comment 16. *See also Circular Welded Non-Alloy Steel Pipe from Mexico: Final Results of Antidumping Duty Administrative Review,* 65 FR 37518 (June 15, 2000) and accompanying Decision Memo at Hylsa Comment 3.

We calculated EP based on the packed free on board (FOB) or cost and freight (C&F) price to unaffiliated purchasers in the United States. In accordance with section 772(c)(2)(A) of the Act, we made deductions from the starting price for foreign movement expenses (including brokerage and handling, port charges, stuffing expenses, and inland freight), international freight, U.S. customs duties, and U.S. brokerage and handling. *See* Analysis Memorandum for the Thai Pineapple Public Co. Ltd., dated April 1, 2004 (TIPCO Analysis Memorandum).

*Vita*

We calculated an EP for all of Vita's sales because the merchandise was sold directly by Vita outside the United States to the first unaffiliated purchaser in the United States prior to importation, and CEP was not otherwise indicated. We calculated EP based on the packed FOB, cost, insurance, and freight (CIF), or C&F prices to unaffiliated purchasers in the United States. In accordance with section 772(c)(2)(A) of the Act, we made deductions from the starting price for international freight, marine insurance, and foreign movement expenses (including terminal handling charge,

bill of lading free, customs clearance (shipping) charge, port charges, document legalization fee, stuffing expenses, inland freight and other miscellaneous charges). *See* Analysis Memorandum for Vita Food Factory (1989) Co., Ltd., dated April 1, 2004 (Vita Analysis Memorandum).

*Kuiburi*

We calculated an EP for all of Kuiburi's sales because the merchandise was sold directly by Kuiburi outside the United States to the first unaffiliated purchaser in the United States prior to importation, and CEP was not otherwise indicated. We calculated EP based on the packed FOB or C&F price to unaffiliated purchasers in the United States. In accordance with section 772(c)(2)(A) of the Act, we made deductions from the starting price for foreign movement expenses and international freight. *See* Analysis Memorandum for Kuiburi Fruit Canning Company Limited, dated April 1, 2004 (Kuiburi Analysis Memorandum).

*Dole*

For this period of review (POR), Dole had both EP and CEP transactions. The CEP transactions were made in the United States by Dole Packaged Foods (DPF), a division of Dole. The EP transactions were made directly from Dole Thailand, Ltd. (DTL) to the United States.

CEP was based on DPF's price to unaffiliated purchasers in the United States. We made deductions from the starting price for discounts in accordance with § 351.401(c) of the Department's regulations. We also made deductions for foreign inland movement expenses, insurance and international freight in accordance with section 772(c)(2)(A) of the Act. For Dole's CEP sales, in accordance with section 772(d)(1) of the Act, we deducted from the starting price those selling expenses associated with selling the subject merchandise in the United States, including direct and indirect selling expenses incurred by DPF in the United States. We also deducted from the starting price an amount for profit in accordance with section 772(d)(3) of the Act. *See* Analysis Memorandum for Dole, dated April 1, 2004 (Dole Analysis Memorandum). We calculated EP based on the packed FOB price to unaffiliated purchasers in the United States. In accordance with section 772(c)(2)(A) of the Act, we made deductions from the starting price for foreign movement expenses. *See* Dole Analysis Memorandum.

**Normal Value**

*A. Selection of Comparison Markets*

Based on a comparison of the aggregate quantity of home market sales and U.S. sales, we determined that the quantity of foreign like product each respondent sold in Thailand did not permit a proper comparison with the sales of the subject merchandise to the United States because the quantity of each company's sales in its home market was less than 5 percent of the quantity of its sales to the U.S. market. *See* section 773(a)(1) of the Act. Therefore, for all respondents, in accordance with section 773(a)(1)(B)(ii) of the Act, we based NV on the price at which the foreign like product was first sold for consumption in each respondent's largest viable third-country market, *i.e.,* Germany for both Vita and TIPCO, Canada for Dole, and Spain for Kuiburi.

*B. Cost of Production Analysis*

Pursuant to section 773(b)(1) of the Act, we initiated a COP investigation of comparison markets for each respondent. Because we disregarded sales that failed the cost test in the last completed review for Dole, Kuiburi, TIPCO, and Vita, we had reasonable grounds to believe or suspect that sales by these companies of the foreign like product under consideration for the determination of NV in this review were made at prices below the COP, as provided by section 773(b)(2)(A)(ii) of the Act.[2] As a result, we initiated an investigation of sales below cost for each of these companies. We conducted the COP analysis as described below.

1. Calculation of COP/Fruit Cost Allocation

In accordance with section 773(b)(3) of the Act, for each respondent, we calculated the weighted-average COP, by model, based on the sum of the costs of materials, fabrication, selling, general and administrative (SG&A) expenses, interest expense, and packing costs. We relied on the submitted COPs except in the specific instances noted below, where the submitted costs were not appropriately quantified or valued. In addition, we have implemented a change in practice regarding the treatment of foreign exchange gains and losses. For all four respondents, we adjusted the reported financial expense ratios to include all foreign exchange gains and losses in each company's interest expenses. *See Stainless Steel Bar From India: Final Results of Antidumping Duty Administrative Review,* 68 FR 47543, 47544 (August 11, 2003).

The Department's long-standing practice, now codified at section 773(f)(1)(A) of the Act, is to rely on a company's normal books and records if such records are in accordance with home country generally accepted accounting principles (GAAP) and reasonably reflect the costs associated with production of the merchandise. In addition, as the statute indicates, the Department considers whether an accounting methodology, particulary an allocation methodology, has been historically used by the company. *See* section 773(f)(1)(A) of the Act. In previous segments of this proceeding, the Department has determined that joint production costs (*i.e.,* pineapple and pineapple processing costs) cannot be reasonably allocated to canned pineapple on the basis of weight. *See Final Determination of Sales at Less Than Fair Value: Canned Pineapple Fruit From Thailand,* 60 FR 29553, 29561 (June 5, 1995), [3] and *Notice of Final Results of Antidumping Duty Administrative Review: Canned Pineapple Fruit From Thailand,* 63 FR 7392, 7398 (February 13, 1998). For instance, cores and shells are used in juice production and the production of dehydrated products, while trimmed and cored pineapple cylinders are used in CPF production. Because these various parts of a pineapple are not interchangeable when it comes to CPF versus juice production, it would be unreasonable to value all parts of the pineapple equally by using a weight-based allocation methodology.

Several respondents that revised their fruit cost allocation methodologies during the 1995/1996 POR changed from their historical net realizable value (NRV) methodology to weight-based methodologies and did not incorporate any measure of the qualitative factor of the different parts of the pineapple. As a result, such methodologies, although in conformity with Thai GAAP, do not reasonably reflect the costs associated with production of CPF. Therefore, for companies whose fruit cost allocation

[2] The 2001/2002 review was not completed until five months after the current review was initiated. Therefore, at the time the questionnaires were issued, we initiated the COP investigations based on the results of the completed 2000/2001 review. *See Notice of Final Results of Antidumping Duty Administrative Review, Rescission of Administrative Review in Part, and Final Determination to Revoke Order in Part: Canned Pineapple Fruit from Thailand,* 67 FR 76718 (December 13, 2002).

[3] This determination was upheld by the Court of Appeals for the Federal Circuit. *The Thai Pineapple Public Co.* v. *United States,* 187 F.3d 1362 (Fed. Cir. 1999) (finding that the Department's cost allocation methodology in the original investigation was reasonable and supported by substantial evidence).

methodology is weight-based, we requested that they recalculate fruit costs allocated to CPF based on NV methodology.

Consistent with prior segments of this proceeding, the NRV methodology that we requested respondents to use was based on company-specific historical amounts for sales and separable costs during the five-year period of 1990 through 1994. We made the following company-specific adjustments to the cost data submitted in this review.

*TIPCO.* We adjusted TIPCO's cost calculation for the second half of the POR to revise the solid pineapple ratio used to allocate costs between the solid pineapple used for CPF products and the solid pineapple used for tropical fruit salad products. This adjustment reflects a correction of the reported relative weight of these products based on the Department's findings at verification. *See* TIPCO's Analysis Memorandum for further information.

*Kuiburi.* As discussed above, since the first administrative review of CPF from Thailand the Department has utilized a NRV methodology to allocate pineapple fruit costs among joint products. Under this methodology, the separable costs for each joint product (*e.g.*, solid pineapple products produced primarily from pineapple cylinders and juice and dehydrated core products made primarily from pineapple cores and shells) are subtracted from the gross revenue for each joint product. The ratio of the net realizable value of each joint product to the total net realizable value of all products is then used as the allocation base.

In the most recently completed review, we rejected Kuiburi's reported allocation methodologies from the historic period (1990 through 1994),[4] and 1997 through 2001, because they were based on relative revenues alone and failed to consider the impact of separable costs.[5] Instead, the Department calculated a facts available (FA) NRV ratio for Kuiburi by averaging the historical NRVs of Dole, TIPCO, SIFCO, and Vita, respondents in that review whose methodologies reflected the Department's preferred methodology. At that time, the Department used this FA NRV surrogate methodology because none of the NRV ratio calculations offered by Kuiburi was deemed appropriate.[6] In the instant review, Kuiburi based its allocation of joint products on the surrogate NRV allocation ratio methodology that the Department developed as FA for Kuiburi in the previous review.[7]

However, Kuiburi also provided an alternative NRV ratio calculation, based on solid and juice revenues without separable costs deducted during the partial historical period (1992–1994). Subsequently, Kuiburi provided two other ratios based on solid and juice revenues during the five-year periods of 1997 through 2001, and 1998 through 2002, but again without separable costs deducted. The Department requested that Kuiburi report the first five-year period for which it could provide both revenues and separable costs. In response, Kuiburi provided a ratio based on the five-year period of 1998–2002, which contains separable costs and revenue. For these preliminary results, we have applied as FA the 1998–2002 ratio with separable costs deducted, and have revised relevant costs accordingly. *See* Kuiburi Analysis Memorandum.

We have concluded that the 1998–2002 ratio is preferable to the averaged NRV because it is calculated from Kuiburi's own books and records and is based on both revenue and separable costs, and therefore satisfies more of the Department's requirements. In previous segments of this proceeding, the Department has excluded NRV ratios based on data from time periods when the Department had determined that CPF was sold at less than fair value. However, in this case, the Department has determined to use Kuiburi's NRV ratio from the 1998–2002 period as FA, because, among the alternatives available on the record, it most clearly approximates the Department's specified methodology used to calculate the historic NRV, by utilizing five years of data, incorporating separable costs and relying on the company's own data. As noted in the most recent previous review, Kuiburi did not exist until 1992, and did not maintain any records of separable costs in its early years.[8] Therefore, Kuriburi does not have the data to provide a full NRV calculation based on the historic period of 1990 through 1994.

In addition to selecting an alternative FA ratio for allocation of Kuiburi's joint costs, we have recalculated the total pineapple fruit usage to which this NRV ratio is applied. In its reported cost calculation, Kuiburi correctly offset pineapple cost with scrap scales of pineapple cores and shells to outside buyers. However, after deducting the offset for scrap sales, Kuiburi further reduced total pineapple usage by deducting the calculated values of cores and shell byproducts consumed internally by Kuiburi in the production of dehydrated pineapple cores (cores) and milled juice (shells). We have disallowed these additional offsets for cores and shells consumed to produce Kuiburi dehydrated cores and milled juice because we regard both products as joint products subject to the NRV-based fruit cost allocation, and have revised relevant cost accordingly. *See* Kuiburi Analysis Memorandum.

Kuburi produces dehydrated cores from both fresh pineapple cores it purchases from other producers and from cores Kuiburi obtains as byproducts from its processing of whole pineapple. Kuiburi can track the cost of the purchased fresh cores separately and has properly not included the cost of the purchased cores in its joint production costs because they represent a distinct part of the pineapple dedicated to the production of a specific product, dehydrated cores. The Department disagrees specifically with Kuiburi's deduction of the calculated cost of Kuiburi's own byproduct cores that it uses in its own dehydrated core production. On the same basis, the Department disagrees with Kuiburi's deduction of the calculated cost of pineapple shell used to produce milled juice. In this case, Kuiburi argued that milled juice is itself a byproduct and therefore the cost of the shell input should be deducted. However, we regard milled juice as well as dehydrated cores as joint products.

Under our NRV methodology, to the extent the dehydrated cores and milled juice are produced from cores and shells obtained as byproducts from Kuiburi's whole fruit purchases, milled juice and dehydrated cores are part of the joint production process and must be included in the NRV allocation. Both dehydrated cores and milled juice are accounted for on the "juice'' side of the NRV allocation. As discussed above, the goal of the NRV methodology is to rationalize cost allocation of pineapple purchased whole, but for which the cylinder portions are normally used for CPF and other higher revenue products while the cores and shell are normally devoted to juice products. With the introduction of new products such as the dehydrated cores, it is important to reemphasize that the purpose of the NRV joint product methodology in this case is to distinguish between products that are primarily made from the cylinder portion of the pineapple and

[4] Kuiburi began operations in 1992, so its reported historical period costs were actually from 1992 through 1994.

[5] *Final Results POR 7* and accompanying Issues and Decision Memorandum at Comment 13.

[6] *Id.*

[7] *See Notice of Final Results, Partial Rescission of Antidumping Duty Administrative Review, and Final Determination to Not Revoke Order in Part: Canned Pineapple Fruit From Thailand,* 68 FR 65247 (November 19, 2003) (*Final Results POR 7*).

[8] *Id.*

other products that are primarily made from the shells and cores.

We also adjusted the general and administrative expenses based on findings at verification. *See* Kuiburi's Analysis Memorandum.

*Dole.* Based on verification findings we adjusted the values of sugar and citric acid as used in Dole's cost calculation. We increased the total value of the sugar used in Dole's cost calculation because we found that Dole had underreported its sugar costs, and we decreased citric acid costs because Dole had overstated them. Additionally, we recalculated Dole's can and labor costs to subtract the costs and labor associated with 6-ounce lithograph cans. *See* Dole Analysis Memorandum for further information.

2. Test of Comparison Market Sales Prices

As required under section 773(b) of the Act, we compared the adjusted weighted-average COP for each respondent to the comparison market sales of the foreign like product to determine whether these sales had been made at prices below the COP within an extended period of time in substantial quantities, and whether such prices were sufficient to permit the recovery of all costs within a reasonable period of time. On a product-specific basis, we compared the revised COP to the comparison market prices, less any applicable movement charges, taxes, rebates, commissions and other direct and indirect selling expenses.

3. Results of the COP Test

Pursuant to section 773(b)(2)(C) of the Act, where less than 20 percent of a respondent's sales of a given product were made at prices below the COP, we do not disregard any below-cost sales of that product because the below-cost sales were not made in "substantial quantities.'' Where (1) 20 percent or more of a respondent's sales of a given product during the POR were made at prices below the COP and thus such sales were made within an extended period of time in substantial quantities in accordance with sections 773(b)(2)(B) and (C) of the Act; and, (2) based on comparisons of price to weighted-average COPs for the POR, we determine that the below-cost sales of the product were at prices which would not permit recovery of all costs within a reasonable time period, in accordance with section 773(b)(2)(D) of the Act, we disregard the below-cost sales.

We found that for certain CPF products, Dole, Kuiburi, TIPCO, and Vita made comparison-market sales at prices below the COP within an extended period of time in substantial quantities. Further, we found that these sales prices did not permit the recovery of costs within a reasonable period of time. We therefore excluded these sales from our analysis in accordance with section 773(b)(1) of the Act.

*C. Calculation of Normal Value Based on Comparison Market Prices*

We determined price-based NVs for each company as follows. For all respondents, we made adjustments for differences in packing in accordance with sections 773(a)(6)(A) and 773(a)(6)(B)(i) of the Act, and we deducted movement expenses consistent with section 773(a)(6)(B)(ii) of the Act. In addition, where applicable, we made adjustments for differences in cost attributable to differences in physical characteristics of the merchandise pursuant to section 773(a)(6)(C)(ii) of the Act, as well as for differences in circumstances of sale (COS) in accordance with section 773(a)(6)(C)(iii) of the Act and § 351.410 of the Department's regulations. We also made adjustments, in accordance with § 351.410(e) of the Department's regulations, for indirect selling expenses incurred on comparison market or U.S. sales where commissions were granted on sales in one market but not in the other (the "commission offset''). Specifically, where commissions were granted in the U.S. market but not in the comparison market, we made a downward adjustment to NV for the lesser of (1) the amount of the commission paid in the U.S. market, or (2) the amount of indirect selling expenses incurred in the comparison market. If commissions were granted in the comparison market but not in the U.S. market, we made an upward adjustment to NV following the same methodology. Company-specific adjustments are described below.

*TIPCO.* We based third-country market prices on the packed, FOB or C&F prices to unaffiliated purchasers in Germany. We adjusted for the following movement expenses: brokerage and handling, port charges, stuffing expenses, inland freight, and international freight. We made COS adjustments by deducting direct selling expenses incurred for third-country market sales (commissions, credit expenses, and bank charges) and adding U.S. direct selling expenses (commissions, credit expenses, and bank charges).

*Vita.* We based third-country market prices on the packed FOB, C&F, or free alongside ship (FAS) prices to unaffiliated purchasers in Germany. We adjusted for the following movement expenses: international freight, inland freight, terminal handling charges, container stuffing charges, bill of lading fees, customs clearance charges, port charges, document legalization fees and other miscellaneous charges. We made COS adjustments by deducting direct selling expenses incurred for third-country market sales (credit expenses, commissions, bank charges, warranty expenses, and packing costs) and adding U.S. direct selling expenses (credit expenses, commissions, and bank charges).

*Kuiburi.* We based third-country market prices on the packed, FOB or C&F prices to an unaffiliated purchaser in Spain. We adjusted for foreign movement and international freight expenses. We made COS adjustments by deducting direct selling expenses incurred for third-country market sales (credit expenses and bank charges) and adding U.S. direct selling expenses (credit expenses, bank charges, and commissions).

*Dole.* We based third-country market prices on Dole Foods of Canada Ltd.'s (DFC) prices to unaffiliated purchasers in Canada. We adjusted for foreign movement expenses and international freight. We made COS adjustments by deducting direct selling expenses incurred for third-country market sales (credit expenses, warranty, advertising, royalties, and commissions) and adding U.S. direct selling expenses (credit expenses, advertising, warranty, and commissions). We adjusted Dole's Canadian interest rate so that it reflects the one month prime commercial paper rate published by the Bank of Canada instead of the prime business rate which Dole had used to calculate credit expenses. In addition, because the NV LOT is more remote from the factory than the CEP LOT (*see* the *Level of Trade* section, below), and available data provide no appropriate basis to determine a LOT adjustment between NV and CEP, we made CEP offset pursuant to section 773(a)(7)(B) of the Act.

*D. Calculation of Normal Value Based on Constructed Value*

In accordance with section 773(e) of the Act, we calculated CV based on the sum of the COM of the product sold in the United States, plus amounts for SG&A expenses, interest expenses, comparison market profit, and U.S. packing costs. We calculated each respondent's CV based on the methodology described in the *Calculation of COP* section of this notice, above. In accordance with section 773(e)(2)A) of the Act, we used the actual amounts incurred and

realized by each respondent in connection with the production and sale of the foreign like product, in the ordinary course of trade, for consumption in the comparison market to calculate SG&A expenses and comparison market profit.

Where we compared U.S. price to CV, we made adjustments to CV for COS differences, in accordance with section 773(a)(8) of the Act and § 351.410 of the Department's regulations, and as described under the *Calculation of Normal Value* section above. We made COS adjustments by deducting direct selling expenses incurred on comparison market sales and adding U.S. direct selling expenses for comparison to EP transactions in the United States. We did not compare U.S. price to CV for Dole, Kuiburi, or TIPCO because all U.S. sales were compared to contemporaneous sales of identical or similar merchandise in the ordinary course of trade. For Vita we compared U.S. price to CV when there were no contemporaneous sales of identical or similar merchandise in the ordinary course of trade.

**Level of Trade**

In accordance with section 773(a)(1)(B) of the Act, to the extent practicable, we determine NV based on sales in the comparison market at the same LOT as the EP or CEP transaction. The NV LOT is that of the starting price sales in the comparison market or, when NV is based on CV, that of the sales from which we derive SG&A expenses and profit. For EP sales, the U.S. LOT is also the level of the starting price sale, which is usually from exporter to importer. For CEP sales, it is the level of the constructed sale from the exporter to the importer.

To determine whether NV sales are at a different LOT than EP or CEP transactions, we examine stages in the marketing process and selling functions along the chain of distribution between the producer and the unaffiliated customer. If the comparison market sales are at a different LOT, and the difference affects price comparability, as manifested in a pattern of consistent price differences between the sales on which NV is based and comparison market sales at the LOT of the export transaction, we make a LOT adjustment under section 773(a)(7)(A) of the Act. Finally, for CEP sales, if the NV LOT is more remote from the factory than the CEP LOT and there is no basis for determining whether the difference in the LOTs between NV and CEP affects price comparability, we adjust NV under section 773(a)(7)(B) of the Act (the CEP offset provision). *See Final Determination of Sales at Less Than Fair Value: Greenhouse Tomatoes From Canada*, 67 FR 8781 (February 26, 2002).

In implementing these principles in this review, we obtained information from each respondent about the marketing stage involved in the reported U.S. and comparison market sales, including a description of the selling activities performed by the respondents for each channel of distribution. In identifying levels of trade for EP and comparison market sales, we considered the selling functions reflected in the starting price before any adjustments. For CEP sales, we considered only the selling activities reflected in the price after the deduction of expenses and profit under section 772(d) of the Act. We expect that, if claimed LOTs are the same, the functions and activities of the seller should be similar. Conversely, if a party claims that LOTs are different for different groups of sales, the functions and activities of the seller should be dissimilar.

In this review, all respondents except Dole, claimed that all of their sales involved identical selling function, irrespective of channel of distribution or market. We examined these selling functions for Vita, TIPCO, and Kuiburi and found that sales activities were limited to negotiating sales prices, processing of purchase orders/contracts, invoicing, and collecting payment. There was little or no strategic and economic planning, advertising or sales promotion, technical services, technical assistance, or after-sale service performed in either market by the respondents. Therefore, for all respondents except Dole, we have preliminarily found that there is an identical LOT in the U.S. and relevant comparison market, and no LOT adjustment is required for comparison of U.S. sales to comparison market sales.

*Dole*

Dole reported six specific customer categories and one channel of distribution (sales through an affiliated reseller) for its comparison market, and eight specific customer categories and two channels of distribution for the U.S. market. The primary channel of distribution reported is sales through an affiliated reseller for its U.S. sales. The second channel of distribution in the United States is direct sales. In its response, Dole claims, and the Department concurs, that all of its sales to unaffiliated comparison market customers (*i.e.,* the six customer categories) are at the same LOT because these sales are made through the same channel of distribution and involve the same selling functions.

Dole had both CEP and EP sales in the U.S. market. Dole reported that its CEP sales were made through a single channel of distribution (*i.e.,* sales through its U.S. affiliate, Dole Packaged Foods (DPF)). After making the appropriate deductions under section 772(d) of the Act for these CEP sales, we found that the remaining expenses associated with selling activities performed by Dole are limited to expenses related to the arrangement of freight and delivery to the port of export, which are incurred for all such sales. Consequently, we find that all CEP sales occurred at the same LOT. In contrast, the NV prices include a number of selling expenses attributable to selling activities performed by DFC in the comparison market, such as inventory maintenance, warehousing, delivery, order processing, advertising, rebate and promotional programs, warranties, and market research. Accordingly, we concluded that CEP is at a different LOT from the NV LOT, (*i.e.,* the CEP sales are less remote from the factory than are the NV sales).

For CEP sales, having determined that the comparison market sales were made at a level more remote from the factory than the CEP transactions, we then examined whether a LOT adjustment or CEP offset may be appropriate. In this case, Dole only sold at one LOT in the comparison market; therefore, there is no information available to determine a pattern of consistent price differences between the sales on which NV is based and the comparison market sales at the LOT of the export transaction, in accordance with the Department's normal methodology as described above. *See Porcelain-on-Steel Cookware from Mexico Final Results of Administrative Review,* 65 FR 30068 (May 10, 2000). Further, we do not have information which would allow us to examine pricing patterns based on respondent's sales of other products, and there are no other respondents or other record information on which such an analysis could be biased. Accordingly, because the data available do not provide an appropriate basis for making a LOT adjustment, but the LOT in the comparison market is at a more advanced stage of distribution than the LOT of the CEP transactions, we made a CEP offset adjustment in accordance with section 773(a)(7)(B) of the Act. This offset is equal to the amount of indirect selling expenses incurred in the comparison market not exceeding the amount of indirect selling expenses deducted from the U.S. price in accordance with 772(d)(1)(D) of the Act.

Additionally, it appears that Dole's Canadian sales involve significantly more selling functions than Dole's U.S. EP sales. Therefore, we conclude that Dole's NV sales are made at a different, and more remote, level of trade than its EP sales. Nonetheless, we are unable to make a LOT adjustment for EP sales because there is no data on the record that would allow the Department to establish whether there is a pattern of consistent price differences between sales at different levels of trade in the comparison market. Therefore, a LOT adjustment is not possible for comparisons of EP sales to comparison market sales.

**Intent To Revoke in Part**

On July 28, 2003, both Kuiburi and TIPCO requests that, pursuant to 19 CFR 351.222(b)(2), the Department revoke the antidumping duty order in part based on their three consecutive years of sales at not less than normal value. On July 31, 2003, Dole made the same request. Dole, Kuiburi and TIPCO submitted, along with their revocation requests, a certification stating that: (1) Each company sold subject merchandise at not less than normal value during the POR, and that in the future each company would not sell such merchandise at less than normal value (*see* 19 CFR 351.222(e)(1)(i); (2) each company has sold the subject merchandise to the United States in commercial quantities during each of the past three years (*see* 19 CFR 351.222(e)(1)(ii); and (3) each company agreed to its immediate reinstatement in the order, as long as any exporter or producer is subject to the order, if the Department concludes that the company, subsequent to the revocation, sold the subject merchandise at less than NV. *See* 19 CFR 351.222(b)(2)(iii), and as referenced at 19 CFR 351.222(e)(1)(iii).

Based on the preliminary results in this review and the final results of the two preceding reviews (*see Notice of Final Results of Antidumping Duty Administrative Review, Rescission of Administrative Review in Part, and Final Determination to Revoke Order in Part: Canned Pineapple Fruit from Thailand,* 67 FR 76718 (December 13, 2002) and *Notice of Final Results of Antidumping Duty Administrative Review, Rescission of Administrative Review in Part, and Final Determination to Not Revoke Order in Part: Canned Pineapple Fruit from Thailand,* 68 FR 65247 (November 19, 2003)), Dole, Kuiburi, and TIPCO have preliminarily demonstrated three consecutive years of sales at not less than normal value. Furthermore, Dole's, Kuiburi's, and TIPCO's aggregate sales to the United States have been made in commercial quantities during the last three segments of this proceeding. *See* the April 1, 2004, Memorandum to Holly Kuga: Preliminary Determination to Revoke in Part the Antidumping Duty Order on Canned Pineapple Fruit from Thailand. Interested parties are invited to comment in their case briefs on all of the requirements that must be met by Dole, Kuiburi, and TIPCO under § 351.222 of the Department's regulations to qualify for revocation from the antidumping duty order. Based on the above facts and absent any evidence to the contrary, the Department preliminarily determines that the continued application of the order to Dole, Kuiburi, and TIPCO is not otherwise necessary to offset dumping. Therefore, if these preliminary findings are affirmed in our final results, we intend to revoke the order with respect to merchandise produced and exported by Dole, Kuiburi, and TIPCO. In accordance with 19 CFR 351.222(f)(3), we will terminate the suspension of liquidation for any such merchandise entered, or withdrawn from warehouse, for consumption on or after July 1, 2003, and will instruct Customs to refund any cash deposit.

**Currency Conversion**

We made currency conversions into U.S. dollars in accordance with section 773A of the Act, based on exchange rates in effect on the date of the U.S. sales as certified by the Federal Reserve Bank.

**Preliminary Results of Review**

As a result of this review, we preliminarily determine that the following weighted-average margins exist for the period July 1, 2002, through June 30, 2003:

| Manufacturer/exporter | Margin (percent) |
|---|---|
| Dole Thailand, Ltd. (Dole) | 0.18 |
| Thai Pineapple Public Co., Ltd. (TIPCO) | 0.12 |
| Kuiburi Fruit Canning Co., Ltd. (Kuiburi) | 0.30 |
| Vita Food Factory (1989) Co., Ltd. (Vita) | 0.96 |

Within five days of the publication of this notice we will disclose to parties to this proceeding the calculations used in our analyses. *See* section 351.224(b) of the Department's regulations. Interested parties are invited to comment on the preliminary results. Interested parties may submit case briefs within 30 days of the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than 37 days after the date of publication. Parties who submit arguments are requested to submit with each argument: (1) A statement of the issue, (2) a brief summary of the argument, and (3) a table of authorities. Further, we would appreciate it if parties submitting written comments would provide the Department with an additional copy of the public version of any such comments on a diskette. Any interested party may request a hearing within 30 days of publication of this notice. *See* section 351.310(c) of the Department's regulations. If requested, a hearing will be held 44 days after the publication of this notice, or the first workday thereafter. The Department will publish a notice of the final results of this administrative review, which will include the results of its analysis of issues raised in any written comments or hearing, within 120 days from publication of this notice.

**Assessment**

Pursuant to § 351.212(b) of the Department's regulations, the Department calculated an assessment rate for each importer of subject merchandise. Upon completion of this review, the Department will instruct CBP to assess antidumping duties on all entries of subject merchandise by those importers. We have calculated each importer's duty assessment rate based on the ratio of the total amount of antidumping duties calculated for the examined sales to the total calculated entered value of examined sales. Where the assessment rate is above *de minimis,* the importer-specific rate will be assessed uniformly on all entries made during the POR.

**Cash Deposit Requirements**

The following deposit rates will be effective upon publication of the final results of this administrative review for all shipments of CPF from Thailand entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(1) of the Act: (1) The cash deposit rate for companies listed above will be the rate established in the final results of this review, except if the rate is less than 0.5 percent and, therefore, *de minimis*, the cash deposit will be zero; (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 LTFV investigation, but the manufacturer is,

the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) if neither the exporter nor the manufacturer is a firm covered in this or any previous review or the LTFV investigation conducted by the Department, the cash deposit rate will be 26.64 percent, the "All Others" rate established in the LTFV investigation.

These cash deposit requirements, when imposed, shall remain in effect until publication of the final results of the next administrative review.

This notice serves as a preliminary reminder to importers of their responsibility under § 351.402(f)(2) of the Department's regulations to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This determination is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: April 1, 2004.

**Jeffrey A. May,**

*Acting Assistant Secretary for Import Administration.*

[FR Doc. 04–8014 Filed 4–7–04; 8:45 am]

BILLING CODE 3510–DS–M

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A-570–892, A-533–838]**

### Carbazole Violet Pigment 23 from India and the People's Republic of China: Notice of Postponement of Preliminary Antidumping Duty Determinations

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**ACTION:** Notice of Postponement of Preliminary Antidumping Duty Determinations in Antidumping Investigations.

**EFFECTIVE DATE:** April 8, 2004.

**FOR FURTHER INFORMATION CONTACT:** David Layton at (202) 482–0371 or Charles Riggle at (202) 482–0650, AD/CVD Enforcement Office 5, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230.

**SUMMARY:** The Department of Commerce (the Department) is postponing the preliminary determinations in the antidumping investigations on carbazole violet pigment 23 (CVP-23) from India and the People's Republic of China (PRC) from April 29, 2004 to June 18, 2004. This postponement is made pursuant to section 733(c)(1)(B) of the Tariff Act of 1930, as amended (the Act).

**SUPPLEMENTARY INFORMATION:**

#### Postponement of Preliminary Determination

The preliminary determinations for these investigations are currently due no later than April 29, 2004. Under section 733(c)(1)(B) of the Act, the Department can extend the period for reaching a preliminary determination until not later than the 190th day after the date on which the administering authority initiates an investigation if the Department concludes that the parties concerned are cooperating and determines that: (i) the case is extraordinarily complicated by reason of (I) the number and complexity of the transactions to be investigated or adjustments to be considered, (II) the novelty of the issues presented, or (III) the number of firms whose activities must be investigated, and (ii) additional time is necessary to make the preliminary determination.

We have concluded that the statutory criteria for postponing the preliminary determinations have been met. Specifically, the parties concerned are cooperating in these investigations. Furthermore, additional time is necessary to complete the preliminary determinations due to the number and complexity of the transactions to be investigated and adjustments to be considered. For example, for the PRC, each respondent has reported a different production process consisting of some 30 inputs, some of which may need to be converted into different concentration levels before being introduced into the main processes. Moreover, there are several inputs that are recycled, further complicating the manner in which we determine normal value. The investigation in India involves potentially complex affiliation issues. In addition, there are numerous respondents subject to the two investigations. Finally, on March 23, 2004, the petitioners (Nation Ford Chemical Company and Sun Chemical Corporation) alleged critical circumstances with respect to imports of CVP-23 from the PRC. We are currently reviewing these allegations.

Pursuant to section 733(c)(1)(B) of the Act, we have determined that these investigations are "extraordinarily complicated" and additional time is necessary. We are, therefore, postponing the preliminary determinations by 50 days to June 18, 2004.

This notice is issued and published pursuant to section 733(c)(2) of the Act and 19 CFR 351.205(f)(1).

Dated: April 1, 2004.

**Jeffrey A. May,**

*Acting Assistant Secretaryfor Import Administration.*

[FR Doc. 04–8013 Filed 4–7–04; 8:45 am]

BILLING CODE 3510–DS–S

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–583–837]**

### Polyethylene Terephthalate Film, Sheet, and Strip from Taiwan: Preliminary Results of Antidumping Duty Administrative Review

**ACTION:** Notice of preliminary results of antidumping duty administrative review.

**SUMMARY:** Upon the request of the petitioners, the Department of Commerce ("the Department") is conducting an administrative review of the antidumping duty order on Polyethylene Terephthalate Film, Sheet, and Strip ("PET film") from Taiwan, with respect to Nan Ya Plastics Corporation, Ltd., ("Nan Ya") and Shinkong Synthetic Fibers Corporation ("Shinkong"), in accordance with 19 CFR 351.213. The period of review ("POR") is December 21, 2001, through June 30, 2003. Our preliminary results of review indicate that Nan Ya and Shinkong have sold subject merchandise at less than normal value ("NV") during the POR. If these preliminary results are adopted in our final results of this administrative review, we will instruct U.S. Customs and Border Protection ("CBP") to assess antidumping duties on Nan Ya's and Shinkong's entries of subject merchandise made during the POR, in accordance with section 751(a)(2)(C) of the Tariff Act of 1930, as amended ("The Act"), and 19 CFR 351.212(b). We invite interested parties to comment on these preliminary results. We will issue the final results of review no later than 120 days from the date of publication of this notice.

**EFFECTIVE DATE:** April 8, 2004.

**FOR FURTHER INFORMATION CONTACT:** Zev Primor or Tom Martin at (202) 482–4114 and (202) 482–3936, respectively; AD/CVD Enforcement Office IV, Group II, Import Administration, Room 1870, International Trade Administration, U.S. Department of Commerce, 14th

Street and Constitution Avenue, NW., Washington, DC 20230.

**SUPPLEMENTARY INFORMATION:**

## Background

The Department initiated this administrative review on August 19, 2003, in response to a request for review by the petitioners.[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part,* 68 FR 50750 (August 22, 2003) (*Initiation Notice*). Since the initiation of this review, the following events have occurred.

On August 27, 2003, the Department issued the antidumping duty questionnaire[2] to Nan Ya and Shinkong. After granting extensions to both respondents, we received responses to our questionnaire from both respondents in September and October 2003, respectively. We issued supplemental questionnaires to both respondents, pertaining to section A of the questionnaire on October 29, 2003, sections B and C of the questionnaire on November 6, 2003, and section D of the questionnaire on November 14, 2003. After the Department granted extensions, Nan Ya and Shinkong responded to these supplemental questionnaires. The Department sent an additional supplemental section B and C questionnaire to Nan Ya on February 9, 2004, and after requesting and receiving an extension of the deadline for the response, Nan Ya responded.

## Scope of Review

For purposes of this administrative review, the products covered are all gauges of raw, pretreated, or primed PET film, whether extruded or coextruded. Excluded are metallized films and other finished films that have had at least one of their surfaces modified by the application of a performance-enhancing resinous or inorganic layer more than 0.00001 inches thick. Imports of PET film are classifiable in the Harmonized Tariff Schedule of the United States ("HTSUS'') under item number 3920.62.00. HTSUS subheadings are provided for convenience and customs purposes. The written description of the scope of this proceeding is dispositive.

## Nan Ya Affiliation

In the less-than-fair-value investigation, the Department found that Nan Ya was affiliated with some of its U.S. customers. *See Notice of Final Determination of Sales at Less Than Fair Value: Polyethylene Terephthalate Film, Sheet, and Strip (PET Film) from Taiwan,* 67 FR 35474 (May 20, 2002) ("*LTFV Investigation*''). In the instant review, Nan Ya claims that it is not affiliated with the U.S. customers found to be its affiliates in the *LTFV Investigation.* In making this claim, Nan Ya named an additional U.S. customer, a customer that was not at issue in the *LTFV Investigation,* and also denied that it was affiliated with Nan Ya. The Department has examined the issue of whether Nan Ya is affiliated with these U.S. customers through a family grouping. For these preliminary results, we continue to find, as we did in the *LTFV Investigation,* that Nan Ya is affiliated with these U.S. customers through this family grouping. We include in this finding the additional customer that was not at issue in the *LTFV Investigation. See* Memorandum from Thomas F. Futtner, Acting Office Director, to Holly A. Kuga, Acting Deputy Assistant Secretary, "Affiliation of Nan Ya Plastics Corporation, Ltd., with Certain U.S Customers,'' dated April 1, 2004 ("Affiliation Memo''). Interested parties are invited to submit comments on this specific issue, especially with regard to affiliation through a family grouping.

## Product Comparisons

In accordance with section 771(16) of the Act, all products produced by the respondents covered by the description in the "Scope of Review'' section, above, and sold in Taiwan during the POR are considered to be foreign like products for purposes of determining appropriate product comparisons to U.S. sales. We have relied upon product type, product application, product thickness, and product grade to match U.S. sales of subject merchandise to comparison-market sales of the foreign like product or CV. Where there were no sales of identical merchandise in the home market to compare to U.S. sales, we compared U.S. sales to the next most similar foreign like product on the basis of the characteristics listed above.

## Nan Ya Margin Calculation

### *A. Export Price and Constructed Export Price*

In calculating U.S. price, we used export price ("EP''), as defined in section 772(a) of the Act, for all sales that Nan Ya reported as sold directly to unaffiliated U.S. customers, and constructed export price ("CEP''), as defined in section 772(b) of the Act, for all sales to customers that the Department has preliminarily determined to be Nan Ya's affiliates. *See* Affiliation Memo. We calculated EP using the packed prices charged to unaffiliated Taiwanese trading companies that requested U.S. shipping marks, or the first unaffiliated end-user in the United States (the starting price), and CEP using the packed price charged by the affiliated customer to the first unaffiliated purchaser in the United States.

We deducted from the starting price, where applicable, amounts for movement expenses in accordance with section 772(c)(2)(A) of the Act. In this case, movement expenses include foreign inland freight, international freight, brokerage and handling charges, and marine insurance. For CEP sales, we deducted these same charges, whether or not paid for by affiliates, in addition to customs duties, U.S. inland freight from port to warehouse, U.S. inland freight to unaffiliated customers, and warehousing, where applicable.

### *B. Normal Value*

1. Selection of Comparison Market

In accordance with section 773(a)(1)(B) of the Act, to determine whether there was a sufficient volume of sales in the home market to serve as a viable basis for calculating NV (*i.e.,* the aggregate volume of home market sales of the foreign like product is greater than or equal to five percent of the aggregate volume of U.S. sales), we compared Nan Ya's volume of home market sales of the foreign like product to the volume of its U.S. sales of subject merchandise. We determined that sales in the home market provide a viable basis for calculating NV. Therefore, we based NV on home market sales to unaffiliated purchasers made in the usual commercial quantities and the ordinary course of trade.

For NV, we used the prices at which the foreign like product was first sold for consumption in Taiwan, in the usual commercial quantities, in the ordinary course of trade, and, to the extent possible, at the same level of trade ("LOT'') as the EP or CEP sales, as appropriate. After testing home market

[1] The petitioners in this review are DuPont Teijin Films, Mitsubishi Polyester Film of America and Toray Plastics (America), Inc. (collectively, the petitioners).

[2] Section A of the questionnaire requests general information concerning a company's corporate structure and business practices, the merchandise under review that it sells, and the manner in which it sells that merchandise in all of its markets. Section B requests a complete listing of all home market sales, or, if the home market is not viable, of sales in the most appropriate third-country market. Section C requests a complete listing of U.S. sales. Section D requests information on the cost of production ("COP'') of the foreign like product and the constructed value ("CV'') of the merchandise under review. Section E requests information on further manufacturing.

viability and whether home market sales were at below-cost prices, we calculated NV as noted in the "Calculation of NV Based on Home Market Prices'' section below.

2. Cost of Production Analysis

Because the Department determined that Nan Ya made sales in the home market at prices below the cost of producing the subject merchandise in the *LTFV Investigation* and excluded such sales from NV, the Department determined that there are reasonable grounds to believe or suspect that Nan Ya made sales in the home market at prices below the cost of producing the merchandise in this administrative review. *See* section 773(b)(2)(A)(ii) of the Act. As a result, the Department initiated a COP inquiry for Nan Ya.

In response to a request made by Nan Ya to report its COP and CV information for period January 2002 through June 2003, instead of the POR, we requested that Nan Ya compare the COP from the first eleven days of the POR (December 21–31, 2001) to the rest of the POR. *See* Letter from Ronald Trentham to Nan Ya Plastics Corporation, dated September 25, 2003. The Department stipulated that if Nan Ya's December 21–31, 2001, costs were significantly different from the weighted-average costs it incurred for calendar year 2002 and through June 2003 (after accounting for exchange rate fluctuations and inflation), then Nan Ya would be responsible for submitting its December 21–31, 2001, COP and CV data. Nan Ya provided the Department with this COP comparison, and demonstrated that its December 21–31, 2001, costs were not significantly different from the weighted-average costs it incurred for calendar year 2002 through June 2003. *See* Memorandum from Thomas Martin, Import Compliance Specialist, to The File, dated October 1, 2003. The Department also applied this practice in *Notice of Final Determination of Sales at Less Than Fair Value: Stainless Steel Bar From Italy,* 67 FR 3155 (January 23, 2002).

*a. Calculation of COP*

In accordance with section 773(b)(3) of the Act, we calculated a weighted-average COP for Nan Ya based on the sum of the cost of materials and fabrication for the foreign like product, plus amounts for the home market general and administrative ("G&A'') expenses, including interest expenses. We relied on the COP data submitted by Nan Ya in its cost questionnaire responses.

*b. Test of Home Market Sales Prices*

On a model-specific basis, we compared the reported COP to the home market prices, adjusted for any applicable discounts and rebates, movement charges, selling expenses, and packing. We then compared the adjusted weighted-average COP for Nan Ya to the adjusted home market sales prices of the foreign like product, as required under section 773(b)(1) of the Act, in order to determine whether these sales had been made at prices below the COP in substantial quantities within an extended period of time (*i.e.,* a period of 18 months), and, whether below-cost prices were sufficient to permit the recovery of all costs within a reasonable period of time.

*c. Results of the COP Test*

Pursuant to section 773(b)(2)(C) of the Act, where less than 20 percent of a respondent's sales of a given product during the POR are at prices less than the COP, we do not disregard any below-cost sales of that product because we determine that the below-cost sales were not made in "substantial quantities'' within an extended period of time. Where 20 percent or more of a respondent's sales of a given product during the POR are at prices less than the COP, we determine such sales to have been made in "substantial quantities'' within an extended period of time in accordance with sections 773(b)(2)(B) and 773(b)(2)(C) of the Act. In such cases, because we compare prices to POR average costs, we also determine that such sales were not made at prices that would permit recovery of all costs within a reasonable period of time, in accordance with section 773(b)(2)(D) of the Act. We compared the COP for subject merchandise to the reported home market prices less all applicable charges. Based on this test, we found that Nan Ya did have sales below cost which failed the cost test and, as a result, were removed from the home market data set.

3. Calculation of NV Based on Home Market Prices

We based home market prices on the packed prices to unaffiliated purchasers in Taiwan. We adjusted the starting price for reported quantity discounts and other discounts, for any differences in packing, in accordance with sections 773(a)(6)(A) and 773(a)(6)(B)(i) of the Act, and we deducted movement expenses pursuant to section 773(a)(6)(B)(ii) of the Act. In addition, where applicable, we adjusted the starting price for differences in circumstances of sale ("COS'') pursuant to section 773(a)(6)(C)(iii) of the Act by deducting direct selling expenses (credit expenses) incurred for home market sales, and adding U.S. direct selling expenses (credit expenses).

4. Level of Trade /Constructed Export Price Offset

In accordance with section 773(a)(1)(B)(i) of the Act, to the extent practicable, we determine NV based on sales in the comparison market at the same LOT as the EP or CEP transactions, as appropriate. The NV LOT is that of the starting-price of sales in the comparison market or, when NV is based on CV, that of the sales from which we derive selling, general, and administrative ("SG&A'') expenses and profit. For EP sales, the U.S. LOT is also the level of the starting-price sale, which is usually from exporter to importer. For CEP, it is the level of the constructed sale from the exporter to an affiliated importer after the deductions required under section 772(d) of the Act.

To determine whether NV sales are at a different LOT than EP or CEP transactions, we examine stages in the marketing process and selling functions along the chain of distribution between the producer and the unaffiliated customer. If the comparison market sales are at a different LOT and the difference affects price comparability, as manifested in a pattern of consistent price differences between the sales on which NV is based and comparison market sales at the LOT of the export transaction, we make a LOT adjustment under section 773(a)(7)(A) of the Act.

We obtained information from Nan Ya about the marketing stages involved in the reported U.S. and home market sales, including a description of the selling activities performed by the respondents for each channel of distribution. In identifying LOTs for EP and CEP sales, and home market sales, we considered the selling functions reflected in the starting price before any adjustments. We expect that, if claimed LOTs are the same, the functions and activities of the seller should be similar. Conversely, if a party claims that LOTs are different for different groups of sales, the functions and activities of the seller should be dissimilar. Nan Ya did not request an LOT adjustment.

Nan Ya reported that it made EP and CEP sales of subject merchandise only to distributors (including the distributors that the Department finds to be affiliates) through a single channel of distribution in the U.S. market. Further, Nan Ya indicated that it performed certain types of selling functions (sales

promotion, warranty services, technical advice and freight and delivery arrangements) for its U.S. distributors. *See* Memorandum from Thomas Martin and Zev Primor, Import Compliance Specialists, to the File, "Level of Trade Analysis for Nan Ya Plastics Corporation, Ltd.,'' dated April 1, 2004 ("Nan Ya LOT Memo''). Because there is only one type of customer, a single channel of distribution, and the same selling functions are performed in equal degrees to all U.S. customers, we preliminarily determine that there is a single LOT with respect to Nan Ya's EP and CEP sales.

In the home market, Nan Ya reported that it sold subject merchandise to distributors and end-users. Further, it indicated that, for each of the two reported channels of distribution, it provided the same types of selling functions (sales promotion, warranty services, technical advice, and freight and delivery arrangements) in the same degree for each of the two types of customers. Because these selling functions are provided in equal degrees to all home market customers, we preliminary find that there is only one LOT in the home market.

Upon review of the record, we find that Nan Ya performed substantially similar selling functions for EP and CEP sales as compared to home market sales. The record indicates that there are minor differences between the selling functions performed for EP and CEP sales and home market sales. For example, Nan Ya provided some technical service for home market customers but not EP and CEP customers. However the information on the record indicates that there is insufficient qualitative differences in the selling functions performed by Nan Ya in making sales in the home market and United States market to find them to be distinct LOTs. Therefore, using the information on the record, we preliminarily determine that Nan Ya makes home market and U.S. sales, both EP and CEP, at the same LOT. As a result, no LOT adjustment is necessary. *See* Nan Ya LOT Memo.

**Shinkong Margin Calculation**

*A. Export Price*

In calculating U.S. price, we used EP, in accordance with section 772(a) of the Act, because Shinkong reported that it sold the merchandise directly to unaffiliated U.S. customers and CEP was not otherwise warranted for these transactions. We deducted from the starting price, where applicable, amounts for movement expenses in accordance with section 772(c)(2)(A) of the Act. In this case, movement expenses include foreign inland freight to the port of export, international freight, brokerage and handling charges, marine insurance, and harbor duties.

*B. Normal Value*

1. Selection of Comparison Market

In accordance with section 773(a)(1)(B) of the Act, to determine whether there was a sufficient volume of sales in the home market to serve as a viable basis for calculating NV (*i.e.*, the aggregate volume of home market sales of the foreign like product is greater than or equal to five percent of the aggregate volume of U.S. sales), we compared Shinkong's volume of home market sales of the foreign like product to the volume of its U.S. sales of subject merchandise. We determined that sales in the home market provide a viable basis for calculating NV. Therefore, we based NV on home market sales to unaffiliated purchasers made in the usual commercial quantities and the ordinary course of trade.

For NV, we used the prices at which the foreign like product was first sold for consumption in Taiwan, in the usual commercial quantities, in the ordinary course of trade, and, to the extent possible, at the same LOT as the EP sales. After testing home market viability and whether home market sales were at below-cost prices, we calculated NV as noted in the "Calculation of NV Based on Home Market Prices'' section below.

2. Cost of Production Analysis

Because the Department determined that Shinkong made sales in the home market at prices below the cost of producing the subject merchandise in the *LTFV Investigation* and, therefore, excluded such sales from NV, the Department determined that there are reasonable grounds to believe or suspect that Shinkong made sales in the home market at prices below the cost of producing the merchandise in this administrative review. *See* section 773(b)(2)(A)(ii) of the Act. As a result, the Department initiated a COP inquiry for Shinkong.

*a. Calculation of COP*

In accordance with section 773(b)(3) of the Act, we calculated a weighted-average COP for Shinkong based on the sum of the cost of materials and fabrication for the foreign like product, plus amounts for the home market G&A expenses, including interest expenses. We relied on the COP data submitted by Shinkong in its cost questionnaire responses.

*b. Test of Home Market Sales Prices*

On a model-specific basis, we compared the reported COP to the home market prices, adjusted for any applicable discounts and rebates, movement charges, selling expenses, and packing. We then compared the adjusted weighted-average COP for Shinkong to the adjusted home market sales prices of the foreign like product, as required under section 773(b) of the Act, in order to determine whether these sales had been made at prices below the COP in substantial quantities within an extended period of time (*i.e.*, a period of 18 months), and, whether below-cost prices were sufficient to permit the recovery of all costs within a reasonable period of time.

*c. Results of the COP Test*

Pursuant to section 773(b)(2)(C) of the Act, where less than 20 percent of a respondent's sales of a given product during the POR are at prices less than the COP, we do not disregard any below-cost sales of that product because we determine that the below-cost sales were not made in "substantial quantities'' within an extended period of time. Where 20 percent or more of a respondent's sales of a given product during the POR are at prices less than the COP, we determine such sales to have been made in "substantial quantities'' within an "extended period of time'' in accordance with sections 773(b)(2)(B) and 773(b)(2)(C) of the Act. We have also compared prices to POR average costs. We determined that such sales were not made at prices that would permit recovery of all costs within a reasonable period of time, in accordance with section 773(b)(2)(D) of the Act, because the prices were below the per unit COP. We compared the COP for subject merchandise to the reported home market prices less all applicable charges. Based on this test, we found that Shinkong did have sales below cost which failed the cost test and, as a result, were removed from the home market data set.

3. Calculation of NV Based on Home Market Prices

We based home market prices on the packed prices to unaffiliated purchasers in Taiwan. We adjusted the starting price for reported quantity discounts and other discounts, for any differences in packing, in accordance with sections 773(a)(6)(A) and 773(a)(6)(B)(i) of the Act, and we deducted movement expenses pursuant to section 773(a)(6)(B)(ii) of the Act. In addition, where applicable, we adjusted the starting price for differences in COS,

pursuant to section 773(a)(6)(C)(iii) of the Act by deducting direct selling expenses (credit expense and warranty expenses) incurred for home market sales, and adding U.S. direct selling expenses (credit expenses). No other adjustments to NV were claimed or allowed.

4. Level of Trade/Constructed Export Price Offset

In accordance with section 773(a)(1)(B)(i) of the Act, to the extent practicable, we determine NV based on sales in the comparison market at the same LOT as the EP transactions. The NV LOT is that of the starting-price of sales in the comparison market or, when NV is based on CV, that of the sales from which we derive SG&A expenses and profit. For EP sales, the U.S. LOT is also the level of the starting-price sale, which is usually from exporter to importer.

To determine whether NV sales are at a different LOT than EP transactions, we examine stages in the marketing process and selling functions along the chain of distribution between the producer and the unaffiliated customer. If the comparison market sales are at a different LOT and the difference affects price comparability, as manifested in a pattern of consistent price differences between the sales on which NV is based and comparison market sales at the LOT of the export transaction, we make a LOT adjustment under section 773(a)(7)(A) of the Act.

We obtained information from Shinkong about the marketing stages involved in the reported U.S. and home market sales, including a description of the selling activities performed by the respondents for each channel of distribution. In identifying LOTs for EP and home market sales, we considered the selling functions reflected in the starting price before any adjustments. We expect that, if claimed LOTs are the same, the functions and activities of the seller should be similar. Conversely, if a party claims that LOTs are different for different groups of sales, the functions and activities of the seller should be dissimilar. Shinkong did not request an LOT adjustment.

Shinkong reported that it made EP sales of subject merchandise to a single type of customer through a single channel of distribution in the U.S. market. Further, Shinkong indicated that it performed certain types of selling functions (packing, freight, and warranty services) for all U.S. customers. Because there is only one type of customer, a single channel of distribution, and the same selling functions are performed for every customer, we preliminarily determine that there is a single LOT with respect to Shinkong's EP sales.

In the home market, Shinkong reported that it sold subject merchandise to distributors and end-users. Further, it indicated that for each of the two reported channels of distribution, it provided the same types of selling functions (packing, freight services, and warranty services) in the same degree for each of the two types of customers. Because these selling functions are provided in equal degrees to all home market customers, we preliminarily find that there is only one LOT in the home market.

Upon review of the record, we find that Shinkong performed the same selling functions for its home market that it does for U.S. sales (packing, freight services, and warranty services), and as such, we preliminarily find that the selling functions performed by Shinkong for the EP transactions and for home market sales are the same, and the prices do not vary according to the services provided. *See* Shinkong's September 22, 2003, response to the Department's Section A questionnaire at A–10,11. Because EP sales are made at the same LOT as home market sales, no LOT adjustment is warranted. *See* Memorandum from Thomas Martin and Zev Primor, Import Compliance Specialists, to the File, "Level of Trade Analysis for Shinkong Synthetic Fibers Corporation,'' dated April 1, 2004.

**Currency Conversions**

We converted foreign currencies into U.S. dollars, pursuant to section 773A of the Act, using the exchange rates in effect on the dates of the U.S. sales, as obtained from the Federal Reserve Bank, the Department's preferred source for exchange rates.

**Preliminary Results of Review**

As a result of our review, we preliminarily determine that the following weighted-average dumping margins exist for the period December 21, 2001, through June 30, 2003:

| Manufacturer/exporter | Margin (percent) |
|---|---|
| Shinkong Synthetic Fibers Corporation | 0.62 |
| Nan Ya Plastics Corporation, Ltd | 85.47 |

The Department will disclose the calculations used in its analysis to parties to this proceeding within five days of the publication date of this notice. *See* 19 CFR 351.224(b). Any interested party may request a hearing within 30 days of the publication date of this notice. *See* 19 CFR 351.310(c). If requested, a hearing will be held 44 days after the date of publication of this notice, or the first business day thereafter. Interested parties may submit case briefs within 30 days of the date of publication of this notice. *See* 19 CFR 351.309(c). Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than 7 days after the deadline for filing case briefs. *See* 19 CFR 351.309(d). Parties who submit written arguments are requested to submit with each argument: (1) A statement of the issue, (2) a brief summary of the argument and (3) a table of authorities. Further, we request that parties submitting written comments provide the Department with an additional copy of the public version of any such comments on a diskette. The Department will publish the notice of the final results of this administrative review, which will include the results of its analysis of issues raised in any written comments or hearing, within 120 days from the publication date of this notice.

**Assessment**

Upon completion of this administrative review, the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries. In accordance with 19 CFR 351.212(b)(1), we have calculated an importer-specific assessment rate for merchandise subject to this review. If the importer-specific assessment rate is above *de minimis*, we will instruct CBP to assess the importer-specific rate uniformly on all entries made during the POR. The Department will issue appropriate assessment instructions directly to the CBP within 15 days of publication of the final results of review. If these preliminary results are adopted in the final results of review, we will direct CBP to assess the resulting assessment rates against the entered customs values for the subject merchandise on each of the importers' entries during the review period.

**Cash Deposit**

The following cash deposit requirements will be effective upon publication of these final results for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of these final results of administrative review, as provided by section 751(a)(1) of the Act: (1) The cash deposit rate for each of the reviewed companies will be the rate listed in the final results of review (except that if the rate for a particular product is *de minimis*, *i.e.*, less than 0.5 percent, no

cash deposit will be required for that company); (2) for previously 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 original *LTFV Investigation*, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be the "all others'' rate of 2.56 percent, which is the "all others'' rate established in the *LTFV Investigation.* These deposit requirements, when imposed, shall remain in effect until publication of the final results of the next administrative review.

**Notification to Interested Parties**

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) 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 the antidumping duties occurred and the subsequent assessment of double antidumping duties.

This determination is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: April 1, 2004.

**Jeffrey A. May,**

*Acting Assistant Secretary for Import Administration.*

[FR Doc. 04–8015 Filed 4–7–04; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–588–845]**

### Stainless Steel Sheet and Strip in Coils From Japan: Rescission of Antidumping Duty Administrative Review

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**ACTION:** Notice of rescission of antidumping duty administrative review.

**SUMMARY:** On August 22, 2003, the Department of Commerce ("Department'') published in the **Federal Register** a notice announcing the initiation of an administrative review of the antidumping duty order on stainless steel sheet and strip in coils ("SSSS'') from Japan. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part*, ("Initiation'') 68 FR 50750 (August 22, 2003). The period of review ("POR'') is July 1, 2002 to June 30, 2003. This review has now been rescinded because there were no entries for consumption of subject merchandise that are subject to review in the United States during the POR.

**EFFECTIVE DATE:** April 8, 2004.

**FOR FURTHER INFORMATION CONTACT:** Kit Rudd or James Doyle, Enforcement Group III, Office 9, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Room 7866, Washington, DC 20230; telephone (202) 482–1385 or (202) 482–0159 respectively.

**Scope of Review**

Upon completion of four changed circumstances reviews pursuant to section 751(b) of the Act and section 351.216 of the Department's regulations, we have excluded certain products from the scope of the order. These four excluded products are identified in the scope, infra.

For purposes of this review, the products covered are certain stainless steel sheet and strip in coils. Stainless steel is an alloy steel containing, by weight, 1.2 percent or less of carbon and 10.5 percent or more of chromium, with or without other elements. The subject sheet and strip is a flat-rolled product in coils that is greater than 9.5 mm in width and less than 4.75 mm in thickness, and that is annealed or otherwise heat treated and pickled or otherwise descaled. The subject sheet and strip may also be further processed (*e.g.*, cold-rolled, polished, aluminized, coated, etc.) provided that it maintains the specific dimensions of sheet and strip following such processing.

The merchandise subject to this order is currently classifiable in the Harmonized Tariff Schedule of the United States ("HTS'') at subheadings: 7219130031, 7219130051, 7219130071, 7219130081 [1], 7219140030, 7219140065, 7219140090, 7219320005, 7219320020, 7219320025, 7219320035, 7219320036, 7219320038, 7219320042, 7219320044, 7219330005, 7219330020, 7219330025, 7219330035, 7219330036, 7219330038, 7219330042, 7219330044, 7219340005, 7219340020, 7219340025, 7219340030, 7219340035, 7219350005, 7219350015, 7219350030, 7219350035, 7219900010, 7219900020, 7219900025, 7219900060, 7219900080, 7220121000, 7220125000, 7220201010, 7220201015, 7220201060, 7220201080, 7220206005, 7220206010, 7220206015, 7220206060, 7220206080, 7220207005, 7220207010, 7220207015, 7220207060, 7220207080, 7220208000, 7220209030, 7220209060, 7220900010, 7220900015, 7220900060, and 7220900080. Although the HTS subheadings are provided for convenience and Customs purposes, the Department's written description of the merchandise under review is dispositive.

Excluded from the scope of this order are the following: (1) Sheet and strip that is not annealed or otherwise heat treated and pickled or otherwise descaled, (2) sheet and strip that is cut to length, (3) plate (*i.e.*, flat-rolled stainless steel products of a thickness of 4.75 mm or more), (4) flat wire (*i.e.*, cold-rolled sections, with a prepared edge, rectangular in shape, of a width of not more than 9.5 mm), and (5) razor blade steel. Razor blade steel is a flat-rolled product of stainless steel, not further worked than cold-rolled (cold-reduced), in coils, of a width of not more than 23 mm and a thickness of 0.266 mm or less, containing, by weight, 12.5 to 14.5 percent chromium, and certified at the time of entry to be used in the manufacture of razor blades. *See* Chapter 72 of the HTS, "Additional U.S. Note'' 1(d).

Flapper valve steel is also excluded from the scope of the order. This product is defined as stainless steel strip in coils containing, by weight, between 0.37 and 0.43 percent carbon, between 1.15 and 1.35 percent molybdenum, and between 0.20 and 0.80 percent manganese. This steel also contains, by weight, phosphorus of 0.025 percent or less, silicon of between 0.20 and 0.50 percent, and sulfur of 0.020 percent or less. The product is manufactured by means of vacuum arc remelting, with inclusion controls for sulphide of no more than 0.04 percent and for oxide of no more than 0.05 percent. Flapper valve steel has a tensile strength of between 210 and 300 ksi, yield strength of between 170 and 270 ksi, plus or minus 8 ksi, and a hardness (Hv) of between 460 and 590. Flapper valve steel is most commonly used to produce specialty flapper valves in compressors.

Also excluded is a product referred to as suspension foil, a specialty steel product used in the manufacture of suspension assemblies for computer disk drives. Suspension foil is described

[1] Due to changes to the HTS numbers in 2001, 7219130030, 7219130050, 7219130070, and 7219130080 are now 7219130031, 7219130051, 7219130071, and 7219130081, respectively.

as 302/304 grade or 202 grade stainless steel of a thickness between 14 and 127 microns, with a thickness tolerance of plus-or-minus 2.01 microns, and surface glossiness of 200 to 700 percent Gs. Suspension foil must be supplied in coil widths of not more than 407 mm, and with a mass of 225 kg or less. Roll marks may only be visible on one side, with no scratches of measurable depth. The material must exhibit residual stresses of 2 mm maximum deflection, and flatness of 1.6 mm over 685 mm length.

Certain stainless steel foil for automotive catalytic converters is also excluded from the scope of this order. This stainless steel strip in coils is a specialty foil with a thickness of between 20 and 110 microns used to produce a metallic substrate with a honeycomb structure for use in automotive catalytic converters. The steel contains, by weight, carbon of no more than 0.030 percent, silicon of no more than 1.0 percent, manganese of no more than 1.0 percent, chromium of between 19 and 22 percent, aluminum of no less than 5.0 percent, phosphorus of no more than 0.045 percent, sulfur of no more than 0.03 percent, lanthanum of less than 0.002 or greater than 0.05 percent, and total rare earth elements of more than 0.06 percent, with the balance iron.

Permanent magnet iron-chromium-cobalt alloy stainless strip is also excluded from the scope of this order. This ductile stainless steel strip contains, by weight, 26 to 30 percent chromium, and 7 to 10 percent cobalt, with the remainder of iron, in widths 228.6 mm or less, and a thickness between 0.127 and 1.270 mm. It exhibits magnetic remanence between 9,000 and 12,000 gauss, and a coercivity of between 50 and 300 oersteds. This product is most commonly used in electronic sensors and is currently available under proprietary trade names such as "Arnokrome III." [2]

Certain electrical resistance alloy steel is also excluded from the scope of this order. This product is defined as a non-magnetic stainless steel manufactured to American Society of Testing and Materials ("ASTM") specification B344 and containing, by weight, 36 percent nickel, 18 percent chromium, and 46 percent iron, and is most notable for its resistance to high temperature corrosion. It has a melting point of 1390 degrees Celsius and displays a creep rupture limit of 4 kilograms per square millimeter at 1000 degrees Celsius. This steel is most commonly used in the production of heating ribbons for circuit breakers and industrial furnaces, and in rheostats for railway locomotives. The product is currently available under proprietary trade names such as "Gilphy 36." [3]

Certain martensitic precipitation-hardenable stainless steel is also excluded from the scope of this order. This high-strength, ductile stainless steel product is designated under the Unified Numbering System ("UNS") as S45500-grade steel, and contains, by weight, 11 to 13 percent chromium, and 7 to 10 percent nickel. Carbon, manganese, silicon and molybdenum each comprise, by weight, 0.05 percent or less, with phosphorus and sulfur each comprising, by weight, 0.03 percent or less. This steel has copper, niobium, and titanium added to achieve aging, and will exhibit yield strengths as high as 1700 Mpa and ultimate tensile strengths as high as 1750 Mpa after aging, with elongation percentages of 3 percent or less in 50 mm. It is generally provided in thicknesses between 0.635 and 0.787 mm, and in widths of 25.4 mm. This product is most commonly used in the manufacture of television tubes and is currently available under proprietary trade names such as "Durphynox 17." [4]

Also excluded are three specialty stainless steels typically used in certain industrial blades and surgical and medical instruments. These include stainless steel strip in coils used in the production of textile cutting tools (*e.g.*, carpet knives).[5] This steel is similar to AISI grade 420 but containing, by weight, 0.5 to 0.7 percent of molybdenum. The steel also contains, by weight, carbon of between 1.0 and 1.1 percent, sulfur of 0.020 percent or less, and includes between 0.20 and 0.30 percent copper and between 0.20 and 0.50 percent cobalt. This steel is sold under proprietary names such as "GIN4 Mo." The second excluded stainless steel strip in coils is similar to AISI 420-J2 and contains, by weight, carbon of between 0.62 and 0.70 percent, silicon of between 0.20 and 0.50 percent, manganese of between 0.45 and 0.80 percent, phosphorus of no more than 0.025 percent and sulfur of no more than 0.020 percent. This steel has a carbide density on average of 100 carbide particles per 100 square microns. An example of this product is "GIN5" steel. The third specialty steel has a chemical composition similar to AISI 420 F, with carbon of between 0.37 and 0.43 percent, molybdenum of between 1.15 and 1.35 percent, but lower manganese of between 0.20 and 0.80 percent, phosphorus of no more than 0.025 percent, silicon of between 0.20 and 0.50 percent, and sulfur of no more than 0.020 percent. This product is supplied with a hardness of more than Hv 500 guaranteed after customer processing, and is supplied as, for example, "GIN6." [6]

Also excluded are stainless steel welding electrode strips that are manufactured in accordance with American Welding Society ("AWS") specification ANSI/AWS A5.9–93. *See Stainless Steel Sheet and Strip in Coils from Japan: Final Results of Changed Circumstance Antidumping Duty Review, and Determination to Revoke Order in Part*, 65 FR 17856 (April 5, 2000). The products are 0.5 mm in thickness, 60 mm in width, and in coils of approximately 60 pounds each. The products are limited to the following AWS grade classifications: ER308L, ER 309L, ER316L and ER347, and a modified ER 309L or 309LCb which meets the following chemical composition limits (by weight):

Carbon—0.03% maximum.
Chromium—20.0–22.0%.
Nickel—10.0–12.0%.
Molybdenum—0.75% maximum.
Manganese—1.0–2.5%.
Silicon—0.65% maximum.
Phosphorus—0.03% maximum.
Sulphur—0.03% maximum.
Copper—0.75% maximum.
Columbium—8 times the carbon level minimum—1.0% maximum.

Also excluded is certain stainless steel used for razor blades, medical surgical blades, and industrial blades, and sold under proprietary names such as DSRIK7, DSRIK8, and DSRIK9. *See Stainless Steel Sheet and Strip in Coils from Japan: Final Results of Changed Circumstance Antidumping Duty Review, and Determination to Revoke Order in Part*, 65 FR 54841 (September 11, 2000). This stainless steel strip in coils is a specialty product with a thickness of 0.15 mm to 1.000 mm, or 0.006 inches to 0.040 inches, and a width of 6 mm to 50 mm, or 0.250 inches to 2.000 inches. The edge of the product is slit, and the finish is bright. The steel contains the following chemical composition by weight: Carbon 0.65% to 1.00%, Silicon 1.00% maximum, Manganese 1.00% maximum, Phosphorus 0.35% maximum, Sulfur 0.25% maximum, Nickel 0.35% maximum, Chromium 0.15% maximum, Molybdenum 0.30% maximum.

[2] "Arnokrome III" is a trademark of the Arnold Engineering Company.

[3] "Gilphy 36" is a trademark of Imphy, S.A.

[4] "Durphynox 17" is a trademark of Imphy, S.A.

[5] This list of uses is illustrative and provided for descriptive purposes only.

[6] "GIN4 Mo," "GIN5" and "GIN6" are the proprietary grades of Hitachi Metals America, Ltd.

Also excluded is certain stainless steel lithographic sheet. *See Stainless Steel Sheet and Strip in Coils from Japan: Final Results of Changed Circumstance Antidumping Duty Review, and Determination To Revoke Order in Part,* 65 FR 64423 (October 27, 2000). This sheet is made of 304-grade stainless steel and must satisfy each of the following fifteen specifications. The sheet must have: (1) An ultimate tensile strength of minimum 75 KSI; (2) a yield strength of minimum 30 KSI; (3) a minimum elongation of 40 percent; (4) a coil weight of 4000–6000 lbs.; (5) a width tolerance of −0/+0.0625 inch; and (6) a gauge tolerance of +/−0.001 inch. With regard to flatness, (7) the wave height and wave length dimensions must correspond to both edge wave and center buckle conditions; (8) the maximum wave height shall not exceed 0.75 percent of the wave length or 3 mm (0.118 inch), whichever is less; and (9) the wave length shall not be less than 100 mm (3.937 inch). With regard to the surface, (10) the surface roughness must be RMS (RA) 4–8; (11) the surface must be degreased and no oil will be applied during the slitting operation; (12) the surface finish shall be free from all visual cosmetic surface variations or stains in spot or streak form that affect the performance of the material; (13) no annealing border is acceptable; (14) the surface finish shall be free from all defects in raised or depression nature (*e.g.*, scratches, gouges, pimples, dimples, etc.) exceeding 15 microns in size and with regard to dimensions; and (15) the thickness will be .0145 +/−.001 and the widths will be either 38″, 38.25″, or 43.5″ and the thickness for 39″ material will be .0118 +/−.001 inches. Also excluded is nickel clad stainless steel sheet and strip in coils from Japan. *See Stainless Steel Sheet and Strip in Coils from Japan: Final Results of Changed Circumstance Antidumping Duty Review, and Determination to Revoke Order in Part,* 65 FR 77578 (December 12, 2000). This nickel clad stainless steel sheet must satisfy each of the following specifications. The sheet must: (1) Have a maximum coil weight of 1000 pounds; (2) with a coil interior diameter of 458 mm to 540 mm; (3) with a thickness of .33 mm and a width of 699.4 mm; (4) fabricated in three layers with a middle layer of grade 316L or UNS 531603 sheet and strip sandwiched between the two layers of nickel cladding, using a roll bonding process to apply the nickel coating to each side of the stainless steel, each nickel coating being not less than 99 percent nickel and a minimum .038 mm in thickness. The resultant nickel clad stainless steel sheet and strip also must meet the following additional chemical composition requirement (by weight): The first layer weight is 14%, specification Ni201 or N02201, Carbon 0.009, Sulfur 0.001, Nickel 99.97, Molybdenum 0.001, Iron 0.01, Copper 0.001 for a combined total of 99.992. The second layer weight is 72%, specification 316L or UNS 513603, Carbon 0.02, Silicon 0.87, Manganese 1.07, Phosphorus 0.033, Sulfur 0.001, Nickel 12.08, Chromium 17.81, Molybdenum 2.26, Iron 65.856 for a combined total of 100. The third layer is 14%, specification Ni201 or N02201, Carbon 0.01, Sulfur 0.001, Nickel 99.97, Molybdenum 0.001, Iron 0.01, Copper 0.001 for a combined total of 99.993. The weight average weight is 100%. The following is the weighted average: Carbon 0.01706, silicon 0.6264, Manganese 0.7704, Phosphorus 0.02376, Sulfur 0.001, Nickel 36.6892, Chromium 12.8232, Molybdenum 1.62748, Iron 47.41912, and Copper is 0.00028. The above-described material is sold as grade 316L and manufactured in accordance with UNS specification 531603. This material is classified at subheading 7219.90.00.20 of the HTS.

## Background

On July 30, 2003, petitioners [7] requested an administrative review of Kawasaki Steel Corporation [8] ("KSC"), a Japanese producer and exporter of SSSS, with respect to the antidumping order published in the **Federal Register**. On August 22, 2003, the Department initiated the review for KSC. *See Initiation* at 50752. Additionally, on September 22, 2003, petitioners requested that the Department conduct a duty absorption inquiry of KSC.

**SUPPLEMENTARY INFORMATION**

## Case History

On September 8, 2003, the Department issued an antidumping duty questionnaire to KSC. On September 16, 2003, KSC informed the Department that it would not be responding to the antidumping duty questionnaire as they had "no reportable sales" of subject merchandise to the United States during the POR. On September 17, 2003 the Department forwarded a no-shipment inquiry to CBP for circulation to all CBP ports requesting information regarding any entries of merchandise subject to this review. CBP indicated to the Department that there was no record of consumption entries during the POR of SSSS from Japan exported by KSC. However, on September 19, 2003, the Department conducted a query of CBP import data via CBP's Automated Broker Interface ("ABI") system using the current review's scope as defined by HTS number and Japan as the country of export. This query provided the Department with data indicating the possibility of entries of merchandise subject to this review. On September 26, 2003, KSC claimed in writing that they "had no reportable sales of merchandise subject to this review in or for export to the United States during the period of review (July 2002 through June 2003)." On October 30, 2003 the Department issued a letter to KSC inquiring about possible entries of subject merchandise by KSC during the POR. On November 14, 2003, KSC replied to the Department's October 30, 2003 submission and requested that all the data from CBP be released to the respondent's counsel to facilitate KSC's reply. On November 19, 2003, the Department sent a letter to KSC providing its counsel with CBP data, subject to an administrative protection order ("APO") on the possible shipments and extending KSC's date to respond to the Department's October 30, 2003 letter to December 8, 2003. On December 17, 2003, the respondent submitted a letter in response to the Department's November 19, 2003 letter. On December 17, 2003, the Department submitted a letter to CBP requesting the complete entry packages for the possible KSC POR shipments. The Department received the complete entry documentation packages from CBP on February 6, 2004. On February 10, 2004 the Department released the entry packages under APO and solicited comments from petitioners and KSC. The Department received comments

[7] Allegheny Ludlum Corp., AK Steel Corporation, J&L Specialty Steel, Inc., North American Stainless, Butler-Armco Independent Union, Zanesville Armco Independent Organization and the United Steelworkers of America, AFL–CIO/CLC.

[8] The Department notes that this administrative review was initiated with respect to subject merchandise manufactured or exported by KSC during the POR. Counsel for KSC has referred to JFE Steel Corporation ("JFE") throughout this segment of the proceeding as the successor to KSC. However, neither KSC nor petitioners have requested that the Department conduct a successor-in-interest analysis in order to confirm whether for antidumping purposes JFE is the successor-in-interest to KSC with respect to the subject merchandise. Moreover, as there was no issue in this segment other than whether KSC had knowledge that certain merchandise it produced was destined for the United States, there was no opportunity for the Department to conduct a successor-in-interest analysis on its own initiative in this context. Therefore, the Department not only will continue to refer to the respondent as KSC but also will issue instructions to U.S. Customs and Border Protection ("CBP") reminding it that only merchandise manufactured or exported by KSC is eligible to enter using its cash deposit rate.

from KSC on February 18, 2004. On February 17, 2004 the petitioners submitted comments and on February 23, 2004, the petitioners submitted a request for an extension of time to comment on KSC's February 18, 2004 submission. The Department received rebuttal comments from KSC on February 25, 2004 and March 17, 2004 and from petitioners on March 10, 2004. In its February 18, 2004 comments, KSC provided data from the official record of the original SSSS investigation and the first administrative review concerning KSC's local and export merchandise identification methodologies which it claimed supports its contention that the company had no knowledge that the entries in question were eventually exported to the United States by an unrelated third party. Based on their contention that they had no knowledge that the entries in question were eventually exported to the United States, KSC concluded that the administrative review should be rescinded. In its March 10, 2004 submission, petitioners agreed that the entries were not KSC sales and that the review should be rescinded.

### Analysis

After analyzing the data contained in the CBP-provided customs entry packages, petitioners' and KSC's comments and rebuttal comments, the Department notes that both parties agree these entries are not KSC shipments and the review should be rescinded. The Department further notes that KSC accounting records, which show that the entries at issue were coded by KSC as a domestic Japanese sale, supports KSC's contention that it had no knowledge these home market sales of subject merchandise were destined for the United States. Moreover, the data contained in the CBP entry packages shows that these entries were more likely shipped by a Japanese reseller to the United States. Further, based on the identities of the Japanese reseller and the Japanese importer, as reported in the CBP entry documentation, these two entities are part of the same corporate group one of whose companies was assigned a rate in the original investigation. Please see the accompanying analysis memorandum for identification of each of these entities. *See Memorandum to the File from Kit L. Rudd, Case Analyst through Edward C. Yang, Director, Office IX regarding Stainless Steel Sheet and Strip in Coils from Japan—Rescission Analysis Memorandum* dated April 1, 2004. We corroborated this understanding by examining the group's website which shows all these entities as part of the same group. *See Id.* As a result of this analysis, we conclude that the exporter's cash deposit rate should have been posted, rather than the manufacturer's (KSC's) rate, and we will instruct CBP to liquidate those entries at that rate. Please refer to CBP for further information as to the circumstances relating to the incorrect rate claimed. For an explanation of the Department's automatic-liquidation regulation concerning circumstances where a reseller has been involved in the chain of commerce, please refer to the Department's May 6, 2003 explanation as published in the **Federal Register**. *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

Accordingly, we are rescinding this review. The cash deposit rate will continue to be the rate established in the most recently completed segment of this proceeding.

This notice is issued and published in accordance with sections 777(i) of the Act and 19 CFR 351.213(d)(4).

Dated: April 1, 2004.

**Jeffrey May,**

*Acting Assistant Secretary for Import Administration.*

[FR Doc. 04–8012 Filed 4–7–04; 8:45 am]

**BILLING CODE 3510–DS–P**

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## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–549–502]**

### Certain Welded Carbon Steel Pipes and Tubes From Thailand: Notice of Preliminary Results of Antidumping Duty Administrative Review

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**SUMMARY:** In response to requests by two domestic producers, Allied Tube and Conduit Corporation, and Wheatland Tube Company (collectively, the "petitioners''), the Department of Commerce ("the Department'') is conducting an administrative review of the antidumping duty order on certain welded carbon steel pipes and tubes from Thailand. This review covers Saha Thai Steel Company, Ltd. ("Saha Thai''), a Thai manufacturer and exporter of the subject merchandise to the United States. The period of review (POR) is March 1, 2002 through February 28, 2003.

We have preliminarily determined that the respondent sold the subject merchandise at less than normal value ("NV'') during the POR. For information on the weighted-average dumping margin, see the "Preliminary Results of Review'' section below. If these preliminary results are adopted in our final results, we will instruct U.S. Customs and Border Protection (CBP) to liquidate appropriate entries during the POR at the proper assessment rates.

Interested parties are invited to comment on these preliminary results. Parties who submit argument in this proceeding should also submit with the argument (1) a statement of the issue, and (2) a brief summary of the argument.

**EFFECTIVE DATE:** April 8, 2004.

**FOR FURTHER INFORMATION CONTACT:** Javier Barrientos or Sally Gannon, Office of AD/CVD Enforcement VII, Room 7866, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–2243 and (202) 482–0162, respectively.

**SUPPLEMENTARY INFORMATION**

### Background

On March 11, 1986, the Department published in the **Federal Register**, an antidumping duty order on circular welded carbon steel pipes and tubes from Thailand. *See Antidumping Duty Order: Circular Welded Carbon Steel Pipes and Tubes from Thailand,* 51 FR 8341 (March 11, 1986). On March 3, 2003, the Department published a notice of opportunity to request an administrative review of this order covering the period March 1, 2002 through February 28, 2003. *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review,* 68 FR 9974 (March 3, 2003). Timely requests for an administrative review of the antidumping order with respect to exports by Saha Thai during the POR were filed by the petitioners. The Department published a notice of initiation of this antidumping duty administrative review on April 21, 2003. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 68 FR 19498 (April 21, 2003).

Because the Department determined that it was not practicable to complete this review within the statutory time limits, on November 7, 2003, we issued a notice of extension of the time limit for this review. *See Certain Welded Carbon Steel Pipes and Tubes From Thailand: Extension of Time Limit for Preliminary Results of Antidumping Administrative Review,* 69 FR 4113

(January 28, 2004). As a result, we extended the deadline for these preliminary results to March 30, 2004. Unless extended, the deadline for the final results will be 120 days after publication of these preliminary results.

**Period of Review**

The POR is March 1, 2002 through February 28, 2003.

**Scope of the Antidumping Duty Order**

The products covered by this antidumping duty order are certain welded carbon steel pipes and tubes from Thailand. The subject merchandise has an outside diameter of 0.375 inches or more, but not exceeding 16 inches. These products, which are commonly referred to in the industry as "standard pipe'' or "structural tubing,'' are hereinafter designated as "pipe and tube.'' The merchandise is classifiable under the Harmonized Tariff Schedule (HTS) item numbers 7306.30.1000, 7306.30.5025, 7306.30.5032, 7306.30.5040, 7306.30.5055, 7306.30.5085, and 7306.30.5090. Although the HTS subheadings are provided for convenience and CBP purposes, our written description of the scope of the order is dispositive.

**Verification**

Pursuant to section 782(i) of the Act, the Department verified the information submitted by Saha Thai for use in our preliminary results. The Department used standard verification procedures including examination of relevant accounting and production records, and original source documents provided by the respondent.

**Date of Sale**

Saha Thai reported contract date as the date of sale for U.S. sales. Invoice date is the Department's presumptive date for date of sale (*see* section 351.401(i) of the Department's regulations). For purposes of this review, however, we examined whether invoice date or some other date better represents the date on which the material terms of sale were established. The Department examined sales documentation, including contracts and invoices, provided by Saha Thai for its U.S. sales, and found that the material terms of sale are set at the contract date. Specifically, any changes in quantity were within the specified contract tolerances and as such were not material. Unit prices for the products themselves did not change between the contract and invoice on the sales examined. As such, we preliminarily determine that contract date is the appropriate date of sale for U.S. sales in this administrative review because it better represents the date upon which the material terms of sale were established. This is consistent with our decision in the last administrative review of this proceeding, where we determined that contract date better represented the date of sale because it better reflected the date on which the material terms of sale, *i.e.*, price and quantity, were established. *See Certain Welded Carbon Steel Pipes and Tubes From Thailand: Final Results of Antidumping Duty Administrative Review,* 66 FR 53388 (October 22, 2001) (*99–00 Final Results*).

With respect to home market sales, the invoice is the first written document that establishes the material terms of sale. Therefore, we are using the invoice date as the date of sale for home market sales, as reported by Saha Thai.

**Normal Value Comparisons**

To determine whether sales of the subject merchandise from Thailand to the United States were made at less than normal value, we compared the export prices to the normal values for Saha Thai as specified in the "Export Price'' and "Normal Value'' sections of this notice. In accordance with section 777A(d)(2) of the Act, we calculated monthly weighted-average prices for normal value and compared these to individual U.S. transactions.

**Export Price**

Based upon our review of the record evidence, we classified all Saha Thai sales to U.S. customers as export price (EP) sales because, as in previous segments of this proceeding, we found that Saha Thai is not affiliated with its U.S. distributors, which are the first purchasers in the United States. *See 99–00 Final Results.* Therefore, we calculated the EP based on the price from Saha Thai to the first unaffiliated purchaser in the United States, in accordance with section 772(a) of the Act.

Where appropriate, in accordance with section 772(c)(2) of the Act, we made deductions from the gross unit price for foreign inland freight, foreign brokerage and handling, foreign inland insurance, bill of lading charges, ocean freight to the U.S. port, U.S. brokerage and handling charges, and, U.S. duty.

Section 772(c)(1)(B) of the Act states that the EP should be increased by the amount of any import duties "imposed by the country of exportation which have been rebated, or which have not been collected, by reason of the exportation of the merchandise to the United States.'' In this review, Saha Thai claimed an adjustment to EP for the amount of duties exempted on its imports of raw materials into a bonded warehouse.

In determining whether or not an adjustment should be made to EP for this exemption, we look for a reasonable link between the duties imposed and those rebated or exempted. We do not require that the imported input be traced directly from importation through exportation. We do require, however, that the company meet the following elements in order for this addition to be made to EP. The first element is that the import duty and rebate or exemption be directly linked to, and dependent on, one another; and the second element is that the company must demonstrate that there were sufficient imports of the imported material to account for the duty drawback paid for the export of the manufactured product (the "two pronged test''). *See e.g., Rajinder Pipes Ltd.* v. *United States,* 70 F. Supp. 2d 1350, 1358 (CIT 1999); *see also Certain Welded Carbon Standard Steel Pipes and Tubes from India: Final Results of New Shippers Antidumping Duty Administrative Review,* 62 FR 47632 (September 10, 1997); *Federal Mogul Corp.* v. *United States,* 862 F. Supp. 384, 409 (CIT 1994).

The company started with the actual per unit amount of raw material input it imported. To this, Saha Thai added a raw material yield/loss credit constant, that was set by the Government of Thailand (GOT), in order to calculate the amount of duty exempted on raw material imports that were incorporated into exported products. *See Memorandum to the File, from Javier Barrientos, AD/CVD Financial Analyst and Jaqueline Arrowsmith, Case Analyst, through Sally Gannon, Program Manager; Verification of Questionnaire Responses submitted by Saha Thai Steel Pipe Company, Ltd. ("Saha Thai''),* March 26, 2004 ("*Cost Verification Report''*) at 16. At verification, we compared the GOT-set yield/loss credit constant on the raw material to the actual production loss rate the company experienced. We found that the GOT-set yield/loss credit constant was not a reasonable reflection of the company's experience because it overstates the yield/loss credit, thus not balancing yielded raw material imports to finished product exports. *Id.* at 14. Therefore, for these preliminary results, we have adjusted Saha Thai's claimed addition to EP to reflect the company's actual usage/yield experience during the period, based on the information found at verification. *See Memorandum to the File, from Javier Barrientos, AD/CVD Financial Analyst, through Sally*

*Gannon, Program Manager; Analysis of Saha Thai Steel Pipe Company, Ltd. for the Preliminary Results* (March 30, 2004).

In addition, the company claimed an adjustment to EP for an exemption it received for antidumping duties on certain imports subject to antidumping duties imposed by the GOT. However, because the Department has not specifically addressed this unique issue of whether to allow an adjustment for exempted antidumping duties on raw material inputs, the Department is requesting interested parties to comment on this issue in their case and rebuttal briefs. Therefore, for purposes of these preliminary results, no adjustment has been made to EP with respect to these exempted antidumping duties.

**Section 201 Duties**

The Department notes that merchandise subject to this review is subject to duties imposed under section 201 of the Trade Act of 1974, as amended (section 201 duties). Because the Department has not previously addressed the appropriateness of deducting section 201 duties from EP and CEP, on September 9, 2003, the Department published a request for public comments on this issue. *See Antidumping Proceedings: Treatment of Section 201 Duties and Countervailing Duties,* 68 FR 53104 (September 9, 2003). Comments were received by October 9, 2003, and rebuttal comments were received by November 7, 2003. As the Department is currently analyzing these comments, for purposes of these preliminary results, no adjustment has been made to EP.

**Normal Value**

*Home Market Viability:* In order to determine whether there is a sufficient volume of sales in the home market to serve as a viable basis for calculating normal value (NV), we compared the volume of Saha Thai's home market sales of the foreign like product to the volume of U.S. sales of subject merchandise, in accordance with section 773(a)(1) of the Act. Based on this comparison, we determined that the aggregate volume of Saha Thai's home market sales of the foreign like product is greater than five percent of the aggregate volume of Saha Thai's U.S. sales. Thus, we determined that Saha Thai had a viable home market during the POR. Consequently, we based normal value on home market sales.

*COP Analysis:* Pursuant to section 773(b)(2)(A)(ii) of the Act, there were reasonable grounds to believe or suspect that Saha Thai had made home market sales at prices below its cost of production ("COP") in this review because the Department had disregarded Saha Thai sales that had failed the cost test in the 1999–2000 administrative review (*i.e.*, the most recently completed review at the time we issued our antidumping questionnaire in the instant review). *See 99–00 Final Results*. As a result, the Department initiated an investigation to determine whether Saha Thai made home market sales during the contemporaneous period at prices below its COP. We calculated the COP based on the sum of respondent's cost of materials and fabrication for the foreign like product, plus an amount for selling, general and administrative expenses ("SG&A"), and packing, in accordance with section 773(b)(3) of the Act.

*Cost Test:* For these preliminary results, we are using respondent's verified COP. Pursuant to section 773(b) of the Act, we compared the COP to the home market sale prices (less any applicable movement charges and discounts) of the foreign like product on a product specific basis, in order to determine whether home market sales had been made at prices below the COP.

In determining whether to disregard home market sales made at prices below the COP, and in accordance with section 773(b)(1) of the Act, we examined whether: (1) Within an extended period of time, such sales were made in substantial quantities and, (2) whether such sales were made at prices which permitted the recovery of all costs within a reasonable period of time in the normal course of trade.

Pursuant to section 773(b)(2)(C) of the Act, when less than 20 percent of the respondent's sales of a given product were at prices less than the COP, we did not disregard any below-cost sales of that product because we determined that the below-cost sales were not made in "substantial quantities." When 20 percent or more of the respondent's sales of a given product during the contemporaneous period were at prices less than the COP, in accordance to with sections 773(b)(2)(B) and (C) of the Act, we determined such sales to have been made in substantial quantities within an extended period of time. In such cases, based on comparisons of prices to weight-averaged costs in the cost reference period, we determined that these sales were made at prices which would not permit recovery of all costs within a reasonable period of time, in accordance with section 773(b)(2)(D) of the Act. Based on this test, we disregarded the below-cost sales.

*Constructed Value:* In accordance with section 773(a)(4) of the Act, we used constructed value (CV) as the basis for NV when there were no contemporaneous sales of identical or similar merchandise in the comparison market that passed the cost test. We calculated CV, in accordance with section 773(e) of the Act, based on the sum of Saha Thai's cost of materials, fabrication, SG&A, profit, and packing. In accordance with section 773(e)(2)(A) of the Act, we based SG&A and profit on the actual amounts incurred and realized by Saha Thai in connection with the production and sale of the foreign like product in the ordinary course of trade, for consumption in the foreign country. For selling expenses, we used the average of the selling expenses reported for home market sales that passed the cost test, weighted by the total quantity of those sales. For profit, we first calculated the difference between the home market sales value and its corresponding COP, and divided the difference by this COP. We then multiplied this percentage by the COP for the respective U.S. model to derive a profit amount.

*Home Market Price:* To calculate Saha Thai's home market net price, we deducted discounts, home market credit expenses, and inland freight, where appropriate. In addition, in accordance with section 773(a)(6) of the Act, we deducted home market packing costs and added U.S. packing costs, U.S. imputed credit, bank charges, and penalty fees.

**Level of Trade**

As set forth in section 773(a)(1)(B)(i) of the Act and in the Statement of Administrative Action, to the extent practicable, we determine NV based on sales in the comparison market at the same level of trade ("LOT") as the EP. The NV LOT is that of the starting-price sale in the comparison market or, when NV is based on CV, that of the sales from which we derive selling, general and administrative expenses and profit. For EP, the U.S. LOT is the level of the starting-price sale, which is usually from exporter to importer. To determine whether NV sales are at a different LOT than EP sales, we examine stages in the marketing process and selling functions along the chain of distribution between the producer and the unaffiliated customer. If the comparison-market sales are at a different LOT, and the difference affects price comparability, as manifested in a pattern of consistent price differences between the sales on which NV is based and comparison-market sales at the LOT of the export transaction, we make an LOT adjustment under section 773(a)(7)(A) of the Act. *See Notice of Final*

*Determination of Sales at Less Than Fair Value: Certain Cut-to-Length Carbon Steel Plate from South Africa*, 62 FR 61731 (November 19, 1997).

For the U.S. market, Saha Thai reported only one LOT for its EP sales. This single LOT represents large volume sales to unaffiliated distributors in the United States. In the home market, Saha Thai reported that it made sales at one LOT. These sales were made to unaffiliated end-users and distributors. We have examined the selling functions in each market and find that there are no significant differences in the selling functions Saha Thai performs for its customers in the home market from those it performs in the United States. Therefore, we conclude that EP and NV sales are made at the same LOT and no adjustment is warranted.

**Currency Conversion**

We made currency conversions into U.S. dollars in accordance with section 773A of the Act, based on exchange rates in effect on the dates of the U.S. sales as certified by the Federal Reserve Bank.

**Preliminary Results of Review**

We preliminarily determine that the following weighted-average dumping margin exists:

| Manufacturer/Exporter | Period | Margin |
|---|---|---|
| Saha Thai Steel Pipe Company, Ltd. | 3/1/02–2/28/03 | 2.00% |

**Assessment Rates**

The Department shall determine, and CBP shall assess, antidumping duties on all appropriate entries. For Saha Thai the assessment rate will be based on the margin above. The Department will issue appropriate appraisement instructions directly to CBP within 15 days of publication of the final results of review. We will direct CBP to assess the resulting assessment rates against the entered customs values for the subject merchandise on each of the entries during the period of review.

**Cash Deposit Requirements**

The following deposit rates will be effective with respect to all shipments of certain welded carbon steel pipes and tubes from Thailand entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results as provided for by section 751(a)(2)(C) of the Act: (1) For Saha Thai, the cash deposit rate will be the company-specific rate established in the final results of this review; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will be the company-specific rate established for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the LTFV investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the subject merchandise; and (4) for all other producers and/or exporters of this merchandise, the cash deposit rate shall be the "all others'' rate established in the LTFV investigation, which is 15.67 percent. *See Order*. These deposit rates, when imposed, shall remain in effect until the publication of the next administrative review.

**Public Comment**

Pursuant to section 351.224(b) of the Department's regulations, the Department will disclose to parties to the proceeding any calculations performed in connection with these preliminary results within five days after the date of publication of this notice. Pursuant to section 351.309 of the Department's regulations, interested parties may submit written comments in response to these preliminary results. Case briefs are to be submitted within 30 days after the date of publication of this notice, and rebuttal briefs, limited to arguments raised in case briefs, are to be submitted no later than five days after the time limit for filing case briefs. Parties who submit arguments in this proceeding are requested to submit with the argument: (1) A statement of the issues, and (2) a brief summary of the argument. Case and rebuttal briefs must be served on interested parties in accordance with section 351.303(f) of the Department's regulations.Also, pursuant to section 351.310 of the Department's regulations, within 30 days of the date of publication of this notice, interested parties may request a public hearing on arguments to be raised in the case and rebuttal briefs. Unless the Secretary specifies otherwise, the hearing, if requested, will be held two days after the date for submission of rebuttal briefs. Parties will be notified of the time and location. The Department will publish the final results of this administrative review, including the results of its analysis of issues raised in any case or rebuttal brief, not later than 120 days after publication of these preliminary results, unless extended.

**Notice to Importers**

This notice serves as a preliminary reminder to importers of their responsibility under section 351.402(f) of the Department's regulations to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

These preliminary results of review and notice are issued in accordance with sections 751(a)(1) and 777(i)(1) of the Act (19 U.S.C. 1675(a)(1) and 19 U.S.C 1677f(i)(1)).

Dated: March 30, 2004.

**Jeffrey May,**

*Acting Assistant Secretary for Import Administration.*

[FR Doc. 04–8011 Filed 4–7–04; 8:45 am]

BILLING CODE 3510–DS–P

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[C–533–825]**

### Notice of Preliminary Results and Rescission in Part of Countervailing Duty Administrative Review: Polyethylene Terephthalate Film, Sheet, and Strip From India

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**ACTION:** Notice of preliminary results of countervailing duty administrative review.

**SUMMARY:** The Department of Commerce (the Department) is conducting an administrative review of the countervailing duty (CVD) order on polyethylene terephthalate film, sheet, and strip (PET film) from India. The review covers one company; the period of review (POR) is October 22, 2001, through December 31, 2002.[1] For

[1] For the purposes of these preliminary results, we have analyzed data for the period January 1, 2001, through December 31, 2001, to determine the

information on the net subsidy rate for the reviewed company, *see* the "Preliminary Results of Administrative Review'' section of this notice. If the final results remain the same as the preliminary results of this review, we will instruct the U.S. Customs and Border Protection (CBP) to assess countervailing duties as detailed in the "Preliminary Results of Administrative Review'' section of this notice. Interested parties are invited to comment on these preliminary results. (*See* the "Public Comment'' section of this notice).

**EFFECTIVE DATE:** April 8, 2004.

**FOR FURTHER INFORMATION CONTACT:** Jeff Pedersen at (202) 482–2769 or Howard Smith at (202) 482–5193, AD/CVD Enforcement Office IV, Group II, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

**SUPPLEMENTARY INFORMATION:**

## Background

On July 1, 2002, the Department published a CVD order on PET film from India. *See Notice of Countervailing Duty Order: Polyethylene Terephthalate Film, Sheet, and Strip (PET Film) from India,* 67 FR 44179 (July 1, 2002) (*PET Film Order*). On July 2, 2003, the Department published in the **Federal Register** a notice of opportunity to request an administrative review of this order. *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 68 FR 39511 (July 2, 2003). On July 31, 2003, Dupont Teijin Films, Mitsubishi Polyester Film of America, Toray Plastics (America) and SKC America, Inc. (the petitioners), requested that the Department conduct an administrative review of the CVD order on PET film from India with respect to Polyplex Corporation Ltd. (Polyplex). Also, on July 31, 2003, Polyplex, Garware Polyester Limited and Global Pet Films (Garware), and Jindal Polyester Limited (Jindal), Indian producers and exporters of subject merchandise, requested that the Department conduct an administrative review of the CVD order on PET film from India with respect to their exports to the United States. Finally, on July 31, 2003, Valencia Specialty Films, Inc. (Valencia), a U.S. importer of subject merchandise, requested that the Department conduct an administrative review of the CVD order on PET film from India with respect to Jindal's exports to the United States. On August 22, 2003, the Department initiated an administrative review of the CVD order on PET film from India covering Garware, Jindal and Polyplex, and the period October 22, 2001, through December 31, 2002. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocation in Part,* 68 FR 50750 (August 22, 2003).

On August 6, 2003, Jindal requested that the Department change the POR to either April 1, 2002, through March 31, 2003 (its fiscal year), or January 1, 2002, through March 31, 2003,[2] in order to facilitate the reporting of the information requested by the Department. Similarly, on August 19, 2003, August 22, 2003, and September 24, 2003, Polyplex argued that the Department should alter the POR to take into account the April through March fiscal year used by the Government of India (GOI) and most Indian companies. On September 26, 2003, the Department denied the companies' request for a change in the POR. *See* letters from the Department to Jindal and Polyplex regarding request for a different period of review, on file in the Central Records Unit (CRU), room B–099 of the main Commerce building.

On August 20, 2003, the Department issued questionnaires to the GOI and Polyplex. We received responses from Polyplex on October 9, 2003, and from the GOI on October 23, 2003. In November and December 2003, and February and March 2004, the Department issued supplemental questionnaires to Polyplex. Polyplex provided timely responses. Also, petitioners submitted comments regarding the questionnaire responses in October and November 2003.

On August 21, 2003, Garware withdrew its request for an administrative review of its exports. Jindal and Valencia, on September 25, 2003, and October 8, 2003, respectively, also withdrew their requests for an administrative review of Jindal. Because no other interested parties requested administrative reviews these companies, as explained in the "Partial Rescission of Review'' section below, we are rescinding the administrative reviews of these companies.

On February 19, 2004, the GOI requested that the Department change the POR to the period April 1, 2002, through March 31, 2003. For the reasons stated in our letters to Jindal and Polyplex, we are denying the GOI's request to change the POR.

In accordance with 19 CFR 351.213(b), this administrative review covers only those producers or exporters for which a review was specifically requested. Polyplex is the only company subject to this review. This review covers 14 programs.

## Scope of the Review

For purposes of this review, the products covered are all gauges of raw, pretreated, or primed PET film, whether extruded or coextruded. Excluded are metallized films and other finished films that have had at least one of their surfaces modified by the application of a performance-enhancing resinous or inorganic layer of more than 0.00001 inches thick. Imports of PET film are classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) under item number 3920.62.00. HTSUS subheadings are provided for convenience and customs purposes. The written description of the scope of this proceeding is dispositive.

## Partial Rescission of Review

As provided in 19 CFR 351.213(d)(1), "the Secretary will rescind an administrative review under this section, in whole or in part, if a party that requested a review withdraws the request within 90 days of the date of publication of notice of initiation of the requested review.'' Jindal and Garware withdrew their requests for an administrative review of their respective companies and Valencia withdrew its request for an administrative review of Jindal within 90 days of the date of publication of the notice of initiation of the instant administrative review. Additionally, no other party requested an administrative review of Jindal or Garware. Therefore, the Department is rescinding the administrative review with respect to Jindal and Garware.

## Subsidies Valuation Information

### Allocation Period

In the investigative segment of this proceeding, the Department determined that Polyplex's non-recurring subsidies should be allocated over an average useful life (AUL) of 18 years. Because there is no new evidence on the record that would cause the Department to

subsidy rate for exports of subject merchandise made during the POR covering 2001. In addition, we have analyzed data for the period January 1, 2002, through December 31, 2002, to determine the subsidy rate for exports during that period. Further, we are using the subsidy rate calculated for calendar year 2002 to establish the cash deposit rate for exports of subject merchandise subsequent to the issuance of the final results of this administrative review.

[2] In its August 6, 2003, request, Jindal noted that the Department's notice of opportunity to request an administrative review identified the POR as the period January 1, 2002, through December 31, 2002. We acknowledge that the information provided in the notice was incorrect. The opportunity notice should have identified the POR as the period October 22, 2001, through December 31, 2002.

reconsider this decision, in this review the Department will continue to use an AUL of 18 years in allocating Polyplex's non-recurring subsidies.

**Benchmarks for Loans and Discount Rate**

*Benchmark for Short-Term Loans*

In accordance with 19 CFR 351.505(a)(3)(i), and consistent with the underlying investigation, for those programs requiring the application of a short-term benchmark interest rate, we used as the benchmark the company-specific, short-term interest rates on commercial loans as reported by Polyplex. In calculating the benefit for pre-shipment export financing, we used as the rupee-denominated, short-term benchmark the weighted-average rate of the company's cash credit loans. The Department has found that cash credit loans are the most comparable type of short-term loans and the rate of these loans is appropriate for use as a benchmark because, like pre-shipment export financing, cash credit loans are denominated in rupees and take the form of a line of credit which can be drawn down by the recipient. *See* PET Film Final Determination Decision Memorandum, at section titled "Benchmark for Loans and Discount Rates'' and also, *Notice of Final Affirmative Countervailing Duty Determination: Certain Hot-Rolled Carbon Steel Flat Products from India,* 66 FR 49635 (September 28, 2001) (*Hot-Rolled Steel Final Determination*) and accompanying Decision Memorandum (Hot-Rolled Steel Final Determination Decision Memorandum), at section titled "Benchmark for Loans and Discount Rates.'' In calculating the benefit for post-shipment export financing, where available, we used as the rupee-denominated, short-term benchmark the weighted-average rate for the company's "inland'' or "local'' bill discounting loans. The Department found, in the investigative segment of this proceeding that "inland'' or "local'' bill discounting loans, like the post-shipment export financing loans, are rupee-denominated working capital loans used to finance receivables. *See Notice of Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Countervailing Determination with Final Antidumping Duty Determination: Polyethylene Terephthalate Film, Sheet, and Strip (PET Film) from India,* 66 FR 53389, 53390, (October 22, 2001) (*PET Film Preliminary Determination*) at section titled "Benchmarks for Loans and Discount Rate,'' unchanged in *PET Film Final Determination.*

Certain Polyplex pre-shipment loans are denominated in U.S. dollars. When loans are denominated in a foreign currency, our practice, in accordance with 19 CFR 351.505, is to use a foreign currency benchmark. *See, e.g., Certain Pasta From Turkey: Final Results of Countervailing Duty Administrative Review,* 66 FR 64398 (December 13, 2001) and accompanying Issues and Decision Memorandum in the section entitled "Benchmark Interest Rates for Short-term Loans.'' Polyplex reported that its working capital demand loans (WCDL) are its only short-term U.S. dollar-denominated loans. Thus, we used the interest rate on these loans as the benchmark for Polyplex's pre-shipment financing denominated in U.S. dollars. Polyplex reports that the WCDL are for financing both inventories and receivables and are provided as part of an overall package by the consortia of banks providing Polyplex with financing. The interest rates are a mark-up over London Interbank Offering Rates (LIBOR) and are fixed for the duration of the loan. These loans have a fixed repayment date.

*Benchmarks for Long-Term Loans*

For those programs requiring a rupee-denominated discount rate or the application of a rupee-denominated, long-term benchmark interest rate, we used, where available, company-specific, weighted-average interest rates on commercial long-term, rupee-denominated loans. We note, however, that Polyplex did not have rupee-denominated, long-term loans from commercial banks for all required years. Therefore, for those years for which we did not have company-specific information, we relied on a rupee-denominated, long-term benchmark interest rate from the immediately preceding year as directed by 19 CFR 351.505(a)(2)(iii).

**Basis for Reporting Consignment Sales**

Polyplex considered consigned merchandise that was consumed by U.S. customers during the POR, but shipped to the United States outside of the POR, to be reportable sales for purposes of calculating *ad valorem* subsidy rates. However, the Department has preliminarily required Polyplex to report its consignment sales on the same basis that it reported its non-consignment sales (date of shipment from Polyplex's factory) in order for the reported sales to correspond more closely to the basis on which CBP assesses countervailing duties.

**Programs Preliminarily Determined To Confer Subsidies**

*1. Pre-Shipment and Post-Shipment Export Financing*

The Reserve Bank of India (RBI), through commercial banks, provides short-term pre-shipment financing, or "packing credits,'' to exporters. Upon presentation of a confirmed export order or letter of credit to a bank, companies may receive pre-shipment loans for working capital purposes, *i.e.*, for the purchase of raw materials, warehousing, packing, and transporting of merchandise destined for export. Companies may also establish pre-shipment credit lines upon which they may draw as needed. Limits on credit lines are established by commercial banks and are based on a company's creditworthiness and past export performance. Credit lines may be denominated either in Indian rupees or in a foreign currency. Companies that have pre-shipment credit lines typically pay interest on a quarterly basis on the outstanding balance of the account at the end of each period. Commercial banks extending export credit to Indian companies must, by law, charge interest at rates determined by the RBI.

Post-shipment export financing consists of loans in the form of discounted trade bills or advances by commercial banks. Exporters qualify for this program by presenting their export documents to the lending bank. The credit covers the period from the date of shipment of the goods to the date of realization of the proceeds from the sale to the overseas customer. Under the Foreign Exchange Management Act of 1999, exporters are required to realize proceeds from their export sales within 180 days after the date of shipment, which is monitored by the RBI. Post-shipment financing is, therefore, a working capital program used to finance export receivables. In general, post-shipment loans are granted for a period of no more than 180 days. If the loans are not repaid within the due date, the exporters lose the concessional interest rate on this financing.

In the *PET Film Final Determination,* the Department determined that the pre- and post-shipment export financing programs conferred countervailable subsidies on the subject merchandise because (1) provision of the export financing constitutes a financial contribution pursuant to section 771(5)(D)(i) of the Act; (2) provision of the export financing conferred benefits on the respondents under section 771(5)(E)(ii) of the Act because the interest rates under these programs were lower than commercially available

interest rates; and (3) these programs are contingent upon export performance, and therefore constitute countervailable export subsidies under section 771(5A)(B) of the Act. *See* PET Film Final Determination Decision Memorandum at section entitled "Pre-shipment and Post-shipment Export Financing.'' No new information or evidence of changed circumstances have been presented to warrant reconsideration of this finding. Therefore, for the purpose of these preliminary results, we continue to find this program countervailable.

To calculate the benefit conferred by the pre-shipment and post-shipment loans taken out by Polyplex, we compared the actual interest paid on the loans with the amount of interest that would have been paid at the benchmark interest rate. Where the benchmark interest exceeds the actual interest paid, the difference constitutes the benefit. For pre-shipment loans, we divided the total benefit by Polyplex's total exports. For post-shipment loans, we divided the total benefit by Polyplex's exports of subject merchandise to the United States. On this basis, we preliminarily determine the net countervailable subsidy rate under the pre-shipment export financing program for Polyplex is 0.45 percent *ad valorem* in 2001 and 0.67 percent *ad valorem* in 2002; the net subsidy rate under the post-shipment export financing program is 0.37 percent ad valorem in 2001 and 0.05 percent *ad valorem* in 2002.

*2. Duty Entitlement Passbook Scheme (DEPS)*

The DEPS enables exporting companies to earn import duty exemptions in the form of passbook credits, rather than cash. These DEPS passbook credits can be used for the future payment of import duties on any subsequent imports, regardless of whether they are consumed in the production of an exported product. DEPS credits are valid for twelve months and are transferable after the foreign exchange is realized from the export sales on which the DEPS credits are earned. All exporters are eligible to earn DEPS credits on a post-export basis, provided that the GOI has established a standard input-output norm (SION) for the exported product.

In the *PET Film Final Determination,* the Department determined that DEPS conferred countervailable subsidies on the respondents because: (1) A financial contribution, as defined under section 771(5)(D)(ii) of the Act, is provided under the program, as the GOI provides the respondents with credits for the future payment of import duties; (2) the GOI does not have in place and does not apply a system that is reasonable and effective for the purposes intended under 19 CFR 351.519(a)(4) and section 771(5)(E) of the Act, to confirm which inputs, and in what amounts, are consumed in the production of the exported products, and thus the entire amount of import duty exemption earned by the respondent constitutes a benefit; and (3) this program can only be used by exporters and, therefore, is specific under section 771(5A)(B) of the Act. *See* PET Film Final Determination Decision Memorandum at section titled "DEPS.'' No new information or evidence of changed circumstances have been presented in this review to warrant reconsideration of these findings. Therefore, we continue to find that the DEPS program is countervailable.

Under 19 CFR 351.524(c), this program provides a recurring benefit. As the subsidies can be tied to a particular product (subject merchandise) in a particular market (the United States), we calculated the subsidy for each calendar year by dividing the total value of the DEPS licenses for subject merchandise sold in the United States, net of application fees paid, by the value of Polyplex's total exports of subject merchandise to the United States during the same year. Accordingly, we preliminarily determine that the net subsidy rates for Polyplex under the DEPS are 14.03 percent *ad valorem* for 2001 and 12.07 percent *ad valorem* for 2002.

*3. Export Promotion Capital Goods Scheme (EPCGS)*

The EPCGS provides for a reduction or exemption of customs duties and an exemption from excise taxes on imports of capital goods. Under this program, producers may import capital equipment at reduced rates of duty by attempting to earn convertible foreign currency equal to four to five times the value of the capital goods within a period of eight years. If the company fails to meet the export obligation, the company is subject to payment of all or part of the duty reduction, depending on the extent of the export shortfall, plus penalty interest.

Polyplex reported that it imported machinery under the EPCGS in the years prior to and during the POR. For some of its imported machinery, Polyplex met its export requirements. As a result, the GOI completely waived import duties. However, Polyplex has not completed its export requirements for other imports of capital machinery. Therefore, although Polyplex received a reduction in import duties when the capital machinery was imported, the final waiver on the obligation to repay the duties has not yet been granted by the GOI.

In the underlying investigation, we referenced and applied the determination reached in *Hot-Rolled Steel Final Determination* that the import duty reduction provided under the EPCGS is a countervailable export subsidy. *See PET Film Preliminary Determination* at section titled "EPCGS'' (unchanged in the final determination). *See also* Hot-Rolled Steel Final Determination Decision Memorandum at section titled "Analysis of Programs.'' No new information or evidence of changed circumstances has been provided in this review to warrant a reconsideration of this determination. Therefore, in accordance with section 771(5A)(B) of the Act, we continue to find that the receipt of benefits under this program is contingent upon export performance and therefore countervailable.

In cases where the GOI has formally waived the unpaid duties on imports, we have treated the full amount of the waived duty exemptions as a grant received in the year in which the GOI officially granted the waiver. The criteria used by the Department in determining whether to allocate or expense the benefits from a countervailable subsidy program are described under 19 CFR 351.524. Specifically, recurring benefits are to be expensed in the year of receipt, while non-recurring benefits are to be allocated over time unless they amount to less than 0.5 percent of the relevant sales.

Normally, tax benefits are considered to be recurring benefits and are expensed in the year of receipt. Because import duties are a type of tax, the benefit provided under this program is a tax benefit, and, thus, normally would be considered a recurring benefit. However, the Department's regulations recognize that, under certain circumstances, it may be more appropriate to allocate over time the benefits of a program normally considered a recurring subsidy, rather than to expense the benefits in the year of receipt. 19 CFR 351.524(c)(2) provides the criteria to apply to determine whether a benefit is recurring or non-recurring. One of these criteria refers to "whether the subsidy was provided for or tied to the capital structure or capital assets of the firm.'' We also stated in the preamble to our regulations (*see Countervailing Duties; Final Rule,* 63 FR 65348, 65393 (November 25, 1998) (*CVD Preamble*)) that, if a government provides an import duty exemption tied to major capital

equipment purchases, it may be reasonable to conclude that, because these duty exemptions are tied to capital assets, the benefits from such duty exemptions should be considered non-recurring, even though import duty exemptions are on the illustrative list of recurring subsidies. *See* 19 CFR 351.524(c). Because the benefit received from the waiver of import duties under the EPCGS is tied to the capital assets of the respondent company, we determine that it is appropriate to treat the waiver of duties as a non-recurring benefit. We note that our approach on this issue is consistent with that taken in *PET Film Preliminary Determination* at section entitled "EPCGS'' (unchanged in the final determination). *See also Notice of Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Countervailing Determination With Final Antidumping Duty Determinations: Certain Hot-Rolled Carbon Steel Flat Products From India,* 66 FR 20240, 20246, 20247 (April 20, 2001) (*Hot-Rolled Preliminary Determination*) (unchanged in the final determination).

In its questionnaire responses, Polyplex reported all of its imports of capital equipment made using EPCGS licenses and the application fees it paid to obtain its EPCGS licenses. We preliminarily determine that the application fees paid by the respondent qualifies as an "* * * application fee, deposit, or similar payment paid in order to qualify for, or to receive, the benefit of the countervailable subsidy,'' which may be subtracted from the numerator when calculating the amount of the countervailable subsidy. *See* section 771(6)(A) of the Act.

In order to calculate the benefit received from the waiver of Polyplex's import duties on their capital equipment imports, we determined the total amount of duties waived (net of application fees). Consistent with the approach followed in the investigative segment of this proceeding, we determine the year of receipt of the benefit to be the year in which the GOI formally waived the respondent company's outstanding import duties. *See PET Film Preliminary Determination* at section titled "EPCGS'' (unchanged in final determination). *See also Hot-rolled Preliminary Determination* at section entitled "EPCGS'' (unchanged in the final determination). Next, we performed the "0.5 percent test,'' as prescribed under 19 CFR 351.524(b)(2) for each year in which the GOI granted the respondent an import duty waiver. Those waivers with face values in excess of 0.5 percent of Polyplex's total export sales in the year in which the waivers were granted were allocated over 18 years, the company-specific AUL, using the Department's standard allocation methodology for non-recurring subsidies under 19 CFR 351.524(b).

A second type of financial contribution and benefit conferred under this program involves the import duty reductions that Polyplex received on the imports of capital equipment for which it has not yet met its export requirements. For those capital equipment imports, Polyplex has unpaid duties that will become due to the GOI if the export requirements are not met. Therefore, we determine that Polyplex had outstanding contingent liabilities during the POR. When a company has an outstanding liability and the repayment of that liability is contingent upon subsequent events, our practice is to treat any balance on that unpaid liability as an interest-free loan. *See* 19 CFR 351.505(d)(1).

We determine that the amount of contingent liability to be treated as an interest-free loan is the amount of the import duty reduction or exemption for which the respondent applied but, as of the end of the POR, had not been finally waived by the GOI. Accordingly, we determine the benefit to be the interest that Polyplex would have paid during the POR had it borrowed the full amount of the duty reduction at the time of importation. We note that this methodology is consistent with our approach in the underlying investigation. *See PET Film Preliminary Determination* at section entitled "EPCGS'' (unchanged in final determination). *See also Hot-rolled Preliminary Determination* at section entitled "EPCGS'' (unchanged in the final determination). Pursuant to 19 CFR 351.505(d)(1), the benchmark for measuring the benefit is a long-term interest rate because the event upon which repayment of the duties depends (*i.e.*, the date of expiration of the time period for the respondent to fulfill its export commitments) occurs at a point in time more than one year after the date of importation of the capital goods.

To calculate the benefit for this program, for each year we combined the total amount of benefits received on waived duties and the total amount of benefits conferred on Polyplex in the form of contingent liability loans. We then divided the total benefits under the program during 2001 and 2002 by the respective total export sales. We preliminarily determine the net countervailable subsidy to Polyplex from this program to be 5.37 percent *ad valorem* for 2001 and 5.93 percent *ad valorem* for 2002.

*4. Income Tax Exemption Scheme 80 HHC*

Under section 80HHC of the Income Tax Act, the GOI allows exporters to deduct from taxable income profits derived from export sales. In prior proceedings, the Department has found this program to be an export subsidy, and thus countervailable, because receipt of the benefit is contingent upon export performance. *See Certain Iron-Metal Castings from India: Preliminary Results and Partial Rescission of Countervailing Duty Administrative Review,* FR 61592 (November 12, 1999) (unchanged in the final results). *See Certain Iron-Metal Castings from India: Final Results of Countervailing Duty Administrative Review,* 65 FR 31515 (May 18, 2000). As stated by the GOI in this proceeding, receipt of the 80HHC tax waiver remains contingent upon export performance. *See* October 23, 2003, GOI questionnaire response at 34, 35. No new information or evidence of changed circumstances has been submitted in this proceeding to warrant reconsideration of this finding. *See id* at 34–39 and exhibit 11. Therefore, in accordance with sections 771(5)(D) and (E) of the Act, we continue to find this program countervailable because it provides a financial contribution by the government in the form of tax revenue not collected which also constitutes the benefit. Moreover, because the tax deduction is contingent upon export performance, we continue to find the program to be an export subsidy under section 771(5A)(B) of the Act and therefore countervailable.

The benefits provided under this program are not tied to the production or sale of a particular product or products. It is the Department's long-standing practice to attribute a benefit from an export subsidy that is not tied to a particular product or market to all products exported by the company. *See, e.g., Final Affirmative Countervailing Duty Determination: Certain Pasta from Turkey,* 61 FR 30366, 30370 (June 14, 1996). Therefore, to calculate the benefit that Polyplex received under section 80HHC for each year, we subtracted the total amount of income tax the company actually paid during the review period from the amount of income tax the company otherwise would have paid had it not claimed a deduction under section 80HHC. We then divided the difference by the fob value of the company's total exports. Thus, we preliminarily determine the net countervailable subsidy from this program to be 1.25 percent *ad valorem* for 2001 and 4.31 percent *ad valorem* for 2002.

*5. Capital Subsidy*

Polyplex received a capital infusion of Rs. 2,500,000 in 1989. This subsidy was only discovered during verification of the underlying investigation. Based on the information obtained at verification, the Department determined that a financial contribution was provided by the GOI, pursuant to section 771(5)(D)(i) of the Act, and a benefit was received by Polyplex, under section 771(E) of the Act, in the amount of the capital subsidy. The Department found that there was insufficient time to determine whether this program is specific under section 771(5A)(D) of the Act and stated its intention to reexamine this program in a future administrative review pursuant to 19 CFR 351.311(c)(2). *See* PET Film Final Determination Decision Memorandum at 14 and 15. *See also* October 9, 2003, questionnaire response at annex 5, containing Memorandum from Mark Manning to the File, Re: Verification Report for Polyplex Corporation Ltd. (February 11, 2002) at 2, 24 and 25.

In the instant review, the Department sent questionnaires to both the GOI and Polyplex and a further supplemental questionnaire to Polyplex, seeking information to determine whether this program is specific under section 771(5A) of the Act. However, due to the considerable time elapsed since the provision of the subsidy and also due to a fire at the former offices of Polyplex where numerous records of the company were destroyed, Polyplex stated that it was unable to provide any information regarding specificity. The GOI stated that neither it, nor the local government, had any details regarding the subsidy. *See* the GOI's October 23, 2003, questionnaire response and Polyplex's October 9, 2003, questionnaire response and Polyplex's November 18, 2003, supplemental questionnaire response.

Section 776(a)(2) of the Act provides that if an interested party or any other person—(A) withholds information that has been requested by the administering authority, (B) fails to provide such information by the deadlines for the submission of the information or in the form and manner requested, subject to subsections (c)(1) and (e) of section 782, the administering authority shall, subject to section 782(d), use the facts otherwise available in reaching the applicable determination under this title. Neither Polyplex nor the GOI have provided the information requested by the Department. However, in light of the circumstances described by the respondent, the Department finds no basis for determining that Polyplex has not cooperated to the best of its ability. Therefore, the Department, has preliminarily determined that the subsidy is specific under section 771(5A)(A) of the Act and, as neutral facts available determination, is allocating the amount over the firm's total sales.

To calculate the subsidy rate for this program, we performed the "0.5 percent test,'' as prescribed under 19 CFR 351.524(b)(2). Because the grant exceeded 0.5 percent of Polyplex's total sales in 1989, the year in which the capital infusion was received, the benefits were allocated over 18 years, the company-specific AUL, using the Department's standard allocation methodology for non-recurring subsidies under section 19 CFR 351.524(b). We preliminarily determine the net countervailable subsidy from this program to be 0.02 percent *ad valorem* for 2001 and 0.02 percent *ad valorem* for 2002.

**Program Preliminarily Determined Not to Confer a Benefit**

*6. Sales Tax Incentives*

The State of Maharashtra and the State of Uttaranchel grant a package scheme of incentives for privately-owned (*i.e.*, not 100 percent owned by the GOI) manufacturers to invest in certain areas of their respective states. One of these incentives consists of either an exemption or deferral of state sales taxes. Through this incentive, companies are exempted from paying state sales taxes on purchases, and collecting sales taxes on sales; or, as an alternative, are allowed to defer submitting sales taxes collected on sales to the SOM for 10 to 12 years. After the deferral period expires, the companies are required to submit the deferred sales taxes to the State of Maharashtra and the State of Uttaranchel in equal installments over five to six years. The total amount of the sales tax incentive either exempted or deferred is based on the size of the capital investment, and the area in which the capital is invested.

In the underlying investigation we found that this program is specific within the meaning of sections 771(5A)(D)(i) and (iv) of the Act because the benefits of this program are limited to privately-owned (*i.e.*, not 100 percent owned by the GOI) industries located within designated geographical regions within the SOM. We also found that the State of Maharashtra and the State of Uttaranchel provided a financial contribution under section 771(5)(D)(i) of the Act, and that the respondents may have benefitted under section 771(5)(E) of the Act through this program. For the sales tax exemption, we found that a benefit exists only to the extent that the taxes paid by the respondent as a result of this program are less than the taxes the respondent would have paid in the absence of the program. *See* 19 CFR 351.510(a)(1).

During the POR, Polyplex utilized only the feature of this program that exempts a company from the collection of the sales tax on its own sales. This exemption did not have the effect of Polyplex paying any less taxes from its own funds. Therefore, consistent with our determination in the investigation, we preliminarily determine that the there was no benefit to Polyplex from this program.

**Programs Preliminarily Determined Not To Be Used**

1. The Sale and Use of Special Import Licenses (SILs) for Quality and SILs for Export Houses, Trading Houses, Star Trading Houses, or Superstar Trading Houses (GOI Program).
2. Exemption of Export Credit from Interest Taxes.
3. Loan Guarantees from the GOI.
4. Benefits for Export Processing Zones /Export Oriented Units (EPZs/EOUs).
5. Electricity Duty Exemption Scheme (SOM).
6. Capital Incentive Schemes (SOM and SUP Program).
7. Waiving of Interest on Loan by SICOM Limited (SOM Program).
8. Infrastructure Assistance Schemes (State of Gujarat Program).

**Preliminary Results of Administrative Review**

In accordance with 19 CFR 351.221(b)(4)(i), we calculated an individual subsidy rate for Polyplex for 2001 and 2002. We preliminarily determine the total net countervailable subsidy rate is 21.49 percent *ad valorem* for 2001 and 23.05 percent *ad valorem* for 2002.

If the final results of this review remain the same as these preliminary results, the Department intends to instruct the CBP, within 15 days of publication of the final results, to liquidate shipments from Polyplex of PET film from India entered, or withdrawn from warehouse, for consumption from October 22, 2001, through December 31, 2001, at 21.49 percent *ad valorem* and from January 1, 2002, through February 19, 2002, as well as from June 27, 2002, through December 31, 2002, at 23.05 percent *ad valorem* of the f.o.b. invoice price. Also, the rate of cash deposits of estimated countervailing duties will be set at 23.05 percent *ad valorem* for all shipments of

PET film made by Polyplex from India entered or withdrawn from warehouse, for consumption on or after the publication of the final results of this administrative review.

Because the Uruguay Round Agreements Act (URAA) replaced the general rule in favor of a country-wide rate with a general rule in favor of individual rates for investigated and reviewed companies, the procedures for establishing countervailing duty rates, including those for non-reviewed companies, are now essentially the same as those in antidumping cases, except as provided for in section 777A(e)(2)(B) of the Act. A requested review will normally cover only those companies specifically named. *See* 19 CFR 351.213(b). Pursuant to 19 CFR 351.212(c), for all companies for which a review was not requested, duties must be assessed at the cash deposit rate, and cash deposits must continue to be collected at the rate previously ordered. As such, the countervailing duty cash deposit rate applicable to a company can no longer change, except pursuant to a request for a review of that company. *See Federal-Mogul Corporation and The Torrington Company* v. *United States*, 822 F. Supp. 782 (CIT 1993) and *Floral Trade Council* v. *United States*, 822 F. Supp. 766 (CIT 1993) (interpreting 19 CFR 353.22(e), the pre-URAA antidumping regulation on automatic assessment, which was identical to 19 CFR 355.22(g)). Therefore, the cash deposit rates for all companies except those covered by this review will be unchanged in the results of this review.

We will instruct the CBP to continue to collect cash deposits for non-reviewed companies at the most recent company-specific or country-wide rate applicable to the company. Accordingly, the cash deposit rates that will be applied to non-reviewed companies covered by this order are those established in the most recently completed administrative proceeding conducted under the URAA. *See PET Film Order*. These rates shall apply to all non-reviewed companies until a review of a company assigned these rates is requested.

**Public Comment**

Pursuant to 19 CFR 351.224(b), the Department will disclose to parties to the proceeding any calculations performed in connection with these preliminary results within five days after the date of the public announcement of this notice. Pursuant to 19 CFR 351.309, interested parties may submit written comments in response to these preliminary results. Unless otherwise indicated by the Department, case briefs must be submitted within 30 days after the date of publication of this notice, and rebuttal briefs, limited to arguments raised in case briefs, must be submitted no later than five days after the time limit for filing case briefs, unless otherwise specified by the Department. Parties who submit argument in this proceeding are requested to submit with the argument: (1) a statement of the issue, and (2) a brief summary of the argument. Parties submitting case and/or rebuttal briefs are requested to provide the Department with copies of the public version of those comments on disk. Case and rebuttal briefs must be served on interested parties in accordance with 19 CFR 351.303(f). Also, pursuant to 19 CFR 351.310, within 30 days of the date of publication of this notice, interested parties may request a public hearing regarding arguments to be raised in the case and rebuttal briefs. Unless the Secretary specifies otherwise, the hearing, if requested, will be held two days after the date for submission of rebuttal briefs, that is, 37 days after the date of publication of these preliminary results.

Representatives of parties to the proceeding may request disclosure of proprietary information under administrative protective order no later than 10 days after the representative's client or employer becomes a party to the proceeding, but in no event later than the date the case briefs are due under 19 CFR 351.309(c)(ii). The Department will publish the final results of this administrative review, including the results of its analysis of arguments made in any case or rebuttal briefs.

This administrative review is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: April 1, 2004.

**Jeffrey A. May,**

*Acting Assistant Secretary for Import Administration.*

[FR Doc. 04–8016 Filed 4–7–04; 8:45 am]

BILLING CODE 3510–DS–P

## DEPARTMENT OF COMMERCE

### International Trade Administration

### Environmental Technologies Trade Advisory Committee (ETTAC)

**AGENCY:** International Trade Administration, U.S. Department of Commerce.

**ACTION:** Notice of open meeting.

*Date:* May 14, 2004.

*Time:* 9 a.m. to 2 p.m.

*Place:* American Water Works Association, 6666 W. Quincy Avenue, Denver, CO 80235.

**SUMMARY:** The Environmental Technologies Trade Advisory Committee (ETTAC) will hold a plenary meeting on May 14, 2004 at the American Water Works Association (AWWA) at 6666 West Quincy Avenue, Denver, CO 80235. For directions, please call AWWA at (303) 794–7711.

The ETTAC will discuss environmental technologies trade policies and programs. Time will be permitted for public comment. The meeting is open to the public.

Written comments concerning ETTAC affairs are welcome anytime before or after the meeting. Minutes will be available within 30 days of this meeting.

The ETTAC is mandated by Public Law 103–392. It was created to advise the U.S. government on environmental trade policies and programs, and to help it to focus its resources on increasing the exports of the U.S. environmental industry. ETTAC operates as an advisory committee to the Secretary of Commerce and the Trade Promotion Coordinating Committee (TPCC). ETTAC was originally chartered in May of 1994. It was recently rechartered until May 30, 2006.

For further information phone Corey Wright, Office of Environmental Technologies Industries (ETI), International Trade Administration, U.S. Department of Commerce at (202) 482–5225. This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to ETI at (202) 482–5225.

Dated: March 30, 2004.

**Carlos F. Montoulieu,**

*Director, Office of Environmental Technologies Industries.*

[FR Doc. 04–7705 Filed 4–7–04; 8:45 am]

BILLING CODE 3510–DR–M

## DEPARTMENT OF COMMERCE

### International Trade Administration

### North American Free Trade Agreement, Article 1904, NAFTA Panel Reviews; Notice of Panel Decision

**AGENCY:** NAFTA Secretariat, United States Section, International Trade Administration, Department of Commerce.

**ACTION:** Notice of panel decision.

**SUMMARY:** On March 5, 2004, the binational panel issued its decision in

the review of the final results of the affirmative antidumping duty re-determination on remand made by the International Trade Administration (ITA) respecting Certain Softwood Lumber Products from Canada (Secretariat File No. USA–CDA–2002–1904–02) affirmed in part and remanded in part the determination of the Department of Commerce. The Department will return the second determination on remand no later than April 21, 2004. A copy of the complete panel decision is available from the NAFTA Secretariat.

**FOR FURTHER INFORMATION CONTACT:** Caratina L. Alston, United States Secretary, NAFTA Secretariat, Suite 2061, 14th and Constitution Avenue, Washington, DC 20230, (202) 482–5438.

**SUPPLEMENTARY INFORMATION:** Chapter 19 of the North American Free-Trade Agreement ("Agreement'') establishes a mechanism to replace domestic judicial review of final determinations in antidumping and countervailing duty cases involving imports from the other country with review by independent binational panels. When a Request for Panel Review is filed, a panel is established to act in place of national courts to review expeditiously the final determination to determine whether it conforms with the antidumping or countervailing duty law of the country that made the determination.

Under Article 1904 of the Agreement, which came into force on January 1, 1994, the Government of the United States, the Government of Canada and the Government of Mexico established *Rules of Procedure for Article 1904 Binational Panel Reviews* ("Rules''). These Rules were published in the **Federal Register** on February 23, 1994 (59 FR 8686).

*Panel Decision:* On March 5, 2004, the Binational Panel affirmed in part and remanded in part the Department of Commerce's final antidumping duty determination on remand. The following issues were remanded to the Department:

1. To recalculate Tembec's General and Administrative expense, using the amounts reflected in the company's books and records as expenses for the Forest Products Group;
2. To calculate the by-product offset to West Fraser's production costs using the company's recorded revenues from chip sales to affiliates in British Columbia during the period of investigation; and
3. To treat Slocan's futures trading profits as an adjustment to that company's indirect selling expenses.

Commerce was directed to issue it's determination on remand within 21 days of the issuance of the panel order dated March 31, 2004, or not later than April 21, 2004.

Dated: April 2, 2004.

**Caratina L. Alston,**

*United States Secretary, NAFTA Secretariat.*

[FR Doc. 04–7933 Filed 4–7–04; 8:45 am]

BILLING CODE 3510–GT–P

## DEPARTMENT OF COMMERCE

### National Institute of Standards and Technology

### Manufacturing Extension Partnership National Advisory Board

**AGENCY:** National Institute of Standards and Technology Department of Commerce.

**ACTION:** Notice of partially closed meeting.

**SUMMARY:** Pursuant to the Federal Advisory Committee Act, 5 U.S.C. app. 2, notice is hereby given that the Manufacturing Extension Partnership National Advisory Board (MEPNAB), National Institute of Standards and Technology (NIST), will meet Thursday, May 6, 2004, from 8 a.m. to 3:30 p.m. The MEPNAB is composed of nine members appointed by the Director of NIST who were selected for their expertise in the area of industrial extension and their work on behalf of smaller manufacturers. The Board was established to fill a need for outside input on MEP. MEP is a unique program consisting of centers in all 50 states and Puerto Rico. The centers have been created by state, federal, and local partnerships. The Board works closely with MEP to provide input and advice on MEP's programs, plans, and policies. The purpose of this meeting is to update the Board on the latest program developments at MEP including a MEP Update, a MEP Metrics Update and Other Agency Collaborations. Discussions scheduled to begin at 1 p.m. and to end at 3:30 p.m. on May 6, 2004, on MEP budget issues will be closed. All visitors to the National Institute of Standards and Technology site will have to pre-register to be admitted. Anyone wishing to attend this meeting must register 48 hours in advance in order to be admitted. Please submit your name, time of arrival, email address and phone number to Carolyn Peters no later than Tuesday, May 4, 2004 and she will provide you with instructions for admittance. Ms. Peter's email address is *carolyn.peters@nist.gov* and her phone number is 301/975–5607.

**DATES:** The meeting will convene May 6, 2004 at 8 a.m. and will adjourn at 3:30 p.m. on May 6, 2004.

**ADDRESSES:** The meeting will be held in the Employees' Lounge, Administration Building, at NIST, Gaithersburg, Maryland 20899. Please note admittance instructions under **SUMMARY** paragraph.

**FOR FURTHER INFORMATION CONTACT:** Carrie Hines, Manufacturing Extension Partnership, National Institute of Standards and Technology, Gaithersburg, Maryland 20899–4800, telephone number (301) 975–3360.

**SUPPLEMENTARY INFORMATION:** The Assistant Secretary for Administration, with the concurrence of the General Counsel, formally determined on December 18, 2003, that portions of the meeting which involve discussion of proposed funding of the MEP may be closed in accordance with 5 U.S.C. 552b(c)(9)(B), because that portion will divulge matters the premature disclosure of which would be likely to significantly frustrate implementation of proposed agency actions; and that portions of the meeting which involve discussion of the staffing of positions in MEP may be closed in accordance with 5 U.S.C. 552b(c)(6), because divulging information discussed in that portion of the meeting is likely to reveal information of a personal nature, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Dated: April 1, 2004.

**Hratch G. Semerjian,**

*Acting Director.*

[FR Doc. 04–7944 Filed 4–7–04; 8:45 am]

BILLING CODE 3510–33–P

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**[I.D. 040204C]**

### Endangered Species; File No. 1227

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Receipt of application for modification

**SUMMARY:** Notice is hereby given that the NMFS Southwest Fisheries Science Center, 8604 La Jolla Shores Drive, La Jolla, CA 92037, has requested a modification to scientific research Permit No. 1227.

**DATES:** Written, telefaxed, or e-mail comments must be received on or before May 10, 2004.

**ADDRESSES:** The modification request and related documents are available for review upon written request or by appointment in the following offices:

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301)713–2289; fax (301)713–0376; and

Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213; phone (562)980–4001; fax (562)980–4018.

Written comments or requests for a public hearing on this request should be submitted to the Chief, Permits, Conservation and Education Division, F/PR1, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular modification request would be appropriate.

Comments may also be submitted by facsimile at (301)713–0376, provided the facsimile is confirmed by hard copy submitted by mail and postmarked no later than the closing date of the comment period.

Comments may also be submitted by e-mail. The mailbox address for providing email comments is *NMFS.Pr1Comments@noaa.gov*. Include in the subject line of the e-mail comment the following document identifier: File No. 1227.

**FOR FURTHER INFORMATION CONTACT:** Patrick Opay, (301)713–1410 or Patricia Lawson, (301)713–2289.

**SUPPLEMENTARY INFORMATION:** The subject modification to Permit No. 1227, issued on May 1, 2000 (65 FR 25312) is requested under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*) and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR 222–226).

Permit No. 1227 authorizes the permit holder to capture leatherbacks (*Dermochelys coriacea*) from the wild or rescue them from ghost fishing gear. It authorizes the researchers to tissue sample, fat sample, flipper and PIT (passive integrated transponder) tag up to 100 of this species over the life of the 5 year permit. Twenty of these 100 may also be satellite tagged. The permit holder requests authorization to attach satellite transmitters using the harness backpack method allowed in the current permit on up to an additional 40 of the remaining leatherbacks that they are already permitted to take in the eastern Pacific Ocean nearshore to California and Oregon through December of 2005. The information from this research is part of studies on the migration and habitat use of these species in the Pacific Ocean. The permit holder also requests authorization to conduct short-term tracking of 20 additional leatherbacks in the Monterey Bay area without having to capture them, using VHF/TDR (time depth recorder)/sonic tag units attached with suction cups. The VHF/TDR/sonic tag units will be used to study the short-term movements, dive behavior and foraging ecology of this species. They will provide fine-scale movements and diving behavior of leatherbacks in the vicinity of Monterey Bay and give important information regarding the foraging ecology of this species off the coast of California.

Dated: April 2, 2004.

**Patrick Opay,**

*Acting Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 04–7983 Filed 4–7–04; 8:45 am]

**BILLING CODE 3510–22–S**

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**[I.D. 040204B]**

### Magnuson-Stevens Act Provisions; General Provisions for Domestic Fisheries; Applications for Exempted Fishing Permits (EFPs)

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

**ACTION:** Notification of a proposal for EFPs to conduct experimental fishing; request for comments.

**SUMMARY:** The Assistant Regional Administrator for Sustainable Fisheries, Northeast Region, NMFS (Assistant Regional Administrator) has made a preliminary determination that an EFP application submitted by the Mount Desert Oceanarium (MDO), Southwest Harbor, ME, contains all of the required information and warrants further consideration. The EFP would allow one fishing vessel to fish for, retain, and land small numbers of regulated fish species and several unmanaged fish and invertebrate species for the purpose of public display. The Assistant Regional Administrator has made a preliminary determination that the activities authorized under these EFPs would be consistent with the goals and objectives of the Fishery Management Plans (FMPs) for these species. However, further review and consultation may be necessary before a final determination is made to issue EFPs.

Regulations under the Magnuson-Stevens Act require publication of this notification to provide interested parties the opportunity to comment on applications for proposed EFPs.

**DATES:** Comments must be received on or before April 23, 2004.

**ADDRESSES:** Written comments should be sent to Patricia A. Kurkul, Regional Administrator, NMFS, NE Regional Office, 1 Blackburn Drive, Gloucester, MA 01930. Mark the outside of the envelope "Comments on MDO Specimen Collection.'' Comments may also be sent via fax to (978) 281–9135. Comments may also be submitted via e-mail to the following address: *da441@noaa.gov*. Include in the subject line of the e-mail "Comments on MDO Specimen Collection.''

**FOR FURTHER INFORMATION CONTACT:** Catherine Tadema-Wielandt, Fishery Management Specialist, 978–281–9244.

**SUPPLEMENTARY INFORMATION:** The Mount Desert Oceanarium of Southwest Harbor, ME, submitted an application for three EFPs on March 10, 2004, to collect several species of fish and invertebrates for public display. The target species would include American plaice (dab), winter flounder (blackback), yellowtail flounder, witch flounder (grey sole), Atlantic halibut, monkfish, eel pouts, sculpins, sea raven, Atlantic cod, lumpfish, Atlantic wolffish, spiny dogfish, little skate, barndoor skate, and various species of the Phyla Arthropoda (excluding lobsters) and Echinodermata.

One chartered fishing vessel would use a shrimp otter trawl with 2–inch (5.08 cm) mesh to collect marine fish and invertebrates for a maximum of 4 days: 2 days during the period May 10, 2004, through May 19, 2004, and 2 days during the period June 23, 2004, through June 30, 2004. The specimens would be cared for in chilled and aerated seawater while on board the fishing vessel and would be transferred live to tanks the day they are caught. The fish would be brought to shore, maintained in tanks for public display for a period of time not to exceed 5 months, and would be returned to the sea in October 2004.

Collection would be made within the Small Mesh Northern Shrimp Fishery Exemption Area (Area) off Maine. Since the shrimp fishery will be closed at the time of the proposed collection, and this area lies within the Gulf of Maine Regulated Mesh Area, an exemption from the Northeast (NE) multispecies minimum mesh requirements of 6–inch

(15.24 cm) diamond/6.5–inch (16.51 cm) square mesh at 50 CFR 648.80(a)(3) would be required.

The applicant would retain a maximum of six individuals per species, juveniles and adults combined, with the exception of Atlantic halibut. The applicant would only be permitted to retain a total of one Atlantic halibut with a minimum length of 36 inches (91.44 cm). The applicant has requested the following exemptions from the NE Multispecies and Monkfish Fishery Management Plans: effort control program requirements at 50 CFR 648.82(a) and 648.92(a); minimum fish sizes at §§ 648.83(a)(1) and 648.93(a)(1), and monkfish possession restrictions at § 648.94(b)(6). The EFP would also exempt the vessels from the possession and landing restrictions for the NE skate complex fishery at § 648.322(c).

Any fishing activity conducted outside the scope of the exempted fishing activity would be prohibited.

**Authority:** 16 U.S.C. 1801 *et seq.*

Dated: April 2, 2004.

**Bruce C. Morehead,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 04–7982 Filed 4–7–04; 8:45 am]

**BILLING CODE 3510–22–S**

## DEPARTMENT OF DEFENSE

### Department of the Army; Corps of Engineers

### Availability of the Final Environmental Impact Statement (FEIS) for the Relocation of Bogue Inlet Channel Between Emerald Isle and Hammocks Beach State Park, and the Placement of the Dredged Material Onto Emerald Isle Beach, in Carteret County, NC

**AGENCY:** Department of the Army, U.S. Army Corps of Engineers, DoD.

**ACTION:** Notice of availability.

**SUMMARY:** In accordance with the requirements of the National Environmental Policy Act (NEPA), the U.S. Army Corps of Engineers (COE) Wilmington District, Wilmington Regulatory Field Office announces the availability of a Regulatory Program Final EIS for the Bogue Inlet Channel Erosion Response Project. The applicant, The Town of Emerald Isle, is requesting Department of the Army authorization, pursuant to section 404 of the Clean Water Act and section 10 of the Rivers and Harbor Act, for the relocation of Bogue Inlet Channel to protect residential homes and town infrastructures, and to place the dredged material on approximately 5.0 miles of beach for nourishment. As required by NEPA, the Final EIS describes the Applicant's preferred alternative and other alternatives, which were evaluated during the scoping process, to provide shoreline protection to residents along the inlet. The preferred alternative proposes to move the main ebb channel in Bogue Inlet to a more central location between the west end of Bogue Banks and the east end of Bear Island (Hammocks Beach State Park). The main ebb channel through Bogue Inlet presently occupies a position juxtaposed to the west end of the town of Emerald Isle and is causing severe erosion that threatens development in the subdivision known as The Pointe. The relocation of the main ebb channel to a central location would restore the channel to a position it occupied in the late 1970's and eliminate the erosive impact of tidal currents on the east shoulder of the inlet. A portion of the material removed to relocate the main ebb channel would be used to close the existing channel with the balance of the material used to nourish the shoreline on the west end of the Town of Emerald Isle.

**DATES:** The Public commenting period on the FEIS will end on May 4, 2004. Written comments must be received at the address listed below no later than 5 p.m.

**ADDRESSES:** Copies of comments and questions regarding the FEIS may be addressed to: U.S. Army Corps of Engineers, Wilmington District, Regulatory Division, Attn: File Number 2001–00632, Post Office Box 1890, Wilmington, NC 28402–1890.

**FOR FURTHER INFORMATION CONTACT:** Questions about the proposed action and the FEIS can be directed to Mr. Mickey Sugg, Wilmington Regulatory Field Office, telephone: (910) 251–4811, facsimile (910) 251–4025, or e-mail at *mickey.t.sugg@usace.army.mil.*

**SUPPLEMENTARY INFORMATION:** The FEIS examines potential impacts to Essential Fish Habitat (EFH), Threatened and Endangered Species (specifically the Piping Plover and Piping Plover Critical Habitat), and includes a comprehensive mitigation and monitoring plan to minimize these potential impacts and to evaluate unforeseen effects of the projects. Such mitigation includes the securing of newly formed lands or spits and prohibiting development on these properties and the implementation of a comprehensive bird management plan that is expected to reduce the potential impacts to newly formed bird forage, resting, feeding, and nesting areas. In addition, aerial photography will be taken for three years after completion of the project in order to assess any project effects and to evaluate unknown risk of shoreline erosion to the oceanfront of Emerald Isle and the inlet shoreline of Bear Island.

The primary purpose of the channel relocation project is to create a stable channel that will divert tidal flow away from the Pointe area of Emerald Isle. Therefore, the design focus is on developing channel dimensions that will capture the majority of the ebb tidal flow through the inlet. An added feature of the overall design would be the closure of the existing channel by constructing a sand dike across the existing channel in the vicinity of the Pointe. The dimensions of the relocated channel will be based on characteristics of the existing ebb tide channel, numerical model studies of tides and currents in the inlet, and channel stability criteria. The numerical model will also be used to evaluate the need for and impacts of closing the existing channel as well as assess the impacts of the repositioned channel on salinity intrusion and flow patterns throughout the entire inlet/estuary complex.

Apart from the channel dimensions, the new channel must be positioned so that it does not cause adverse impacts on the adjacent shorelines or result in unacceptable loss of estuarine habitat. The selection of a channel location is being based on detailed geomorphic analysis of the inlet and adjacent shorelines, conducted by Dr. William J. Cleary, University of North Carolina at Wilmington. The geomorphic analysis will utilize an assortment of aerial photographs of the inlet covering the period from 1938 to 2001. However the primary emphasis will be on changes in the inlet and the adjacent shorelines between 1973 and 2001. The geomorphic analysis consists of an evaluation of the following: (a) Location of the channel midpoint relative to the Pointe, (b) the orientation of the inlet's ebb tide delta channel, (c) the configuration of the ebb tide delta, *i.e.,* the percent of the ebb tide delta east and west of the main ebb channel, (d) inlet shoulder changes (the Pointe shoreline and the west tip of Bear Island), (e) changes in the ocean shoreline on the west end of Bogue Banks and the east end of Bear Island (Hammocks Beach State Park), and (f) changes in the interior marsh islands (primarily Dudley Island and Island 2). The measured changes the adjacent shorelines, inlet shoulders, and the interior marshes will be related to changes in the physical make up of the inlet including the position and orientation of the ebb tide

delta channel and the configuration of the ebb tide delta.

Geomorphic analysis indicates that the cumulative shoreline changes on each island were averaged over 3,500 feet of shoreline immediately adjacent to the inlet. When the percent of the ebb tide delta on the Bogue Banks side is small, as it was between 1984 and 2001, the bar channel was located close to Bogue Banks and the portion of the delta on the Bogue Banks side was providing some degree of wave sheltering for the west end of the island. The particular ebb tide delta configuration resulted in a considerable amount of accretion along the 3,500-foot shoreline immediately east of the inlet while Bear Island experienced an almost mirror image response on its ocean shoreline, *i.e.,* erosion. Even though the present ebb tide delta configuration is favorable for the extreme west end of Emerald Isle, the eastward migration of the inlet channel that led to the existing inlet configuration also caused the inlet shoreline of Bogue Banks (the Pointe shoreline) to erode. Not only has the Bogue Banks inlet shoreline eroded in response to the eastward movement of the channel, so has the Bear Island ocean and inlet shorelines. Based on these and numerous other comparisons, the preliminary results of the geomorphic analysis indicates that a centrally located channel, approximating the position and orientation of the channel in 1978, may be beneficial to the inlet shoreline on Bogue Banks (the Pointe shoreline) and the east end of Bear Island.

Copies of the Final EIS will also be available on our regulatory home page at *http://www.saw.usace.army.mil/WETLANDS/*, and click on Emerald Isle Bogue Inlet Channel Relocation Project heading at the top right corner under Fast Track.

Dated: April 1, 2004.

**Charles R. Alexander, Jr.,**

*Colonel, U.S. Army, District Engineer.*

[FR Doc. 04–7968 Filed 4–7–04; 8:45 am]

**BILLING CODE 3710–GN–M**

## DEPARTMENT OF DEFENSE

### Department of the Army; Corps of Engineers

### Availability for the Draft Feasibility Report and Environmental Impact Statement/Environmental Impact Report for the Hamilton City Flood Damage Reduction and Ecosystem Restoration, Glenn County, CA

**AGENCY:** Department of the Army, U.S. Army Corps of Engineers, DoD.

**ACTION:** Notice; extension of comment period.

**SUMMARY:** The comment period for the Draft Feasibility Report and Environmental Impact Statement/Environment Impact Report (DFR/DEIS–EIR) published in the **Federal Register** on Wednesday, March 31, 2004 (69 FR 16902), required comments be submitted on or before May 17, 2004. The comment period has been extended to May 24, 2004.

**FOR FURTHER INFORMATION CONTACT:** Ms. Erin Taylor, Environmental Manager, U.S. Army Corps of Engineers, 1325 J Street, Sacramento, CA 95814–2922, (916) 557–5140 or fax (916) 557–7202.

**Brenda S. Bowen,**

*Alternate Army Federal Register Liaison Officer.*

[FR Doc. 04–7965 Filed 4–7–04; 8:45 am]

**BILLING CODE 3710–EZ–M**

## DEPARTMENT OF DEFENSE

### Department of the Army; Corps of Engineers

### Intent To Prepare a Draft Programmatic Environmental Impact Statement for the Near-Term Ecosystem Restoration Plan for the Louisiana Coastal Area

**AGENCY:** Department of the Army, U.S. Army Corps of Engineers, DoD.

**ACTION:** Notice of intent.

**SUMMARY:** The U.S. Army Corps of Engineers, New Orleans District (Corps) intends to refocus and modify the Draft Programmatic Supplemental Environmental Impact Statement (Draft PSEIS) for the Louisiana Coastal Area—Louisiana Comprehensive Coastwide Ecosystem Restoration Feasibility Study (LCA Comprehensive Study) and prepare a Draft Programmatic Environmental Impact Statement (Draft PEIS) for a Near-Term Ecosystem Restoration Plan for the Louisiana Coastal Area. This is a modification of the notice of intent published in the **Federal Register** (67 FR 169093). The intent of this notice is to describe the rationale for revising the purpose and need for action, the scope of the analysis, and intent to prepare a Draft PEIS for the Near-Term Ecosystem Restoration Plan for the Louisiana Coastal Area.

On April 4, 2002, the Corps announced in the **Federal Register** (67 FR 169093) its intention to prepare a Draft PSEIS for the LCA Comprehensive Study. The original proposed scope of the Draft PSEIS analysis was threefold: (1) Supplement previous Louisiana coastal restoration NEPA-compliance studies; (2) utilize the "lessons learned'' from previous Louisiana coastal wetlands restoration efforts; and (3) determine the feasibility of developing the existing Coast 2050 restoration strategies into projects for the creation of a comprehensive coastwide ecosystem restoration plan. Six public scoping meetings regarding preparation of the Draft PSEIS and the feasibility of comprehensive coastwide ecosystem restoration of coastal Louisiana were held at various locations throughout Louisiana in late April 2002. The scoping report was provided to scoping participants and published on the Coast 2050 Web site (*Coast2050.gov*) in August 2002.

The President's FY05 Budget, released on February 2, 2004 (*http:www.whithouse.gov/omb/budget/fyw005/corps.html*), contained specific language that refocuses and advances planning, scientific, and restoration efforts that are already underway:

> In 2004, the Corps will work to issue a draft report that identifies the most critical ecological needs and proposes a near-term program of highly cost-effective projects to address them. The report will also highlight the key long-term scientific uncertainties and engineering challenges facing the effort to protect and restore the ecosystem, and propose demonstration projects and studies to help answer these questions. The report will focus on the specific coastal areas that require the most immediate attention and on the best way to sequence the proposed work over the next 10 or so years, as we learn what works best. In 2004, the Corps will begin developing studies of potentially promising, long-term ecosystem restoration concepts, with the objective of determining whether they would provide a cost-effective way to create coastal wetlands. An existing Federal-State Task Force established under 1990 legislation will increase its efforts to build and evaluate highly cost-effective fresh-water and sediment diversion projects. This coordinated approach to restoration combines a commitment to address the highest priority needs with a search for innovative solutions. It also ensures that the coastal Louisiana restoration effort will, in the long-term, be able to adapt and evolve as needed, based on the best available science.

The Corps believes these events and activities have influenced the purpose and need for action and the scope of the analysis of the LCA Comprehensive Study. Hence, the Corps proposes to prepare a Draft PEIS for the Near-Term Ecosystem Restoration Plan for the Louisiana Coastal Area.

**DATES:** Scoping meetings will be held in May 2004. Written scoping comments will be accepted from the date of this notice until May 20, 2004.

**ADDRESSES:** Scoping comments regarding the Draft PEIS for the LCA Near-Term Plan may be sent to Dr. William P. Klein, Jr., CEMVN–PM–RS, P.O. Box 60267, New Orleans, LA 70160–0267. Comments may also be made via facsimile (fax) at 504–862–1892. Comments will not be accepted if submitted by e-mail or Internet.

**FOR FURTHER INFORMATION CONTACT:** Major Jason A. Kirk, Senior Project Manager, CEMVN–PM–Coastal Restoration, P.O. Box 60267, New Orleans, LA 70160–0267, telephone: 504–862–1222; fax: 504–862–1892; and e-mail: *Jason.A.Kirk.MAJ@mvn02.usace.army.mil,* or Mr. Howard H. Gonzales, Project Manager, CEMVN–PM–Coastal Restoration, P.O. Box 60267, New Orleans, LA 70160–0267, telephone: 504–862–1672; fax 504–862–1892; and e-mail: *Howard.H.Gonzales@mvn02.usace.army.mil.*

**SUPPLEMENTARY INFORMATION:**

1. *Scoping Process.* The Council on Environmental Quality (CEQ) regulations implementing the NEPA process directs federal agencies that have made a decision to prepare an environmental impact statement to engage in a public scoping process. The scoping process is designed to provide an early and open means of determining the scope of issues (problems, needs, and opportunities) to be identified and addressed in the draft environmental impact assessment, which in this case is a Draft PEIS. Scoping is the process used to: (a) Identify the affected public and agency concerns; (b) facilitate an efficient PEIS preparation process; (c) define the issues and alternatives that will be examined in detail in the PEIS; and (d) save time in the overall process by helping to ensure that the draft statements adequately address relevant issues. Scoping is a process, not an event or a meeting. It continues throughout the planning for a PEIS and may involve meetings, telephone conversations, and/or written comments. (Council on Environmental Quality, Memorandum for General Counsel, April 30, 1981).

2. *Request for Scoping Comments.* In May 2004, the Corps will conduct scoping meetings. Notices will be mailed to the affected and interested public once the dates and locations of the scoping meetings have been established. The Corps invites scoping input in writing, or in person, concerning the following scoping questions: Question #1: What are the critical natural and human ecological needs that should be addressed in the PEIS? For example, critical natural and human ecological needs may include: deltaic processes, sustainability, hurricane and flood protection, protection of human infrastructure, and others. Question #2: What are the significant resources that should be considered in the PEIS for the LCA Near-Term Ecosystem Restoration Plan? For example, significant resources may include: gulf hypoxia, barrier islands, offshore sand resources, water quality, and others.

The Corps also requests comments regarding the following nine LCA Near-Term Plan Identification Criteria. (1) Prevents future land loss where predicted to occur: one of the most fundamental measures of ecosystem degradation in coastal Louisiana has been the conversion of land (mostly emergent vegetated habitat) to open water. Thus, the projection of the future condition of the ecosystem must be based upon the determination of future patterns of land and water. Based on the U.S. Geological Survey open file report 03–334 "Historical and Predicted Coastal Louisiana Land Changes: 1978–2050'', do proposed projects prevent or reduce future land loss or restore areas of past loss where scientists have documented these losses to occur. (2) Sustainability—restores or mimics fundamentally impaired deltaic process: this criterion refers primarily to projects or opportunities to restore or mimic natural connections between the river and the basins (or estuaries) and includes distributary flows, crevasses, and over-bank flow. Activities that mechanically move sediment from river to basins are also viewed as mimicking deltaic processes, especially if nourished by a small diversion. (3) Sustainability—restores endangered or critical ecological structure: this criterion refers to projects or opportunities to restore or maintain geomorphic features that are essential to maintaining the integrity of coastal ecosystems; includes natural features such as barrier islands, distributary ridges, cheniers, and beach and lake rims. (4) Engineering and design complete and construction started within 10 years. (5) Protects vital local, regional, and national community and socioeconomic resources: this criterion would identify the local, regional, and national social, economic, and cultural resources that are affected by the proposed opportunities and/or projects. These existing resources include, but are not limited to, noise, population, esthetics, housing, cultural, leisure opportunities, community cohesion and growth, public facilities and services, employment, business and industry, agriculture, and flood protection. Effects include both beneficial and detrimental impacts to human culture and their economic activities. (6) Public acceptability based on scoping and public meeting comments. (7) Based upon sufficient scientific and engineering understanding of processes. (8) Capitalizes on existing structure, resources, etc.: this criterion would identify the proposed project elements (*i.e.* freshwater diversions, sediment delivery via pipeline, march creation, etc.) that capitalize on existing infrastructure and resources to achieve the objective of the element. Existing infrastructure may include, but is not limited to, diversion structures that are in place but require modification and/or improvements; diversion structures that are in place and operating but potentially not at full capacity (*e.g.* Davis Pond Freshwater Diversion Structure). Existing resources may include, but are not limited to, sediment deposition areas that are adjacent to or near proposed march creation elements or shoreline restoration elements; sediment-rich waterways that may be tapped for influence in disconnected and degraded coastal regions. (9) Construction does not preclude other options and/or projects.

Scoping comments will be compiled, analyzed, and utilized in the plan formulation process. A Scoping Report, summarizing the comments, will be made available to all scoping participants and published on the Louisiana Coastal Area Web site (*LCA.gov*). Scoping comments will be accepted throughout the scoping comment period (see **DATES**).

3. *Public Involvement.* Scoping is a critical component of the overall public involvement program. An intensive public involvement program will continue throughout the study to solicit input from affected Federal, State, and local agencies, Indian tribes, and other interested parties.

4. *Interagency Coordination.* The Department of Interior, U.S. Fish and Wildlife Service (USFWS), will provide a Fish and Wildlife Coordination Act Report. Coordination will be maintained with the USFWS and the NOAA Fisheries regarding threatened and

endangered species under their respective jurisdictional responsibilities. Coordination will be maintained with the Natural Resources Conservation Service regarding prime and unique farmlands. The U.S. Department of Agriculture will be consulted regarding the "Swampbuster'' provisions of the Food Security Act. Coordination will be maintained with the Advisory Counsel on Historic Preservation and the State Historic Preservation Officer. The Louisiana Department of Natural Resources will be consulted regarding consistency with the Coastal Zone Management Act. The Louisiana Department of Wildlife and Fisheries will be contacted concerning potential impacts to Natural and Scenic Streams.

5. *Availability of Draft PEIS.* It is anticipated that the Draft PEIS will be available for public review during the summer of 2004. A 45-day review period will be provided so that all interested agencies, groups and individuals will have an opportunity to comment on the Draft PEIS. In addition, public meetings will be held during the review period to receive comments and address questions concerning the Draft PEIS.

**Brenda S. Bowen,**

*Alternate Army Federal Register Liaison Officer.*

[FR Doc. 04–7967 Filed 4–7–04; 8:45 am]

**BILLING CODE 3710–84–M**

## DEPARTMENT OF DEFENSE

### Department of the Army; Corps of Engineers

### Grant of Partially Exclusive Licenses

**AGENCY:** Department of the Army, U.S. Corps of Engineers, DoD.

**ACTION:** Notice.

**SUMMARY:** In accordance with 37 CFR 404.7(a)(1)(i), announcement is made of a prospective partially exclusive license for the manufacture, use, and sale of building elements or blocks based on U.S. Patent Number 6,264,735 entitled "Low-Lead Leaching Foamed Concrete Bullet Barrier'' and U.S. Patent Number 6,620,236 entitled "Material, and Method of Producing it, for Immobilizing Heavy Metals Later Entrained Therein'' having a unit weight of 100 pounds or less.

**ADDRESSES:** United States Army Engineer Research and Development Center, Waterways Experiment Station, ATTN: CEERD–OP–MS (Mr. Phillip Stewart), 3909 Halls Ferry Road, Vicksburg, MS 39180–6199.

**DATES:** Written objections must be filed not later than 30 days after publication of this notice.

**FOR FURTHER INFORMATION CONTACT:** Mr. Phillip Stewart, ATTN: CEERD–OP–MS; (601) 634–4113, FAX (601) 634–4110; e-mail: *phillip.stewart@erdc.usace.army.mil*; U.S. Army Engineer Research and Development Center, Waterways Experiment Station, 3909 Halls Ferry Road, Vicksburg, MS 39180–6199.

**SUPPLEMENTARY INFORMATION:** These patents relate to a low-lead leaching foamed concrete having properties that make it a highly desirable material for use as a bullet barrier. Bullets will not ricochet upon impact, but remain embedded in the concrete. The material is non-flammable, and the calcium phosphate and aluminum hydroxide in the admixture react with the lead fragments from the bullets to produce an insoluble lead aluminum phosphate coating that keeps lead out of the environment, eliminating the high disposal costs associated with what would otherwise be a hazardous material. This concrete material is being made and sold under the trademark name of SACON® shock absorbing concrete. Patent number 6,264,735 claims the addition of phosphate to a foamed cement-based mortar and patent number 6,620,236 claims the addition of phosphate and aluminum compounds to a foamed Portland cement-based mortar. The United States of America, as represented by the Secretary of the Army, intends to grant an exclusive license for the manufacture, use, and sale of building elements or blocks having a unit weight of less than 100 pounds or less that are based on the subject patents to Mississippi Prison Industries Corporation, a non-profit corporation created in 1990 by the state of Mississippi with principal offices located in Jackson, Mississippi. Pursuant to 37 CFR 404.7(b)(1)(i), any interested party may file a written objection to this prospective exclusive license agreement.

**Richard L. Frenette,**

*Counsel.*

[FR Doc. 04–7966 Filed 4–7–04; 8:45 am]

**BILLING CODE 3710–92–P**

## DEPARTMENT OF EDUCATION

### Office of Postsecondary Education

### Overview Information; Training Program for Federal TRIO Programs (Training Program); Notice Inviting Applications for New Awards for Fiscal Year (FY) 2004

*Catalog of Federal Domestic Assistance (CFDA) Number:* 84.103A.

*Dates:*

Applications Available: May 6, 2004.

Deadline for Transmittal of Applications: June 28, 2004.

Deadline for Intergovernmental Review: August 27, 2004.

*Eligible Applicants:* Institutions of higher education and other public and private nonprofit institutions and organizations.

*Estimated Available Funds:* $6,000,000.

*Estimated Range of Awards:* $300,000–$500,000.

*Estimated Average Size of Awards:* $400,000.

*Maximum Award:* We will reject any application that proposes a budget exceeding the maximum amount listed for each of the five absolute priorities, listed below, for a single budget period of 12 months:

Priority 1: $500,000;
Priority 2: $500,000;
Priority 3: $300,000;
Priority 4: $400,000; and
Priority 5: $300,000.

The Assistant Secretary for Postsecondary Education may change the maximum amount through a notice published in the **Federal Register**.

In addition, successful applicants must provide training to at least one trainee for each $1,500 awarded, unless we specifically approve another amount.

*Estimated Number of Awards:* 10–15.

**Note:** The Department is not bound by any estimates in this notice.

*Project Period:* Up to 24 months.

### Full Text of Announcement

### I. Funding Opportunity Description

*Purpose of Program:* To improve the operation of projects funded under the Federal TRIO Programs, the Training Program provides grants to train staff and leadership personnel employed in, participating in, or preparing for employment in projects funded under the TRIO Programs.

*Priorities:* In accordance with 34 CFR 75.105(b)(2)(iv) and 34 CFR 75.105(b)(2)(ii), these priorities are from section 402G(b) of the Higher Education Act of 1965, as amended (HEA); and the

regulations for this program (34 CFR 642.34). Each successful applicant must provide at least one training session on each requisite topic listed within a specific priority that is tailored to the needs of TRIO staff with less than two years of TRIO project experience.

Each application must clearly identify the specific priority number for which a grant is requested, and must address each of the topics listed under that specific priority. An application for a grant under a specific priority must not include information concerning any other priority. For example, an application for a grant under Priority 1 must address only training to improve budget management, recordkeeping and reporting student and project performance, and evaluation of project performance. The application should not include information concerning any other topic or priority.

*Absolute Priorities:* For FY 2004, these priorities are absolute priorities. Under 34 CFR 75.105(c)(3), we consider only applications that meet these priorities. These priorities are:

*Priority 1.* Training to improve: budget management; recordkeeping and reporting student and project performance; and evaluation of project performance.

Number of expected awards: 1–3.

Maximum award amount: $500,000.

*Priority 2.* Training on: the legislative and regulatory requirements for operation of the Federal TRIO Programs; personnel management; and student financial aid.

Number of expected awards: 1–3.

Maximum award amount: $500,000.

*Priority 3.* Training on: counseling; and retention and graduation strategies.

Number of expected awards: 1–3.

Maximum award amount: $300,000.

*Priority 4.* Training to coordinate project activities with other available resources and activities and training to design and operate a model TRIO project.

Number of expected awards: 1–3.

Maximum award amount: $400,000.

*Priority 5.* Training in the use of educational technology.

*Number of expected awards:* 1–3.

*Maximum award amount:* $300,000.

*Maximum number of applications for a priority:* An applicant may submit only one application for a grant under each priority. If an applicant submits more than one application under a specific priority, we will accept only the first application submitted and we will reject all other applications. Each application must clearly identify the specific priority number for which a grant is requested, and must address each of the topics listed under the specific priority. An application for a grant under a specific priority must not include information concerning any other priority. For example, an application for a grant under Priority 1 must address only training to improve budget management; record keeping and reporting student and project performance; and evaluation of project performance.

*Program Authority:* 20 U.S.C. 1070a–11 and 20 U.S.C. 1070a–17.

*Applicable Regulations:* (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 84, 85, 86, 97, 98, and 99. (b) The regulations for this program in 34 CFR part 642.

**Note:** The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian Tribes.

**Note:** The regulations in 34 CFR part 86 apply to institutions of higher education only.

## II. Award Information

*Type of Award:* Discretionary grants.

*Estimated Available Funds:* $6,000,000.

*Estimated Range of Awards:* $300,000–$500,000.

*Estimated Average Size of Awards:* $400,000.

*Maximum Award:* We will reject any application that proposes a budget exceeding the maximum amount listed for each of the five absolute priorities, listed below, for a single budget period of 12 months:

Priority 1: $500,000;
Priority 2: $500,000;
Priority 3: $300,000;
Priority 4: $400,000; and
Priority 5: $300,000.

The Assistant Secretary for Postsecondary Education may change the maximum amount through a notice published in the **Federal Register**.

In addition, successful applicants must provide training to at least one trainee for each $1,500 awarded, unless we specifically approve another amount.

*Estimated Number of Awards:* 10–15.

**Note:** The Department is not bound by any estimates in this notice.

*Project Period:* Up to 24 months.

## III. Eligibility Information

1. *Eligible Applicants:* Institutions of higher education and other public and private nonprofit institutions and organizations.

2. *Cost Sharing or Matching:* This competition does not involve cost sharing or matching.

3. *Other:* An applicant may submit only one application for a grant under each priority. Each application must clearly identify the specific priority number for which a grant is requested, and must address each of the topics listed under that specific priority. An application for a grant under a specific priority must not include information concerning any other priority.

Successful applicants will be expected to provide training to at least one trainee for each $1,500 awarded, unless we specifically approve another amount.

Each successful applicant also must provide at least one training session on each listed topic in a specific priority that is tailored to the needs of new project directors and TRIO staff with less than two years of TRIO project experience.

## IV. Application and Submission Information

1. *Address to Request Application Package:* Patricia S. Lucas or Virginia A. Mason, U.S. Department of Education, 1990 K Street, NW., suite 7000, Washington, DC 20006–8510. Telephone: (202) 502–7600 or by e-mail: *TRIO@ed.gov.*

If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) 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 one of the program contact persons listed in this section.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this competition. Page Limit: You must limit the entire application (cover to cover, including all required forms, assurances and certifications) to no more than 50 pages using the following standards:

- A "page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application in the application narrative, including titles, headings, footnotes, quotations, references, and captions. However, you may single space all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).

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:* May 6, 2004.

*Deadline for Transmittal of Applications:* June 28, 2004.

The dates and times for the transmittal of applications by mail or by hand (including a courier service or commercial carrier) are in the application package for this competition. The application package also specifies the hours of operation of the e-Application Web site.

We do not consider an application that does not comply with the deadline requirements.

*Deadline for Intergovernmental Review:* August 27, 2004.

4. *Intergovernmental Review:* This competition 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 competition.

5. *Funding Restrictions:* We specify unallowable costs in 34 CFR 642.41. We reference additional regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Other Submission Requirements:* Instructions and requirements for the transmittal of applications by mail or by hand (including a courier service or commercial carrier) are in the application package for this competition. Application Procedures: The Government Paperwork Elimination Act (GPEA) of 1998, (Pub. L. 105–277) and the Federal Financial Assistance Management Improvement Act of 1999, (Pub. L. 106–107) encourage us to undertake initiatives to improve our grant processes. Enhancing the ability of individuals and entities to conduct business with us electronically is a major part of our response to these Acts. Therefore, we are taking steps to adopt the Internet as our chief means of conducting transactions in order to improve services to our customers and to simplify and expedite our business processes.

Some of the procedures in these instructions for transmitting applications differ from those in the Education Department General Administrative Regulations (EDGAR) (34 CFR 75.102). Under the Administrative Procedure Act (5 U.S.C. 553), the Department generally offers interested parties the opportunity to comment on proposed regulations. However, these amendments make procedural changes only and do not establish new substantive policy. Therefore, under 5 U.S.C. 553(b)(A), the Secretary has determined that proposed rulemaking is not required.

We are requiring that applications for grants under the Training Program—CFDA Number 84.103A—be submitted electronically using the Electronic Grant Application System (e-Application) available through the Department's e-GRANTS system. The e-GRANTS system is accessible through its portal page at: *http://e-grants.ed.gov.*

If you are unable to submit an application through the e-GRANTS system, you may submit a written request for a waiver of the electronic submission requirement. In your request, you should explain the reason or reasons that prevent you from using the Internet to submit your application. Address your request to: Linda Byrd-Johnson, Ph.D., U.S. Department of Education, 1990 K Street, NW., room 7085, Washington, DC 20006–8510. Please submit your request no later than two weeks before the application deadline date.

If, within two weeks of the application deadline date, you are unable to submit an application electronically, you must submit a paper application by the application deadline date in accordance with the transmittal instructions in the application package. The paper application must include a written request for a waiver documenting the reasons that prevented you from using the Internet to submit your application.

*Pilot Project for Electronic Submission of Applications*

We are continuing to expand our pilot project for electronic submission of applications to include additional formula grant programs and additional discretionary grant competitions. The Training Program—CFDA 84.103A is one of the programs included in the pilot project. If you are an applicant under the Training Program—CFDA 84.103A you must submit your application to us in electronic format or receive a waiver.

The pilot project involves the use of e-Application. If you use e-Application, you will be entering data online while completing your application. You may not e-mail an electronic copy of a grant application to us. The data you enter online will be saved into a database. We shall continue to evaluate the success of e-Application and solicit suggestions for its improvement.

If you participate in e-Application, please note the following:

• When you enter the e-Application system, you will find information about its hours of operations. We strongly recommend that you do not wait until the application deadline date to initiate an e-Application package.

• You will not receive additional point value because you submit a grant application in electronic format, nor will we penalize you if you submit an application in paper format.

• You must submit all documents electronically, including the Application for Federal Education Assistance and Supplement to Application for Federal Education Assistance (ED 424), Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.

• Your e-Application must comply with any page limit requirements described in this notice.

• After you electronically submit your application, you will receive an automatic acknowledgement, which will include a PR/Award number (an identifying number unique to your application).

• Within three working days after submitting your electronic application, fax a signed copy of the Application for Federal Education Assistance (ED 424) to the Application Control Center after following these steps:

1. Print ED 424 from e-Application.

2. The applicant's Authorizing Representative must sign this form.

3. Place the PR/Award number in the upper right hand corner of the hard copy signature page of the ED 424.

4. Fax the signed ED 424 to the Application Control Center at (202) 260–1349.

• We may request that you give us original signatures on all other forms at a later date.

*Application Deadline Date Extension in Case of System Unavailability:* If you are prevented from submitting your application on the application deadline date because the e-Application system is unavailable, we will grant you an extension of one business day in order to transmit your application electronically, by mail, or by hand delivery. We will grant this extension if—

1. You are a registered user of e-Application and you have initiated an e-Application for this competition; and

2. (a) The e-Application system is unavailable for 60 minutes or more between the hours of 8:30 a.m. and 3:30 p.m., Washington, DC time, on the application deadline date; or

(b) The e-Application system is unavailable for any period of time during the last hour of operation (that is, for any period of time between 3:30 p.m. and 4:30 p.m., Washington, DC time) on the application deadline date.

We must acknowledge and confirm these periods of unavailability before granting you an extension. To request this extension or to confirm our acknowledgement of any system unavailability, you may contact either (1) the persons listed elsewhere in this notice under **FOR FURTHER INFORMATION CONTACT** (*see* VII. Agency Contacts) or (2) the e-GRANTS help desk at 1–888–336–8930.

You may access the electronic grant application for the Training Program—CFDA 84.103A at: *http://e-grants.ed.gov.*

## V. Application Review Information

1. *Selection Criteria:* The selection criteria for this program competition are in 34 CFR Part 642.31 and the application package.

**Note:** For the FY 2004 competition, the Secretary has identified need for training projects through the selection of five absolute priorities. Therefore, the Secretary will consider that an applicant has satisfied the "need'' criterion listed in 34 CFR 642.31(f) by applying for a grant under one of these priorities, and applicants do not have to address this criterion. The application package contains instructions on addressing the selection criteria.

2. *Review and Selection Process:* Within the specific absolute priority for which a grant is requested, the Secretary will select an application for funding in rank-order based on the application's total score for the selection criteria and the applicant's prior experience, pursuant to 34 CFR 642.30–646.32. Within each absolute priority, if there are applications with the same total scores, the Secretary will select for funding the applicant that has the greatest capacity to provide training in all regions of the Nation in order to assure accessibility to prospective training participants.

## 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 provide an annual performance report that provides the most current performance and financial expenditure information as specified by the Secretary in 34 CFR 75.118.

4. *Performance Measures:* The success of the Training Program will be measured by its cost-effectiveness, based on the percentage of TRIO personnel receiving training each year and by the percentage of those receiving training who rate the training as highly useful. All grantees will be expected to submit an annual performance report documenting their success in training TRIO personnel, including the average cost per trainee and the trainees' evaluations of the effectiveness of the training provided.

## VII. Agency Contacts

**FOR FURTHER INFORMATION CONTACT:** Patricia S. Lucas or Virginia A. Mason, U.S. Department of Education, 1990 K Street, NW., suite 7000, Washington, DC 20006–8510. Telephone: (202) 502–7600 or by e-mail: *TRIO@ed.gov*

If you use a telecommunications device for the deaf (TDD), you may call the Federal Information 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 one of 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: *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: April 5, 2004.

**Sally L. Stroup,**

*Assistant Secretary for Postsecondary Education.*

[FR Doc. 04–8021 Filed 4–7–04; 8:45 am]

BILLING CODE 4000–01–P

## DEPARTMENT OF ENERGY

### Record of Decision on Mode of Transportation and Nevada Rail Corridor for the Disposal of Spent Nuclear Fuel and High-Level Radioactive Waste at Yucca Mountain, Nye County, NV

**AGENCY:** Office of Civilian Radioactive Waste Management, U.S. Department of Energy.

**ACTION:** Record of decision.

**SUMMARY:** On July 23, 2002, the President signed into law (Pub. L. 107–200) a joint resolution of the U.S. House of Representatives and the U.S. Senate designating the Yucca Mountain site in Nye County, Nevada, for development as a geologic repository for the disposal of spent nuclear fuel and high-level radioactive waste. In the event the Nuclear Regulatory Commission (NRC) authorizes construction of the repository and receipt and possession of spent nuclear fuel and high-level radioactive waste at Yucca Mountain, the Department of Energy (Department or DOE) would be responsible for transporting these materials to the Yucca Mountain Repository as part of its obligations under the Nuclear Waste Policy Act (NWPA). Pursuant to the NWPA and the National Environmental Policy Act (NEPA), DOE issued the "Final Environmental Impact Statement for a Geologic Repository for the Disposal of Spent Nuclear Fuel and High-Level Radioactive Waste at Yucca Mountain, Nye County, Nevada'' (DOE/EIS–0250F, February 2002) (Final EIS). That document analyzed the environmental impacts of the proposed action of constructing, operating and monitoring, and eventually closing a geologic repository for the disposal of 70,000 metric tons of heavy metal (MTHM) of spent nuclear fuel and high-level radioactive waste at Yucca Mountain, as well as of transporting spent nuclear fuel and high-level radioactive waste from commercial and DOE sites to the Yucca Mountain site.

In preparing the Final EIS, DOE initiated public scoping in 1995, and subsequently issued for public comment a Draft EIS in 1999 and a Supplement to the Draft EIS in 2000. During the 199–day public comment period on the Draft EIS, DOE held public hearings in 21

locations across the country, 10 of which were held throughout the State of Nevada. An additional hearing was convened in Las Vegas for members of Native American Tribes in the region. During the 56–day public comment period on the Supplement to the Draft EIS, DOE held three public hearings in Nevada. The Department received more than 13,000 comments on the Draft EIS and the Supplement to the Draft EIS; about 3,600 of these comments addressed transportation related matters.

DOE is now in the process of preparing an application to the Nuclear Regulatory Commission (NRC) seeking authorization to construct the repository. In addition, in order to be in a position to transport waste to the repository should the NRC approve construction and waste receipt, DOE must proceed with certain decisions relating to the transportation of this material. In particular, the Department has decided to select the mostly rail scenario analyzed in the Final EIS as the transportation mode both on a national basis and in the State of Nevada. Under the mostly rail scenario, the Department would rely on a combination of rail, truck and possibly barge to transport to the repository site at Yucca Mountain up to 70,000 MTHM of spent nuclear fuel and high-level radioactive waste, with most of the spent nuclear fuel and high-level radioactive waste being transported by rail. This will ultimately require construction of a rail line in Nevada to the repository. In addition, the Department has decided to select the Caliente rail corridor [1] in which to examine potential alignments within which to construct that rail line. Should the Department select an alignment within that corridor, it will obtain all necessary regulatory approvals before beginning construction.

**ADDRESSES:** Copies of the Final EIS and this Record of Decision may be obtained by calling or mailing a request to: Ms. Robin Sweeney, Office of National Transportation, Office of Civilian Radioactive Waste Management, U.S. Department of Energy, 1551 Hillshire Drive, M/S 011, Las Vegas, NV 89134, Telephone 1–800–967–3477. The Final EIS, including the Readers Guide and Summary, is available via the Internet at *http://www.ocrwm.doe.gov/ documents/ feis_a/index.htm*. This Record of Decision is available at *http:// www.ocrwm.doe.gov* under "What's New''. Questions regarding the Final EIS or this Record of Decision can be submitted by calling or mailing them to Ms. Robin Sweeney at the above phone number or address.

**FOR FURTHER INFORMATION CONTACT:** For general information regarding the DOE National Environmental Policy Act (NEPA) process contact: Ms. Carol M. Borgstrom, Director, Office of NEPA Policy and Compliance (EH–42), U.S. Department of Energy, 1000 Independence Ave., SW., Washington, DC 20585, Telephone 202–586–4600, or leave a message at 1–800–472–2756.

**SUPPLEMENTARY INFORMATION:**

## Transportation-Related Decisions

The analyses in the Final EIS provide the bases for the following three decisions under NEPA related to the establishment of a transportation program under which the Department would transport spent nuclear fuel and high-level radioactive waste to a repository at Yucca Mountain:

1. Outside Nevada, the selection of a national mode of transportation scenario (mostly rail or mostly legal-weight truck),
2. In Nevada, the selection among transportation mode scenarios (mostly rail, mostly legal-weight truck, or mostly heavy-haul truck with an associated intermodal transfer station), and
3. In Nevada, if the mostly rail scenario or mostly heavy-haul truck scenario were selected, the selection among rail corridor implementing alternatives, or heavy-haul truck route implementing alternatives with use of an associated intermodal transfer station.

See Figure 2–5 on page 2–7 of the Final EIS for a graphical depiction of the different transportation scenarios and implementing alternatives.

## Part I. Record of Decision for Mode of Transportation

### *Proposed Action and Transportation Mode Scenarios Considered in the Final EIS*

The Final EIS examines a Proposed Action under which DOE would ship spent nuclear fuel and high-level radioactive waste from 72 commercial and 5 DOE sites [2] to the Yucca Mountain Repository. The Final EIS considers the potential environmental impacts of transporting spent nuclear fuel and high-level radioactive waste to the repository under a variety of modes, including legal-weight truck, rail, heavy-haul truck, and possibly barge. The Final EIS also considers the environmental impacts of two No-Action Alternatives, one under which spent nuclear fuel and high-level radioactive waste would remain at the 72 commercial and five DOE sites under institutional control for at least 10,000 years, and one under which these materials would remain at the 77 sites in perpetuity, but under institutional control for only 100 years.

At the outset, we note that over the past 30 years, more than 2,700 shipments of spent nuclear fuel have been completed, none of which has resulted in an identified injury caused by the release of radioactive material. That basic fact provides important context for our decisionmaking today.

The Final EIS examines various national transportation scenarios and Nevada transportation implementing alternatives to reflect the range of potential environmental impacts that could occur. Two national transportation scenarios, referred to as the "mostly legal-weight truck'' scenario and the "mostly rail'' scenario, and three Nevada scenarios, referred to as the legal-weight truck scenario, the rail scenario, and the heavy-haul truck scenario, were evaluated. The three broad scenarios discussed below represent the combinations of the scenarios and implementing alternatives as analyzed in the Final EIS.

[1] A corridor is a strip of land, approximately 0.25 miles (400 meters) wide, that encompasses one of several possible routes through which DOE could build a rail line. An alignment is the specific location of a rail line in a corridor.

[2] Fifty-four additional sites (primarily domestic research reactors) were expected to ship spent nuclear fuel to two DOE sites prior to disposal at the repository. DOE plans to consolidate these materials at the two DOE sites are independent of the decisions relating to a repository at Yucca Mountain. Shipments from these sites to DOE sites were analyzed in the "Programmatic Spent Nuclear Fuel Management and Idaho National Engineering Laboratory Environmental Restoration and Waste Management Programs Environmental Impact Statement'' (PEIS) (DOE/EIS–0202–F; April 1995), and associated Records of Decision (June 1, 1995; 60 FR 28680 and March 8, 1996; 61 FR 9441). The direct impacts of this consolidation are not included in the analysis of the alternatives analyzed in the Final EIS for the repository, because they would occur whether or not DOE proceeds with the repository at Yucca Mountain. Since the PEIS was published, three research reactors have closed. As provided for in the Record of Decision (ROD) for the PEIS, spent nuclear fuel from one reactor was sent to the Savannah River Site and fuel from another reactor was sent to the Idaho National Engineering and Environmental Laboratory (INEEL). Fuel from the third reactor, which the ROD for the PEIS anticipated would be consolidated at INEEL, was sent on an interim basis to the United States Geological Survey (USGS) site in Lakewood, Colorado (which also was one of the fifty-four sites analyzed in the PEIS). It is still ultimately expected to be consolidated at INEEL as provided in the ROD for the PEIS, whence it will be shipped to the repository. The fuel that went to USGS is within the amounts analyzed by the PEIS as going from USGS to INEEL. Moreover, since the change in interim storage plans does not affect the shipment of fuel to Yucca Mountain, it does not affect the transportation analysis in the Final EIS for the repository.

*Mostly Rail to the Yucca Mountain Repository—Preferred Mode of Transportation*

Under the preferred mode of transportation as analyzed in the Final EIS (the mostly rail scenario), DOE would ship most of the spent nuclear fuel and high-level radioactive waste from the 77 sites to the Yucca Mountain Repository by rail. DOE would construct a rail line in one of five rail corridors considered in the Final EIS to connect the repository at Yucca Mountain to an existing main rail line in Nevada.

Under the mostly rail scenario analyzed in the Final EIS, radioactive materials from certain commercial nuclear sites that do not have the capability to load rail-shipping casks would be shipped by legal-weight truck to the repository. For other commercial sites that have the capability to load rail shipping casks, but do not have rail access, materials would be shipped either by heavy-haul truck or possibly barge to a nearby railhead outside Nevada for shipment by rail to the repository at Yucca Mountain.

Under the mostly rail alternative, about 9,000 to 10,000 train shipments (assuming one cask per train [3]) of spent nuclear fuel and high-level radioactive waste would travel on the nation's rail network over the anticipated 24–year period (DOE's current plan calls for three casks per train shipment, about 3,000 to 3,300 total shipments). In addition, there would be about 1,000 legal-weight truck shipments from commercial sites that do not have the capability to load rail-shipping casks to the repository at Yucca Mountain.

*Mostly Rail to Nevada With Transfer to Heavy-Haul Truck for Shipment to the Repository*

Under this scenario as analyzed in the Final EIS, DOE would ship most spent nuclear fuel and high-level radioactive waste from the 77 sites to Nevada by rail. Rail shipments would terminate in Nevada at an intermodal transfer station where shipping casks would be transferred from rail cars to heavy-haul trucks for shipment to the Yucca Mountain Repository. DOE would construct an intermodal transfer station at one of three locations analyzed in the Final EIS. One of the five heavy-haul routes analyzed in the Final EIS would be upgraded to improve transportation operations, reduce traffic congestion, and enable year-round shipments to the repository.

Under this scenario, radioactive materials from certain commercial nuclear sites that do not have the capability to load rail-shipping casks would be shipped by legal-weight truck directly to the repository.

Under this alternative, about 9,000 to 10,000 train shipments (assuming one cask per train) of spent nuclear fuel and high-level radioactive waste would travel on the nation's rail network to Nevada over the 24-year period. There also would be about 9,000 to 10,000 heavy-haul truck shipments in Nevada from the intermodal transfer station to the repository. In addition, there would be about 1,000 legal-weight truck shipments from commercial sites that do not have the capability to load rail-shipping casks to the repository at Yucca Mountain.

*Mostly Legal-Weight Truck to the Yucca Mountain Repository*

Under the mostly legal-weight truck scenario, as analyzed in the Final EIS, DOE would ship most spent nuclear fuel and high-level radioactive waste from the 77 sites to the repository by legal-weight truck. About 53,000 legal-weight trucks carrying these materials would travel primarily on the nation's interstate highway system during the 24-year period. About 300 shipments of naval spent nuclear fuel would travel from the Idaho National Engineering and Environmental Laboratory to Nevada by rail, where the rail casks would be transferred to heavy-haul trucks for shipment to the repository.

*Environmentally Preferable Transportation Mode Alternative*

In making this determination, DOE considered human health and environmental impacts that could occur from shipping spent nuclear fuel and high-level radioactive waste from the 77 sites to the repository at Yucca Mountain. DOE also considered the human health and environmental impacts that could occur from the construction of a rail line and from any upgrades to existing highways (the heavy-haul truck routes) in Nevada.

The Final EIS indicates that some potential non-radiological fatalities could occur as a result of traffic accidents during the transportation of spent nuclear fuel and high-level radioactive waste to the repository at Yucca Mountain. The Final EIS indicates that the highest number of potential traffic fatalities (about five) could occur under the mostly legal-weight truck scenario, whereas the mostly rail scenario could result in about three potential traffic fatalities during the 24-year period of shipping spent nuclear fuel and high-level radioactive waste to the repository at Yucca Mountain.

The Final EIS also considers the potential health effects that could result from radiation exposure to workers during shipping and from cask loading and unloading, and to the general population along the transportation routes to the repository. Under the mostly legal-weight truck scenario, the Final EIS indicates that about 12 worker and three general public latent cancer fatalities could occur from routine (incident-free) exposures during the 24-year period of shipping spent nuclear fuel and high-level radioactive waste to the repository. Under the mostly rail scenario, about three worker and one general public latent cancer fatalities could occur during the 24-year period. The radiation dose to any one individual would be extremely small.

DOE also estimated the potential health effects to the general public that could result from a severe transportation accident during shipments to the repository (referred to in the Final EIS as a maximum reasonably foreseeable accident). The probability that this accident could occur is extremely unlikely—about three chances in 10 million per year. If such an accident were to occur in an urban population setting, less than one latent cancer fatality could be expected under the mostly legal-weight truck scenario, whereas about five latent cancer fatalities could be expected under the mostly rail scenario, primarily because of the greater amounts of radioactive materials that could be released from a rail cask in such an accident.

In Nevada, construction of a rail line, regardless of the rail corridor selected, would involve the disturbance of land (and associated impacts, although low, to natural resources such as biological and cultural resources) in amounts greater than those associated with any heavy-haul truck alternative. For example, construction of a rail line in the shortest rail corridor (Valley Modified) would result in the disturbance of about 1,240 acres; rail line construction in the longest corridor (Carlin) would disturb about 4,900 acres. Construction of an intermodal transfer station and the upgrade of the longest heavy-haul route would result in the disturbance of about 1,000 acres. Furthermore, the construction of any rail line would involve various land use conflicts that, for the most part, would not occur with the limited construction required to improve any of the heavy-haul truck routes. No land disturbances

[3] The final EIS stated that DOE anticipated as many as 5 casks per train. However, DOE conservatively estimated 1 cask per train for analytical purposes to ensure that it considered routine and accident transportation risks that could result from a larger number of train shipments (9,000 to 10,000).

would occur under the legal-weight truck alternative.

The Department also evaluated the risk of sabotage, including terrorism. For reasons the NRC has carefully explained, this analysis is most likely not required by NEPA.[4] It is not possible to predict whether such acts would occur and, if they did, the nature of such acts. Moreover, such analysis does not advance the public participation purpose of NEPA, since there are serious limits on what information can responsibly be disseminated on these issues without risking disclosure of information that might be used in planning or carrying out such an act.[5] Nevertheless, the Final EIS includes the consequences of a potentially successful attempt on a cask during shipment via rail or legal-weight truck. In both instances, a successful attack would result in the release of contaminants into the environment. The consequences estimated for a rail shipment would be less than those estimated for a legal-weight truck shipment, mostly because the thicker shield wall of the heavier rail cask would tend to mitigate the effects of the sabotage event when compared to the lighter, legal-weight truck transportation cask.

None of the three transportation scenarios analyzed in the Final EIS is clearly environmentally preferable. Each would result in some impact to the environment, and public health and safety, although all impacts would be small. For example, transporting by either rail or heavy-haul truck in Nevada would result in some land disturbance, although the impacts would be greater for rail because more land would be disturbed during the construction of a rail line than during the upgrading of existing highways to accommodate heavy-haul trucks. Radiation exposure to workers and the public from either routine rail or truck shipments to the repository at Yucca Mountain would be very small, and the differences among the different modes of transportation also would be very small. Similarly, accident risks under each alternative would be very small, and associated differences among alternatives also very small. The Department does not consider the differences among modes to be sufficiently distinct to make any of them clearly environmentally preferable.

Although the potential impacts of any of the transportation alternatives would be small, they would be greater than the transportation-related impacts of the No-Action Alternatives. Overall however, as analyzed in the Final EIS, the impacts of proceeding with construction and operation of a repository at Yucca Mountain, including transportation, would cause relatively small public health impacts through the period 10,000 years after repository closure and would cause fewer public health impacts than the No-Action Alternative. For the No-Action Alternative with institutional controls for 10,000 years, the potential long-term environmental impacts also would be small, but significantly greater than the proposed action because the potential for nonradiological fatalities to workers under this alternative is significantly greater. Additional information may be found on pages S–82 through S–88 and Chapters 2 and 7 of the Final EIS. The cost of this No-Action Alternative is also significantly greater than that of the proposed action ($42.7 billion to $57.3 billion (in 2001 dollars) for the proposed action versus $167 billion to $184 billion for the first 300 years of institutional control and $519 million to $572 million per year thereafter). Additionally, the public health and safety impacts of the No-Action Alternative without effective institutional control are significantly greater than the proposed action. Likewise, in the long run, securing these materials by consolidating them and disposing of them in a secure, remote location, better protects against terrorist attack than leaving them at 72 commercial and 5 DOE sites in 35 states within 75 miles of more than 161 million Americans.[6] Moreover, for the reasons expressed by the Secretary and the President in their site recommendations and by the Congress in passing the joint resolution, it is in the national interest to move forward with this project.

In any event, in the Yucca Mountain Development Act, Pub. L. 107–200, Congress directed DOE to proceed with the development of a license application for a repository for the disposal of spent nuclear fuel and high-level radioactive waste. DOE believes that this statute and the NWPA make it incumbent on DOE to proceed with appropriate transportation planning so the Department will be in a position to fulfill its responsibility under the NWPA to begin disposal of this material promptly, should the NRC grant the necessary authorizations for it to do so.

*Transportation-Related Comments on the Final EIS*

DOE distributed about 6,200 copies of the Final EIS and has received written comments on the Final EIS from the White Pine County Nuclear Waste Project Office, White Pine County Board of County Commissioners, Board of County Commissioners Lincoln County, Board of Mineral County Commissioners, and a member of the public. Although comments were received on a variety of issues, the following summation addresses only those few comments related to the transportation of spent nuclear fuel and high-level radioactive waste to a Yucca Mountain repository.

Commenters stated that DOE should develop specific transportation-related mitigation measures, and encouraged DOE to do so in a cooperative manner. Commenters also stated that additional, more detailed and community-specific transportation analyses are needed for purposes of mitigation planning, as well as to support DOE in its transportation decisionmaking, such as the decision on the mode of transportation. Commenters also encouraged DOE to develop plans for transportation, such as route selection for shipments of spent nuclear fuel and high-level radioactive waste, and emergency planning and response. Commenters also requested clarification of the roles of the NRC and DOE's transportation services contractors, and whether counties are eligible for technical assistance and funding under Section 180(c) of the Nuclear Waste Policy Act (NWPA).

As discussed below in Use of All Practicable Means to Avoid or Minimize Harm (Parts I and II), DOE has already adopted measures to avoid or minimize environmental harm that could result from the transportation of spent nuclear fuel and high-level radioactive waste. Additional potential mitigation measures associated with the construction of a rail line will be identified during preparation of an environmental impact statement that considers alternative alignments within the Caliente corridor for construction of the rail line (see PART II of this ROD). DOE also will consult with states, Native American tribes, local governments, utilities, the transportation industry and other interested parties in a cooperative

[4] *See Duke Cogema Stone & Webster,* 56 N.R.C. 335 (2002); *Private Fuel Storage, L.L.C.,* 56 N.R.C. 340 (2002); *Duke Energy Corp.,* 56 N.R.C. 358 (2002); *Dominion Nuclear Connecticut, Inc.,* 56 N.R.C. 367 (2002); *Pacific Gas & Electric Company,* 57 N.R.C. 1 (2003); and *Pacific Gas & Electric Company,* 58 N.R.C. 185 (2003), appeal docketed, No. 03–74628 (9th Cir. Dec. 12, 2003).

[5] *See* materials cited in footnote 4

[6] As explained in footnote 2, some additional materials are currently stored at 50 additional sites (54 at the time of site recommendation), consisting primarily of research reactors, in four additional states, but DOE plans to consolidate these materials at two DOE sites for reasons unrelated to its repository plans.

manner to refine the transportation system as it is developed. Furthermore, DOE must comply with the transportation-related provisions of the NWPA. Spent nuclear fuel and high-level radioactive waste will be shipped to Yucca Mountain in casks that have been certified by the NRC (Section 180(a)). Prior to these shipments, DOE will comply with the regulations of the NRC regarding advanced notification of state and local governments (Section 180(b)).

*Transportation Mode Decision*

Under the NWPA, the Department is responsible for planning that will allow for the transportation of spent nuclear fuel and high-level radioactive waste in the event the NRC authorizes receipt and possession of these materials at Yucca Mountain. Accordingly, as the next step in fulfilling that responsibility, the Department is issuing this Record of Decision to select a transportation mode. The Department has decided to select the preferred mode of transportation analyzed in the Final EIS, the mostly rail scenario, both on a national basis and in the State of Nevada. Under this decision, the Department would rely on a combination of rail, truck and possibly barge to transport to the repository up to 70,000 MTHM of spent nuclear fuel and high-level radioactive waste. Most of the spent nuclear fuel and high-level radioactive waste would be transported by rail. The Department would use truck transport where necessary, depending on certain factors such as the timing of the completion of the rail line proposed to be constructed in Nevada. This could include building an intermodal capability at a rail line in Nevada to take legal-weight truck casks from rail cars and transport them the rest of the way to the repository via highway, should the rail system be unavailable at the time of the opening of the repository [7]. In addition, since some commercial utilities are not able to accommodate rail casks, they would ship by legal-weight truck to the repository. Additionally, the Department would use heavy-haul truck and possibly barge as needed to ship spent nuclear fuel from commercial nuclear sites to nearby railheads outside Nevada for shipment to the repository.

*Basis for Transportation Mode Decision*

As we explain below, the Department has concluded that it should use mostly rail nationwide and in Nevada based, in large part, on the analyses of the Final EIS. The Department also considered the preferences for rail transportation expressed by the State of Nevada and other factors described below.

The analyses in the Final EIS demonstrate that the potential radiation doses to workers and the general public from rail, truck or barge transportation would be very small, and that the differences in resulting potential impacts from such exposures among the different modes of transportation also would be very small. Nevertheless, using mostly rail tends to minimize the potential environmental impacts that could occur. The decision to rely primarily on the nation's rail system to ship these materials would result in fewer shipments than would occur if legal-weight trucks were the primary mode of transportation. This in turn would result in fewer trucks on public highways. The lower number of rail shipments as compared to truck shipments is estimated to result in fewer potential traffic fatalities and, under routine conditions, slightly fewer latent cancer fatalities to workers and the general public relative to mostly legal-weight truck shipments.

In reaching its decision, DOE also considered the number of commercial nuclear sites having, or expected to have, the capability to handle rail casks, the distances to suitable railheads near the commercial nuclear sites, and historical experience using rail to ship spent nuclear fuel and other large reactor-related components. The Department found that the preponderance of commercial sites have the capability and experience to ship to nearby railheads.

The Department also considered preferences expressed by the State of Nevada in its comments on the Draft EIS. In these comments, the state indicated that DOE should plan its transportation system to maximize the use of rail.

The Department also considered irreversible and irretrievable commitments of resources and cumulative impacts in making its decision. There would be an irreversible and irretrievable commitment of resources, such as land, electric power, fossil fuels and construction materials, associated with the construction of a rail line in Nevada, although this commitment of resources would not significantly diminish these resources, either nationwide or in Nevada. DOE also recognizes that for all alternatives involving transportation of spent nuclear fuel and high-level radioactive waste, there could be cumulative impacts from past, present and reasonably foreseeable future activities involving transportation of other radioactive materials. Based on the analyses in the Final EIS, DOE does not expect that any cumulative impacts would be significant over the duration of shipping spent nuclear fuel and high-level radioactive waste to the repository.

Based on these various considerations, DOE concludes that shipping by mostly rail, both nationally and in the State of Nevada, would be preferable to shipping by mostly truck or using heavy-haul trucks in Nevada.

*Use of All Practicable Means To Avoid or Minimize Harm—Transportation Mode*

The shipment of spent nuclear fuel and radioactive waste is highly regulated and subject to the utmost scrutiny. DOE carefully follows the Department of Transportation (DOT) and NRC transportation rules now and will follow or exceed any others that may be established in the future whether by the Congress or by DOT or NRC. DOE also will consult with states, Native American tribes, local governments, utilities, the transportation industry and other interested parties in a cooperative manner to refine the transportation system as it is developed.

Measures DOE will implement to avoid or minimize harm include the following [8]: prior to the shipment of spent nuclear fuel, the shipper or carrier must select routes and prepare a written plan listing origin and destination of the shipment, scheduled route, all planned stops, estimated time of departure and arrival, and emergency telephone numbers; advance notice must be provided to State and local governments prior to shipping irradiated reactor fuel through their states; anyone involved in the preparation or transport of radioactive materials will be required to have proper training; carriers must be provided with shipping papers containing emergency information, including contacts and telephone numbers, readily available during transport for inspection by appropriate officials; clearly identifiable markings, labels, and placards of hazardous contents must be provided; and all spent nuclear fuel and high-level

[7] In March 2004, DOE issued a Supplement Analysis and determined, in accordance with 10 CFR 1021.314, that this rail/legal-weight truck scenario would not constitute a substantial change to the proposal previously analyzed in the Final EIS or significant new circumstances or information relevant to environmental concerns, as discussed in 40 CFR 1502.9(c)(1).

[8] Application of these measures to national security activities may, in some respects, be subject to section 7 of the Nuclear Waste Policy Act, 42 U.S.C. section 10106.

radioactive waste shipments would be in the most rugged casks (Type B, which range from small containers of sealed radioactive sources to heavily shielded steel casks that sometimes weigh as much as 150 tons).

The NRC has promulgated rules (10 CFR 73.37) and interim compensatory measures (March 4, 2002; 67 FR 9792) specifically aimed at protecting the public from harm that could result from sabotage of spent nuclear fuel casks. These security rules are designed to minimize the possibility of sabotage and facilitate recovery of spent nuclear fuel shipments that could come under the control of unauthorized persons. The use of armed escorts for all shipments; safeguarding the detailed shipping schedule information, monitoring of shipments through satellite tracking and a communication center with 24-hour staffing; and coordinating logistics with state and local law enforcement agencies all contribute to shipment security. Additionally, the cask safety features that provide containment, shielding, and thermal protection provide protection against sabotage. The Department and other agencies continue to examine the protections built into their physical security and safeguards systems for transportation shipments.

DOE is now developing its transportation security plan and its design basis threat for transportation. The transportation security plan will be developed in cooperation with other Federal agencies, including the NRC, DOT, and the Department of Homeland Security. The Office of Civilian Radioactive Waste Management is exploring the use of armed Federal agents as escorts for all shipments and other operational techniques employed by the National Nuclear Security Administration's Office of Secure Transportation as well as the design of special security cars for rail transport, to further mitigate the potential threat of a terrorist act. In addition to its domestic efforts, the Department is a member of the International Working Group on Sabotage for Transport and Storage Casks, which is investigating the consequences of a potential act of sabotage and is exploring opportunities to enhance the physical protection of casks. As a result of the above efforts, DOE will modify its methods and systems as appropriate between now and the time shipments start.

In compliance with section 180(c) of the NWPA, DOE will provide technical assistance and funds to states for training public safety officials of appropriate units of local government and Native American tribes through whose jurisdictions the Department plans to ship spent nuclear fuel and high-level radioactive waste. The training of public safety officials will cover procedures required for safe routine transportation of these materials and for dealing with emergency response situations.

Pursuant to the NWPA, spent nuclear fuel and high-level radioactive waste will be transported in casks certified by the NRC. The NRC regulates and certifies the design, manufacture, testing and use of these casks. Additionally, the NWPA requires that DOE comply with NRC regulations regarding advance notification of State and local governments prior to transportation of spent nuclear fuel or high-level radioactive waste.

At this stage in the decision-making, the Department believes it has incorporated all practicable mitigation measures. The Department will continue to identify and evaluate potential mitigation measures as the transportation system develops and as a result of the lessons learned from the shipping of spent nuclear fuel and high-level radioactive waste.

## Part II. Record of Decision for Nevada Rail Corridor

### *Background*

As noted above, the mostly rail scenario assumes that DOE will ultimately construct a rail line in Nevada to ship spent nuclear fuel and high-level radioactive waste to the repository. To implement that scenario, DOE therefore needs to select among alternative rail corridors within which to study possible alignments in which it will pursue construction of a rail line that would connect the repository at Yucca Mountain to an existing main rail line in Nevada in the event the NRC authorizes construction of a repository at Yucca Mountain. In the Final EIS, DOE analyzed five potential rail corridors—Caliente, Carlin, Caliente-Chalk Mountain, Jean and Valley Modified—for this potential rail line. Additional descriptive information, including variations associated with each corridor, may be found in section 2.1.3.3 and Appendix J, section J.3.1.2, of the Final EIS. The Final EIS did not specify a corridor preference, but in December 2003, DOE announced its preference for the Caliente corridor (*Notice of Preferred Nevada Rail Corridor*; 68 FR 74951; December 29, 2003.

### *Proposed Action and Nevada Rail Corridors Considered in the Final EIS*

A. Caliente Rail Corridor—Preferred Alternative

The Caliente corridor originates at an existing siding to the mainline railroad near Caliente, Nevada. The corridor extends in a westerly direction to the northwest corner of the Nevada Test and Training Range (previously known as Nellis Air Force Range), before turning south-southeast to the repository at Yucca Mountain. The corridor ranges between 318 miles (512 kilometers) and 344 miles (553 kilometers), depending on the variations to the corridor considered in the Final EIS. Construction of a rail line within the Caliente corridor would take about 46 months. The total life-cycle cost for construction and operation of the rail line is estimated to be $880 million (2001 dollars).

B. Carlin Rail Corridor

The Carlin corridor originates at the mainline railroad near Beowawe in north central Nevada. The Carlin and Caliente corridors converge near the northwest boundary of the Nevada Test and Training Range. Past this point, they are identical. The Carlin corridor ranges between 319 miles (513 kilometers) and 338 miles (544 kilometers) long, depending on the variations to the corridor. Construction of a rail line within the Carlin corridor would take about 46 months. The total life-cycle cost for construction and operation of the rail line is estimated to be $821 million (2001 dollars).

C. Caliente-Chalk Mountain Rail Corridor

The Caliente-Chalk Mountain corridor is identical to the Caliente corridor until it approaches the northern boundary of the Nevada Test and Training Range. At that point the Caliente-Chalk Mountain corridor turns south through the Nevada Test and Training Range and the Nevada Test Site to the Yucca Mountain site. Depending on the variations, the corridor is between 214 miles (344 kilometers) and 242 miles (382 kilometers) long from the tie-in at the mainline near Caliente to the Yucca Mountain site. Construction of a rail line within the Caliente-Chalk Mountain corridor would take about 43 months. The total life-cycle cost for construction and operation of the rail line is estimated to be $622 million (2001 dollars). The Department designated the Caliente-Chalk Mountain alternative as non-preferred in the Final EIS due to national security concerns raised by the U.S. Air Force.

D. Jean Rail Corridor

The Jean corridor originates at the existing mainline railroad near Jean, Nevada. The corridor ranges between 112 miles (181 kilometers) and 127 miles (204 kilometers) long from the tie-in with the mainline to the Yucca Mountain site. Construction of a rail line within the Jean corridor would take about 43 months. The total life-cycle cost for construction and operation of the rail line is estimated to be $462 million (2001 dollars).

E. Valley Modified Rail Corridor

The Valley Modified corridor originates at an existing rail siding off the mainline railroad northeast of Las Vegas. Depending on the variations, the corridor is between 98 miles (157 kilometers) and 101 miles (163 kilometers) long from the tie-in with the mainline to the Yucca Mountain site. Construction of a rail line within the Valley Modified corridor would take about 40 months. The total life-cycle cost for construction and operation of the rail line is estimated to be $283 million (2001 dollars).

*Environmentally Preferable Rail Corridor Alternative*

DOE considered human health and environmental impacts that could occur from the construction of a rail line, as well as from shipping spent nuclear fuel and high-level radioactive waste in Nevada.

Construction of a rail line, regardless of the rail corridor selected, would involve the disturbance of land and associated impacts, although low, to natural resources such as biological and cultural resources. For example, construction of a rail line in the Valley Modified corridor (shortest) would result in the disturbance of about 1,240 acres; rail line construction in the Carlin corridor (longest) would disturb about 4,900 acres.

Construction of any rail line in Nevada also would conflict with existing land uses. Depending on the variations considered, privately-owned lands occur on less than one percent of the lands analyzed under the Caliente (ranges from 222 to 618 acres), Caliente-Chalk Mountain (ranges from 198 to 272 acres) and Valley Modified (ranges from 0 to 44 acres) corridors, but up to about five and seven percent of the lands analyzed under the Jean (ranges from 32 to 865 acres) and Carlin (ranges from 1,804 to 3,756 acres) corridors, respectively. The Caliente and Carlin corridors cross Timbisha-Shoshone trust lands, and a relatively short distance on the Nevada Test and Training Range, although variations are available that would avoid these lands. The Caliente corridor crosses two wilderness study areas, and the Valley Modified corridor passes through the Desert National Wildlife Range, although variations may be available to avoid these lands. The Caliente-Chalk Mountain corridor crosses land dedicated to testing and training activities of the U.S. Air Force and Department of Defense on the Nevada Test and Training Range; no variations are available that would avoid the Range under this corridor alternative.

Under any rail corridor alternative, water would be used for compaction of the rail bed and dust suppression, and by workers during construction. Water consumption would vary, primarily because of the length of the corridor, ranging from 320 acre-feet for the Valley Modified corridor to 710 acre-feet for the Caliente corridor.

During the 24-year shipping period, assuming standard nationwide rail routing practices, the incident-free (routine) collective dose to members of the public from the transportation of spent nuclear fuel and high-level radioactive waste by rail would result in less than one latent cancer fatality regardless of which corridor is selected. The difference in impacts among the corridors is minimal. Similarly, less than one latent cancer fatality would occur in the exposed worker population, and that is not affected by the Nevada corridor selection.

DOE also estimated the potential health effects to the general public that could result from a severe transportation accident during shipments to the repository (referred to in the Final EIS as a maximum reasonably foreseeable accident). If such an accident were to occur in a rural population setting, the collective radiological dose to members of the public would result in less than one latent cancer fatality. The probability that this accident could occur is extremely unlikely—about 2 chances in 1 million per year.

The environmental impacts identified in the Final EIS do not provide a clear basis for discriminating among alternative rail corridors in Nevada. Each of these alternatives would result in some impact to the environment and public health and safety. Construction of a rail line within any rail corridor would involve certain land use conflicts, and land disturbance with attendant impacts (although small, the impacts tend to increase with increasing corridor length). Radiation exposure to workers and the public in Nevada would be small, and the differences among the rail corridor alternatives also would be very small.

For these reasons, DOE does not consider the differences among the corridor alternatives to be sufficient to make any of them clearly environmentally preferable.

Finally, although the potential impacts of any of the five potential rail corridors would be small, they would be greater than the potential transportation-related impacts of the No-Action Alternatives. Nevertheless, as explained above, the impacts of proceeding with construction and operation of a repository at Yucca Mountain, including transportation, are relatively small and less than either of the No-Action Alternative scenarios. Part I (of this ROD) provides further comparison of the proposed action and the No-Action Alternative scenarios. In any event, given DOE's responsibilities under the Yucca Mountain Development Act and the NWPA, DOE believes it is obligated to proceed with appropriate transportation planning, including, given its selection of the mostly rail scenario in Nevada, the selection of a corridor in which to study possible alignments for the Nevada rail line, in preference to either No-Action Alternative scenario.

*Comments on Preferred Rail Corridor*

DOE noticed its preference for the Caliente corridor in the **Federal Register** (December 29, 2003; 68 FR 74951). The Carlin corridor was identified as a secondary preference. The Department has received comments on the preference announcement. Concerns expressed in these comments included the need for a comprehensive programmatic EIS covering all aspects of nuclear waste transportation to Yucca Mountain, avoidance of all major population centers with transportation routes, and provision of documentation supporting the preference decision. Other comments addressed the need for adequate opportunities for public participation and comment on the corridor preference announcement, including a request for cooperating agency status for any future rail alignment EIS. Selection of a corridor preference prior to having a mode of transportation decision was raised as a concern. In addition, there was confusion regarding the designation of the Carlin corridor as a secondary preference and its relationship to the upcoming rail alignment EIS process. Furthermore, commenters indicated that a rail line in the Caliente corridor would have significant negative impacts on cultural, socioeconomic, and wildlife resources, as well as a massive modern

sculpture project. Others raised the potential for impacts to ranchers living in proximity to the proposed Caliente corridor, including questions regarding the design and operation of a rail line and the nature of measures that could mitigate resulting adverse impacts. Finally, several commenters thanked DOE for announcing its corridor preference, recognizing the challenges and opportunities and associated need to coordinate closely as DOE proceeds with transportation planning.

Comments calling for DOE to prepare a programmatic transportation EIS and the need to avoid all major Nevada population centers with transportation routes were addressed in the response to comments in the Final EIS. DOE believes a programmatic EIS to be unnecessary as its Final EIS provides the environmental impact information necessary to make certain broad transportation-related decisions (as described above in Transportation-Related Decisions).

With regard to avoiding population centers, the analyses of the Final EIS illustrate that potential public health and safety impacts would be so low for individuals who lived and worked along any route that individual impacts would not be discernible, even if the corresponding doses could be measured.

Although some commenters stated that DOE's intent in identifying the Carlin corridor as a secondary preference was unclear, the decision to select the Caliente corridor also represents DOE's intent to no longer consider the Carlin corridor for development of a rail line. This decision and the basis for not selecting the Carlin corridor are discussed below in Rail Corridor Decision and Basis for Rail Corridor Decision.

The remaining concerns and issues regarding potential environmental impacts associated with the development of a rail line, potential mitigation measures, and opportunities for public involvement and project participation will be addressed during the future preparation of a rail alignment EIS. As part of developing this documentation, DOE will identify and adopt measures to avoid or minimize environmental harm that could result from the construction and operation of a rail line within the Caliente corridor.

*Rail Corridor Decision*

In Part I of this Record of Decision, the Department selected, both on a national basis and in the State of Nevada, the mostly rail scenario. That decision is premised on the assumption that DOE will ultimately construct a rail line to connect the repository site to an existing rail line in the State of Nevada. To that end, the Department has decided to select the preferred rail corridor alternative, the Caliente corridor, in which to evaluate alignments for a rail line.

*Basis for Rail Corridor Decision*

The Department decided to evaluate alignments within the Caliente corridor for possible construction of a rail line based, in large part, on the analyses of the Final EIS. The Department, however, also considered other factors discussed below, such as potential for construction delay, direct and indirect costs of each alternative, and comments received from the public.

The Department considered irreversible and irretrievable commitments of resources and cumulative impacts in making its decision. There would be an irreversible and irretrievable commitment of resources, such as electric power, fossil fuels, construction materials, and water associated with the construction of a rail line in Nevada, although this commitment of resources would not significantly diminish the resources in question in Nevada. DOE recognizes that for all rail corridors there could be cumulative impacts from past, present and reasonably foreseeable future activities.

The Department considered potential land use conflicts and their potential to affect adversely construction of a rail line, as analyzed in the Final EIS in making this decision. If the Department were to select the Valley Modified rail corridor there may be conflicts with the Desert National Wildlife Range and local community plans for development in the greater Las Vegas metropolitan area. If the Department were to select the Caliente-Chalk Mountain corridor there would be conflicts with U.S. Air Force and Department of Defense testing and training activities directly related to national security interests on the Nevada Test and Training Range. If the Department were to select the Jean corridor it may require crossing relatively greater amounts of private land, and would pose greater potential land use conflicts because of its proximity to the greater Las Vegas metropolitan area. If the Department were to select the Carlin corridor it would also require crossing relatively greater amounts of private land. Moreover, little infrastructure, such as roads and electric power, is available over long segments, which would tend to make logistics during construction as well as emergency response capabilities more challenging. Overall, the Caliente rail corridor appears to have the fewest land use or other conflicts that could lead to substantial delays in acquiring the necessary land and rights-of-way, or in beginning construction.

DOE also considered concerns expressed by the public in Nevada. In these comments, the public stated that DOE should avoid rail corridors in the Las Vegas Valley.

The Department also considered the direct costs of constructing and operating a rail line, and the indirect costs resulting from potential delays in the availability of the rail line. The Jean and Valley Modified corridors are the shortest and have the lowest estimated construction costs. The Carlin and Caliente corridors are the longest and on the basis of construction cost alone would be more expensive to develop. However, delays in the construction of the rail line because of land use or other conflicts and the resulting inability to accept large amounts of spent nuclear fuel and high-level radioactive waste transported by a railroad to the repository in a timely manner could add to both the liability costs for delayed acceptance of commercial spent nuclear fuel and the costs of continued storage of DOE wastes.

Based on all of the above, DOE concludes that the Caliente corridor is preferable to the other corridors it evaluated as a potential corridor in which to construct a rail line. Therefore, DOE has decided to select the Caliente corridor as the one within which to evaluate possible alignments for the rail line connecting the repository to an existing main rail line in Nevada.

*Use of All Practicable Means To Avoid or Minimize Harm—Rail Corridor*

In the Final EIS, DOE identified transportation-related measures that would be implemented, and other measures that would require further consideration and refinement before adoption to avoid or minimize environmental harm. As described in Part I, this decision adopts all practicable measures to avoid or minimize adverse environmental impact that could result from the transportation of spent nuclear fuel and high-level radioactive wastes to a repository at Yucca Mountain appropriate at this stage of decision-making. Construction of a rail line will be consistent with applicable Federal, state and Native American tribal requirements. In addition to these measures, other potential mitigation measures associated with the construction of a rail line will be identified and evaluated during preparation of future NEPA documentation.

Issued in Washington, DC April 2, 2004.

**Margaret S. Y. Chu,**

*Director, Office of Civilian Radioactive Waste Management.*

[FR Doc. 04–7949 Filed 4–7–04; 8:45 am]

**BILLING CODE 6450–01–P**

## DEPARTMENT OF ENERGY

### Notice of Intent to Prepare an Environmental Impact Statement for the Alignment, Construction, and Operation of a Rail Line to a Geologic Repository at Yucca Mountain, Nye County, NV

**AGENCY:** U.S. Department of Energy.

**ACTION:** Notice of intent.

**SUMMARY:** The U.S. Department of Energy (DOE or the Department) announces its intent to prepare an environmental impact statement (EIS) under the National Environmental Policy Act (NEPA) for the alignment, construction, and operation of a rail line for shipments of spent nuclear fuel, high-level radioactive waste, and other materials from a site near Caliente, Lincoln County, Nevada, to a geologic repository at Yucca Mountain, Nye County, Nevada. On April 2, 2004, the Department signed a Record of Decision announcing its selection, both nationally and in the State of Nevada, of the mostly rail scenario analyzed in the "Final Environmental Impact Statement for a Geologic Repository for the Disposal of Spent Nuclear Fuel and High-Level Radioactive Waste at Yucca Mountain, Nye County, Nevada'' (DOE/EIS–0250F, February 2002) (Repository Final EIS). This decision will ultimately require the construction of a rail line to connect the repository site at Yucca Mountain to an existing rail line in the State of Nevada for the shipment of spent nuclear fuel and high-level radioactive waste, in the event that the Nuclear Regulatory Commission authorizes construction of the repository and receipt and possession of these materials at Yucca Mountain. To that end, the Department also decided to select the Caliente rail corridor [1] in which to examine possible alignments for construction of a rail line that would connect the repository at Yucca Mountain to an existing main rail line in Nevada. DOE is now announcing its intent to prepare this Rail Alignment EIS to assist in selecting this alignment. The EIS also would consider the potential construction and operation of a rail-to-truck intermodal transfer facility, proposed to be located at the confluence of an existing mainline railroad and a highway, to support legal-weight truck transportation until the rail system is fully operational.

**DATES:** The Department invites and encourages comments on the scope of the EIS (hereafter referred to as the Rail Alignment EIS) to ensure that all relevant environmental issues and reasonable alternatives are addressed. Public scoping meetings are discussed below in the **SUPPLEMENTARY INFORMATION** section. DOE will consider all comments received during the 45-day public scoping period, which starts with the publication of this Notice of Intent and ends May 24, 2004. Comments received after the close of the public scoping period will be considered to the extent practicable.

**ADDRESSES:** Written comments on the scope of this Rail Alignment EIS, questions concerning the proposed action and alternatives, requests for maps that illustrate the Caliente corridor and alternatives, or requests for additional information on the Rail Alignment EIS or transportation planning in general should be directed to: Ms. Robin Sweeney, EIS Document Manager, Office of National Transportation, Office of Civilian Radioactive Waste Management, U.S. Department of Energy, 1551 Hillshire Drive, M/S 011, Las Vegas, NV 89134, Telephone 1–800–967–3477, or via the Internet at *http://www.ocrwm.doe.gov* under "What's New.''

**FOR FURTHER INFORMATION CONTACT:** For general information regarding the DOE NEPA process contact: Ms. Carol M. Borgstrom, Director, Office of NEPA Policy and Compliance (EH–42), U.S. Department of Energy, 1000 Independence Ave., SW., Washington, DC 20585, Telephone 202–586–4600, or leave a message at 1–800–472–2756.

**SUPPLEMENTARY INFORMATION:**

### Background

On July 23, 2002, the President signed into law (Pub. L. 107–200) a joint resolution of the U.S. House of Representatives and the U.S. Senate designating the Yucca Mountain site in Nye County, Nevada, for development as a geologic repository for the disposal of spent nuclear fuel and high-level radioactive waste. Subsequently, the Department issued a Record of Decision (April 2, 2004) to announce its selection, both nationally and in the State of Nevada, of the mostly rail scenario analyzed in the Repository Final EIS as the mode of transportation of spent nuclear fuel and high-level radioactive waste to the repository. Under the mostly rail scenario, the Department would rely on a combination of rail, truck and possibly barge to transport to the repository site at Yucca Mountain up to 70,000 metric tons of heavy metal (MTHM) of spent nuclear fuel and high-level radioactive waste. Most of the spent nuclear fuel and high-level radioactive waste, however, would be transported by rail.

The Department's decision to select the mostly rail scenario in Nevada will ultimately require the construction of a rail line to connect the repository site at Yucca Mountain to an existing rail line in the State of Nevada for the shipment of spent nuclear fuel and high-level radioactive waste in the event that the Nuclear Regulatory Commission authorizes construction of the repository and receipt and possession of these materials at Yucca Mountain. To that end, in the same Record of Decision, the Department also decided to select the Caliente rail corridor to study possible alignments for this rail line.

In the Repository Final EIS, DOE defined a rail corridor as a 0.25 miles (400-meter) wide strip of land that encompasses one of several possible alignments or specific locations within which DOE could build a rail line. The Caliente rail corridor was described as originating at an existing siding to the mainline railroad near Caliente, Nevada, and extending in a westerly direction to the northwest corner of the Nevada Test and Training Range, before turning south-southeast to the repository at Yucca Mountain.

In the Repository Final EIS, DOE also identified eight variations along the Caliente corridor that may minimize or avoid environmental impacts and/or mitigate construction complexities. Variations were defined as a strip of land 0.25 miles (400-meters) wide that describes a different route, from one point along the corridor to another point on the corridor. Thus, the Caliente corridor ranges between 318 miles (512 kilometers) and 344 miles (553 kilometers) in length, depending on the variations considered. In the Repository Final EIS, DOE did not identify variations for about 55 percent of the length of the corridor (hereafter these areas are referred to as "common segments'').

DOE proposes to consider the common segments and the eight variations as preliminary alternatives to be evaluated in the Rail Alignment EIS. These alternatives are described in the *Preliminary Alternatives* section. In addition, DOE will consider other potential variations outside of the 0.25

[1] A corridor is a strip of land 0.25 miles (400 meters) wide that encompasses one of several possible routes through which DOE could build a rail line. An alignment is the specific location of a rail line in a corridor.

mile wide corridor that might minimize, avoid or mitigate adverse environmental impacts.

For purposes of analysis in the Rail Alignment EIS, a rail line alignment is defined as a strip of land 100 feet (30 meters) on either side of the centerline of the track within the Caliente corridor, passing through the common segments and variations. DOE will define regions of influence for each environmental resource (for example, biological or cultural resources) that will extend beyond the dimensions of the alignment and allow DOE to estimate environmental impacts over the geographic area in which the impact is likely to be realized. Within these regions of influence, DOE will estimate environmental impacts of the common segments and alternatives, both separately and in aggregate. In this way, the analyses of the Rail Alignment EIS will offer DOE flexibility to minimize, avoid or otherwise mitigate potential environmental impacts of the final alignment chosen for construction.

**Proposed Action**

In the Rail Alignment EIS, the Proposed Action is to determine a rail alignment, and to construct and operate a rail line for shipments of spent nuclear fuel, high-level radioactive waste, and other materials [2] from a site near Caliente, Lincoln County, Nevada to a geologic repository at Yucca Mountain, Nye County, Nevada. Under the Proposed Action, the Caliente rail line would be designed and built consistent with Federal Railroad Administration safety standards. Construction would take between three and four years.

Construction activities would include the development of construction support areas; construction of access roads to the rail line construction initiation points [3] and to major structures to be built, such as bridges and culverts; and movement of materials and equipment to the construction initiation points. The number and location of construction initiation points would be based on such variables as the length of the rail line, the construction schedule, the number of contractors used for construction, the number of structures to be built, the supply of materials, and the locations of existing access roads adjacent to the rail line.

The construction of the rail line would require the clearing and excavation of previously undisturbed lands, and the establishment of borrow and spoils [4] areas. To establish a stable base for the rail track, construction crews would excavate some areas and fill (add more soil to) others, as determined by terrain features. To the extent possible, material excavated from one area would be used in areas that required fill material. However, if the distance to an area requiring fill material were excessive, the excavated material would be disposed of in spoils areas, and a borrow area would be established adjacent to the area requiring fill material. Access roads to spoils and borrow areas would be built during the track base construction work.

Under the Proposed Action, DOE would construct a secure railyard and facilities at the operational interface with the mainline railroad near Caliente, Nevada. The facilities would include sidings connected to the mainline, and buildings and associated equipment for track and equipment maintenance, locomotive refueling, and train crew quarters.

DOE also will consider the potential construction and operation of a rail-to-truck intermodal transfer facility to support limited legal-weight truck transportation until the rail system is fully operational. This intermodal transfer facility could be constructed at the confluence of an existing mainline railroad and a highway.

Typical construction equipment (front-end loaders, power shovels, and other diesel-powered support equipment) would be used for clearing and excavation work. Trucks would spray water along graded areas for dust control and soil compaction. The fill material used along the rail line to establish a stable base for the track would be compacted to meet design requirements. Water could be shipped from other locations or obtained from wells drilled along the rail line.

Railroad track construction would consist of the placement of railbed material (sub-ballast), ballast (support and stabilizing materials for the rail ties), ties and rail over the completed railbed base. Other activities would include: installation of at-grade crossings, fencing as needed, train monitoring and signals and communication equipment, and final grading of slopes, rock-fall protection devices, and restoration of disturbed areas.

Operation of the Caliente rail line would be consistent with Federal Railroad Administration standards for maintenance, operations, and safety. A typical spent nuclear fuel and high-level radioactive waste train would consist of two diesel-electric locomotives; three or more rail cars containing spent nuclear fuel or high-level radioactive waste; buffer cars; and an escort car. A typical train carrying construction materials would not have buffer cars or an escort car.

At the Yucca Mountain repository, rail cars containing casks of spent nuclear fuel and high-level radioactive waste would move through a security check into the radiologically controlled area. The casks would be inspected and protective barriers removed, in preparation for waste handling at the repository. Rail cars carrying construction materials would be offloaded and the materials stockpiled on site.

**Preliminary Alternatives**

As required by the Council on Environmental Quality and Department regulations that implement NEPA, the Rail Alignment EIS will analyze and present the environmental impacts associated with the range of reasonable alternatives to meet DOE's purpose and need for a rail line, and a no action alternative. The preliminary alternatives for the alignment comprise a series of common segments and alternatives (maps may be obtained as described above in **ADDRESSES**). The Department is particularly interested in identifying and subsequently evaluating any additional reasonable alternatives that would reduce or avoid known or potential adverse environmental impacts, national security activities, features having aesthetic values, and land-use conflicts, or alternatives that should be eliminated from detailed consideration. This could include identifying alternatives that could avoid wilderness study areas or other land use conflicts. The preliminary alternatives include:

*Interface With Mainline Railroad*

Three alternatives are available to connect to the existing mainline railroad, each of which would intersect the common segment of the rail alignment about 4 miles (6.5 kilometers) southwest of Panaca, Nevada, along U.S. 93 in the Meadow Valley area. The Caliente Alternative would begin at the town of Caliente, enter Meadow Valley at Indian Cove and extend north

[2] Other materials refer to materials related to the construction (*e.g.,* reinforcing steel, cement) and operation (*e.g.,* waste packages, fuel oil) of the repository.

[3] DOE anticipates that construction of the rail line may occur at several locations simultaneously along the alignment.

[4] Borrow areas are areas outside of the rail alignment where construction personnel could obtain earthen materials such as aggregate for construction of the rail line. Spoil areas are areas outside of the alignment for the deposition of excess earthern materials excavated during construction of the rail line.

through Meadow Valley to converge with the common segment. This alternative is about 10.5 miles (17 kilometers) in length.

The Eccles Alternative would begin at the Eccles siding along Clover Creek about 5 miles (8 kilometers) east of Caliente, trend generally north entering Meadow Valley on the southeast, and would then trend northward to converge with the common segment. This alternative is about 11 miles (18 kilometers) in length.

The Crestline Alternative would begin north of the Crestline siding in Sheep Spring Draw, extend west after crossing Lincoln County Road 75, and pass north of the Cedar Range. It would then veer northwesterly just north of Miller Spring Wash and converge with the common segment just south of the Big Hogback. This alternative is about 23 miles (38 kilometers) in length.

*White River*

The two White River Alternatives would depart from the common segment about 1.5 miles (2.5 kilometers) west of its crossing of the White River immediately west of State Route 318. The northern White River Alternative (WR1) would follow the White River, curve around the northern end of the Seaman Range, and then turn southwest entering Coal Valley. This alternative is about 25 miles (40 kilometers) in length.

The southern White River Alternative (WR2) would depart the same common segment but would extend westerly along the flanks of Timber Mountain, proceed through Timber Mountain Pass, and then enter Coal Valley. This alternative is about 18.5 miles (30 kilometers) in length.

Once in Coal Valley, both alternatives would merge with the Garden Valley Alternatives. Several options are available to merge the White River Alternatives with the Garden Valley Alternatives.

*Garden Valley*

The southern Garden Valley Alternative (GV2) would start about 2 miles (3 kilometers) east of the water gap located along Seaman Wash Road, proceed westward through the Golden Gate Mountains, and turn southwesterly through Garden Valley to reconnect to a common segment about 2.5 miles (4 kilometers) northeast of the pass between the Worthington Mountains and the Quinn Canyon Range. This alternative is about 17 miles (27.5 kilometers) in length.

The northern Garden Valley Alternative (GV1) would diverge from the same common segment as Alternative GV2, but would pass through the Golden Gate Mountains about 4 miles (6.5 kilometers) further north of the Alternative GV2 location. Alternative GV1 would then continue southwesterly through Garden Valley to reconnect with the common segment described for Alternative GV2. This alternative is about 19 miles (31 kilometers) in length.

*Mud Lake*

The Mud Lake Alternatives would depart a common segment located near the northwest corner of the Nevada Test and Training Range (previously known as Nellis Air Force Range) immediately north of Mud Lake. The western Mud Lake Alternative (ML1) would pass about 1.5 miles (2.5 kilometers) northwest of Mud Lake avoiding its western shoreline, and would extend southward to reconnect with a common segment. This alternative is about 3 miles (5 kilometers) in length.

The eastern Mud Lake Alternative (ML2) also would skirt Mud Lake to avoid its western shoreline and would reconnect with the same common segment as the western Mud Lake Alternative. This alternative is about 4 miles (6.5 kilometers) in length.

*Goldfield*

There are two alternatives associated with Goldfield. The western Goldfield Alternative (GF1), from its connection to Alternative ML1, would extend southward into the Goldfield Hills area passing about 1 mile (1.5 kilometers) east of Black Butte. This alternative would then turn east to pass about 1 mile (1.5 kilometers) northeast of Espina Hill and then would bear south to pass about 1 mile (1.5 kilometers) east of Blackcap Mountain. Alternative GF1 would then continue in a southerly direction following an abandoned rail line to reconnect to a common segment located about 2.5 miles (4 kilometers) north-northeast of Ralston, Nevada. This alternative is about 25 miles (41 kilometers) in length.

From its connection with Alternative ML2, the eastern Goldfield Alternative (GF2) would extend south-southeast into the Nevada Test and Training Range, and then would emerge from the Range turning southwest to converge with the western Goldfield Alternative (GF1) as it enters Stonewall Flat. This alternative is about 22 miles (35.5 kilometers) in length.

DOE is aware of concerns raised by the Department of Defense and the U.S. Air Force regarding the alternatives that intersect the Nevada Test and Training Range lands, and will consult with the Department of Defense and the U.S. Air Force during the Rail Alignment EIS process to ensure the transportation alignment selected does not compromise public safety, national security interests, or training and testing at the Nevada Test and Training Range.

*Bonnie Claire*

Bonnie Claire comprises two alternatives that would depart a common segment located about 3.3 miles (5.5 kilometers) southeast of Lida Junction, Nevada. The western Bonnie Claire Alternative (BC1) would follow an abandoned rail line to cross U.S. 95 about 1 mile (1.5 kilometers) south of Stonewall Pass, and would then trend southeast paralleling U.S. 95 on the west across Sarcobatus Flat. This alternative would then cross State Route 267 about 1.5 miles (2.5 kilometers) southwest of Scotty's Junction, continuing southeasterly until crossing U.S. 95 again on the eastern edge of Sarcobatus Flat about 14 miles (22.5 kilometers) northwest of Springdale, Nevada. This alternative is about 22 miles (35.5 kilometers) in length.

The eastern Bonnie Claire Alternative (BC2) would parallel the contours of Stonewall Mountain to the southeast and would then extend south, adjacent to the western edge of Pahute Mesa. This alternative would then parallel the northern side of U.S. 95 about 1 mile (1.5 kilometers) until it converges with the western Bonnie Claire Alternative (BC1) on the eastern edge of Sarcobatus Flat. This alternative is about 25.5 miles (41 kilometers) in length.

DOE is aware of concerns raised by the Department of Defense and the U.S. Air Force regarding the alternatives that intersect the Nevada Test and Training Range lands, and will consult with the Department of Defense and the U.S. Air Force during the Rail Alignment EIS process to ensure the transportation alignment selected does not compromise public safety, national security interests, or training and testing at the Nevada Test and Training Range.

*Oasis Valley*

Oasis Valley includes two alternatives that would avoid naturally-occurring springs. Both alternatives would depart a common segment about 2 miles (3 kilometers) east-northeast of Oasis Mountain. Alternative OV1 is about 3 miles (5 kilometers) in length. Alternative OV2, which is about 3.5 miles (5.5 kilometers) in length, would cross Oasis Valley further to the east of Alternative OV1, thereby increasing the distance to the springs.

*Beatty Wash*

The Beatty Wash alternatives would depart from a common segment about 3

miles (5 kilometers) east-northeast of the hot springs north of Beatty and about 2 miles (3 kilometers) north-northeast of Beatty Wash. The eastern Beatty Wash Alternative (BW2) would extend east for about 5 miles (8 kilometers), then turn southward crossing a pass about 1 mile (1.5 kilometers) east of the Silicon and Thompson Mines. Alternative BW2 would then turn south to converge with Alternative BW1 about 4 miles (6.5 kilometers) east-northeast of Merklejoho Peak. This alternative is about 14 miles (22 kilometers) in length.

The western Beatty Wash Alternative (BW1) would extend south from the common segment described for Alternative BW2, crossing Beatty Wash and proceeding to the west of the Silicon and Thompson Mines before reconnecting with a common segment. This alternative is about 8 miles (13 kilometers) in length.

*No Action Alternative*

The No Action Alternative would evaluate the consequences of not constructing a rail line in Nevada for the transportation of spent nuclear fuel, high-level radioactive waste and other materials. Under the No Action Alternative, these materials would be shipped by legal-weight and heavy-haul truck within the State of Nevada to a repository at Yucca Mountain. About 53,000 legal-weight truck and 300 heavy-haul truck shipments of spent nuclear fuel and high-level radioactive waste would be required.

**Environmental Issues and Resources To Be Examined**

To facilitate the scoping process, DOE has identified a preliminary list of issues and environmental resources that it may consider in the Rail Alignment EIS. The list is not intended to be all-inclusive or to predetermine the scope or alternatives of the Rail Alignment EIS, but should be used as a starting point from which the public can help DOE define the scope of the EIS. DOE anticipates incorporating by reference the relevant analyses of the Repository Final EIS, supplemented as appropriate.

- Potential impacts to the concept of multiple use as it applies to public land use planning and management specified by the Federal Land Policy and Management Act of 1976.
- Potential impacts to land use and ownership.
- Potential impacts to plants, animals and their habitats, including impacts to wetlands, and threatened and endangered and other sensitive species.
- Potential impacts to cultural and Native American resources.
- Potential impacts to paleontological resources.
- Potential impacts to the public from noise and vibration.
- Potential impacts to the general public and workers from radiological exposures during incident-free operations of the rail line in Nevada.
- Potential impacts to the general public and workers from radiological exposures from potential accidents during operations of the rail line in Nevada.
- Potential impacts to water resources and floodplains.
- Potential impacts to aesthetic values.
- Potential disproportionately high and adverse impacts to low-income and minority populations (environmental justice).
- Irretrievable and irreversible commitment of resources.
- Compliance with applicable Federal, state and local requirements.

The Department specifically invites comments on the following:

1. Should additional alternatives be considered that might minimize, avoid or mitigate adverse environmental impacts (for example, looking beyond the 0.25 mile wide corridor, avoiding wilderness study areas, Native American Trust Lands, or encroachment on the Nevada Test and Training Range)?
2. Should any of the preliminary alternatives be eliminated from detailed consideration?
3. Should additional environmental resources be considered?
4. Should DOE allow private entities to ship commercial commodities on its rail line?
5. What mitigation measures should be considered?
6. Are there national security issues that should be addressed?

**Schedule**

The DOE intends to issue the Draft Rail Alignment EIS early in 2005 at which time its availability will be announced in the **Federal Register** and local media. A public comment period will start upon publication of the Environmental Protection Agency's Notice of Availability in the **Federal Register**. The Department will consider and respond to comments received on the Draft Rail Alignment EIS in preparing the Final Rail Alignment EIS.

**Other Agency Involvement**

The Department expects to invite the following agencies to be cooperating agencies in the preparation of the Rail Alignment EIS: U.S. Bureau of Land Management, the U.S. Air Force, and the U.S. Surface Transportation Board. These agencies were selected because they have management and regulatory authority over lands traversed by an alternative rail alignment within the Caliente rail corridor, or special expertise germane to the construction and operation of a rail line. DOE will consult with the U.S. Bureau of Indian Affairs, U.S. Army Corps of Engineers, U.S. Fish and Wildlife Service, U.S. Nuclear Regulatory Commission, Native American Tribal organizations, the State of Nevada, and Nye, Lincoln and Esmeralda Counties regarding the environmental and regulatory issues germane to the Proposed Action. DOE invites comments on its identification of cooperating and consulting agencies and organizations.

**Public Scoping Meetings**

DOE will hold public scoping meetings on the Rail Alignment EIS. The meetings will be held at the following locations and times:

- Amargosa Valley, Nevada. Longstreet Inn and Casino, Highway 373, May 3, 2004 from 4–8 p.m.
- Goldfield, Nevada. Goldfield Community Center, 301 Crook Street, May 4, 2004 from 4–8 p.m.
- Caliente, Nevada. Caliente Youth Center, U.S. Highway 93, Caliente, Nevada, May 5, 2004 from 4–8 p.m.

The public scoping meetings will be an open meeting format without a formal presentation by DOE. Members of the public are invited to attend the meetings at their convenience any time during meeting hours and submit their comments in writing at the meeting, or in person to a court reporter who will be available throughout the meeting. This open meeting format increases the opportunity for public comment and provides for one-on-one discussions with DOE representatives involved with the Rail Alignment EIS and Nevada transportation project.

The public scoping meetings will be held during the public scoping comment period. The comment period begins with publication of this NOI in the **Federal Register** and closes May 24, 2004. Comments received after this date will be considered to the extent practicable. Written comments may be provided in writing, facsimile, or by email to Ms. Robin Sweeney, EIS Document Manager (see **ADDRESSES** above).

**Public Reading Rooms**

Documents referenced in this Notice of Intent and related information are available at the following locations: Beatty Yucca Mountain Information Center, 100 North E. Avenue, Beatty, NV

89003, (775) 553–2130; Yucca Mountain Information Center, 105 S. Main Street, Goldfield, NV 89013, (775) 485–3419; Las Vegas Yucca Mountain Information Center, 4101–B Meadows Lane, Las Vegas, NV 89107, (702) 295–1312; Lincoln County Nuclear Waste Project Office, 100 Depot Avenue, Caliente, NV 89008, (775) 726–3511; Nye County Department of Natural Resources and Federal Facilities, 1210 E. Basin Road, Suite #6, Pahrump, NV 89060 (775) 727–7727; Pahrump Yucca Mountain Information Center, 1141 S. Highway 160, Suite #3, Pahrump, NV 89041, (775) 727–0896; University of Nevada, Reno, The University of Nevada Libraries, Business and Government Information Center, M/S 322, 1664 N. Virginia Street, Reno, NV 89557, (775) 784–6500, Ext. 309; and the U.S. Department of Energy Headquarters Office Public Reading Room, 1000 Independence Avenue SW., Room 1E–190 (ME–74) FORS, Washington, DC 20585, 202–586–3142.

Issued in Washington, DC, on April 2, 2004.

**Beverly A. Cook,**

*Assistant Secretary, Environment, Safety and Health.*

[FR Doc. 04–7950 Filed 4–7–04; 8:45 am]

**BILLING CODE 6450–01–P**

## ENVIRONMENTAL PROTECTION AGENCY

**[FRL–7642–2]**

## Office of Research and Development; Ambient Air Monitoring Reference and Equivalent Methods: Designation of a New Equivalent Method for $PM_{10}$

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of the designation of a new equivalent method for monitoring ambient air quality.

**SUMMARY:** Notice is hereby given that the Environmental Protection Agency (EPA) has designated, in accordance with 40 CFR part 53, a new equivalent method for measuring concentrations of particulate matter as $PM^{10}$ in the ambient air.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Hunike, Human Exposure and Atmospheric Sciences Division (MD–D205–03), National Exposure Research Laboratory, U.S. EPA, Research Triangle Park, North Carolina 27711. Phone: (919) 541–3737, e-mail: *Hunike.Elizabeth@epa.gov.*

**SUPPLEMENTARY INFORMATION:** In accordance with regulations at 40 CFR part 53, the EPA evaluates various methods for monitoring the concentrations of those ambient air pollutants for which EPA has established National Ambient Air Quality Standards (NAAQSs) as set forth in 40 CFR part 50. Monitoring methods that are determined to meet specific requirements for adequacy are designated by the EPA as either reference methods or equivalent methods (as applicable), thereby permitting their use under 40 CFR part 58 by States and other agencies for determining attainment of the NAAQSs.

The EPA hereby announces the designation of one new equivalent method for measuring concentrations of particulate matter as $PM_{10}$ in ambient air. This designation is made under the provisions of 40 CFR part 53, as amended on July 18, 1997 (62 FR 38764).

The new equivalent method for $PM_{10}$ is an automated method (analyzer) that utilizes a measurement principle based on sample collection by filtration and analysis by beta-ray attenuation. The newly designated equivalent method is identified as follows:

EQPM–0404–151, "Environnement S.A. Model MP101M $PM_{10}$ Beta Gauge Monitor,'' configured with the louvered $PM_{10}$ inlet specified in 40 CFR 50 Appendix L or its flat-topped predecessor version and one of the three optional temperature-regulated sampling tubes (RST), and operated with a full scale measurement range of 0–0.500 mg/$m^3$ (0–500 ug/$\mu m^3$), with the sample flow rate set to 1.00 $m^3$/h and flow regulation set to yes, the "norms selection'' set to $m^3$ (actual volume), the "cycle'' set to 24 hours, the "period'' set to none, and the "counting time'' set to 200 seconds.

An application for an equivalent method determination for this method was received by the EPA on October 3, 2003. The method is available commercially from the applicant, Environnement S.A., 111, Bd Robespierre, 78304 Poissy, Cedex, France *(http://www.environnement-sa.com).*

Test analyzers representative of this method have been tested by the applicant in accordance with the applicable test procedures specified in 40 CFR part 53 (as amended on July 18, 1997). After reviewing the results of those tests and other information submitted by the applicant, EPA has determined, in accordance with part 53, that this method should be designated as an equivalent method. The information submitted by the applicant will be kept on file, either at EPA's National Exposure Research Laboratory, Research Triangle Park, North Carolina 27711 or in an approved archive storage facility, and will be available for inspection (with advance notice) to the extent consistent with 40 CFR part 2 (EPA's regulations implementing the Freedom of Information Act).

As a designated reference or equivalent method, this method is acceptable for use by states and other air monitoring agencies under the requirements of 40 CFR part 58, Ambient Air Quality Surveillance. For such purposes, the method must be used in strict accordance with the operation or instruction manual associated with the method and subject to any specifications and limitations (*e.g.*, configuration or operational settings) specified in the applicable designation method description (see the identification of the method above).

Users of the method should also note that its equivalent method designation applies only to 24-hour average $PM_{10}$ concentration measurements. The Model MP101M Monitor may also provide average $PM_{10}$ concentration measurements over other, shorter averaging periods, including one-hour averages. However, such shorter average concentration measurements may be less precise than the 24-hour measurements and are not required for use in determining attainment under the air quality surveillance requirements of part 58 (although they may be useful for other purposes). Use of the method should also be in general accordance with the guidance and recommendations of applicable sections of the "Quality Assurance Handbook for Air Pollution Measurement Systems, Volume I,'' EPA/600/R–94/038a and "Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II, Part 1,'' EPA–454/R–98–004. Vendor modifications of a designated reference or equivalent method used for purposes of part 58 are permitted only with prior approval of the EPA, as provided in part 53. Provisions concerning modification of such methods by users are specified under section 2.8 (Modifications of Methods by Users) of appendix C to 40 CFR part 58.

In general, a method designation applies to any sampler or analyzer which is identical to the sampler or analyzer described in the application for designation. In some cases, similar samplers or analyzers manufactured prior to the designation may be upgraded or converted (*e.g.*, by minor modification or by substitution of the approved operation or instruction manual) so as to be identical to the designated method and thus achieve designated status. The manufacturer should be consulted to determine the

feasibility of such upgrading or conversion.

Part 53 requires that sellers of designated reference or equivalent method analyzers or samplers comply with certain conditions. These conditions are specified in 40 CFR 53.9 and are summarized below:

(a) A copy of the approved operation or instruction manual must accompany the sampler or analyzer when it is delivered to the ultimate purchaser.

(b) The sampler or analyzer must not generate any unreasonable hazard to operators or to the environment.

(c) The sampler or analyzer must function within the limits of the applicable performance specifications given in 40 CFR parts 50 and 53 for at least one year after delivery when maintained and operated in accordance with the operation or instruction manual.

(d) Any sampler or analyzer offered for sale as part of a reference or equivalent method must bear a label or sticker indicating that it has been designated as part of a reference or equivalent method in accordance with part 53 and showing its designated method identification number.

(e) If such an analyzer has two or more selectable ranges, the label or sticker must be placed in close proximity to the range selector and indicate which range or ranges have been included in the reference or equivalent method designation.

(f) An applicant who offers samplers or analyzers for sale as part of a reference or equivalent method is required to maintain a list of ultimate purchasers of such samplers or analyzers and to notify them within 30 days if a reference or equivalent method designation applicable to the method has been canceled or if adjustment of the sampler or analyzer is necessary under 40 CFR 53.11(b) to avoid a cancellation.

(g) An applicant who modifies a sampler or analyzer previously designated as part of a reference or equivalent method is not permitted to sell the sampler or analyzer (as modified) as part of a reference or equivalent method (although it may be sold without such representation), nor to attach a designation label or sticker to the sampler or analyzer (as modified) under the provisions described above, until the applicant has received notice under 40 CFR part 53.14(c) that the original designation or a new designation applies to the method as modified, or until the applicant has applied for and received notice under 40 CFR 53.8(b) of a new reference or equivalent method determination for the sampler or analyzer as modified.

Aside from occasional breakdowns or malfunctions, consistent or repeated noncompliance with any of these conditions should be reported to: Director, Human Exposure and Atmospheric Sciences Division (MD–E205–01), National Exposure Research Laboratory, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

Designation of this new equivalent method is intended to assist the States in establishing and operating their air quality surveillance systems under 40 CFR part 58. Questions concerning the commercial availability or technical aspects of the method should be directed to the applicant.

**Jewel F. Morris,**

*Acting Director, National Exposure Research Laboratory.*

[FR Doc. 04–7978 Filed 4–7–04; 8:45 am]

BILLING CODE 6560–50–P

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## ENVIRONMENTAL PROTECTION AGENCY

**[FRL–7645–2]**

## Second Meeting of the World Trade Center Expert Technical Review Panel to Continue Evaluation on Issues Relating to Impacts of the Collapse of the World Trade Center Towers; Correction

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of meeting; correction.

**SUMMARY:** The Environmental Protection Agency published a document in the **Federal Register** of March 26, 2004, concerning notice of the second meeting of the World Trade Center Expert Technical Review Panel to provide for greater input on ongoing efforts to monitor the situation for New York residents and workers impacted by the collapse of the World Trade Center. The focus of the second meeting is to discuss a draft resampling proposal to evaluate the incidence of recontamination in apartments cleaned in the EPA cleanup effort around the World Trade Center site. The panel will also begin discussing the appropriateness of the use of asbestos as a surrogate measure for other contaminants of concern. The meeting location has changed because the original venue is out of commission due to water damage.

**FOR FURTHER INFORMATION CONTACT:** For meeting information, registration and logistics, please see the Web site *http://www.epa.gov/wtc/panel* or contact ERG at (800) 803–2833 or (781) 674–7374. The meeting agenda and logistical information will be posted on the web site and will also be available in hard copy. For further information regarding the technical panel, contact Ms. Lisa Matthews, EPA Office of the Science Advisor, telephone (202) 564–4499.

### Correction

In the **Federal Register** of March 26, 2004, in FR Doc. 04–6826, on page 15832, in the first column, correct the "Address'' caption to read:

**ADDRESSES:** The meeting will be held at the Tribeca Performing Arts Center at Borough of Manhattan Community College, Theatre Two, 199 Chambers Street (between West Side Highway/West Street and Greenwich Street), New York, NY 10007.

Dated: April 6, 2004.

**Paul Gilman,**

*EPA Science Advisor and Assistant Administrator for Research and Development.*

[FR Doc. 04–8077 Filed 4–7–04; 8:45 am]

BILLING CODE 6560–50–P

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## ENVIRONMENTAL PROTECTION AGENCY

**[FRL–7644–6]**

## Notice of Availability of Proposed National Pollutant Discharge Elimination System (NPDES) General Permit for Offshore Oil and Gas Exploration, Development and Production Operations off Southern California

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of Availability of Proposed NPDES General Permit (Reissuance).

**SUMMARY:** EPA Region 9 is reopening the public comment period for its general NPDES permit (permit No. CAG280000) for discharges from offshore oil and gas exploration, development and production facilities located in Federal waters off the coast of Southern California. The original public comment period for the permit ran from July 20, 2000 to September 5, 2000 and included a public hearing on August 23, 2000. EPA is now requesting public comment concerning proposed modifications to the July 2000 proposed permit which are primarily the result of a review of the permit by the California Coastal Commission (CCC). The proposed modifications are discussed in more detail below. EPA is not reopening the entire permit for public comment at this time; public comment is only being

requested regarding the specific modifications discussed below.

**DATES:** Comments on the proposed general permit must be received or postmarked no later than May 15, 2004.

**ADDRESSES:** Public comments on the proposed permit should be sent to: Environmental Protection Agency, Region 9, Attn: Lisa Honor, CWA Standards and Permits Office (WTR–5), 75 Hawthorne Street, San Francisco, California 94105–3901.

**FOR FURTHER INFORMATION CONTACT:** Eugene Bromley, EPA, Region 9, CWA Standards and Permits Office (WTR–5), 75 Hawthorne Street, San Francisco, California 94105–3901, or telephone (415) 972–3510. Copies of the proposed general permit and the July 2000 fact sheet and its 2004 addendum will be provided upon request and are also available at EPA, Region 9's Web site at *http://www.epa.gov/region09/water/.*

Administrative Record: The proposed general permit and other related documents in the administrative record are on file and may be inspected any time between 8:30 a.m. and 4 p.m., Monday through Friday, excluding legal holidays, at the following address: U.S. EPA, Region 9, CWA Standards and Permits Office (WTR–5), 75 Hawthorne Street, San Francisco, CA 94105–3901.

**SUPPLEMENTARY INFORMATION:**

A. *Proposed Permit Modifications and Recertification under the CZMA.* On December 20, 2000, EPA submitted a certification under the Coastal Zone Management Act (CZMA) to the CCC that the general permit was consistent with the approved California Coastal Management Plan (CMP). The permit and the consistency certification were considered by the CCC at a meeting held on January 9, 2001. At the January 9, 2001 meeting, EPA agreed to revise the permit/fact sheet in response to concerns raised by the CCC. The modifications were: (1) for produced water discharges, inclusion in the permit of effluent standards based on the more stringent of EPA water quality criteria or California Ocean Plan objectives (both applied at the boundary of the 100-meter mixing zone); (2) revision of the scope and timing of the study requirements in the permit for alternative disposal for certain discharges; and (3) revision of the fact sheet to include a description of a commitment by EPA regarding third party monitoring. With these changes, the CCC concurred that the permit was consistent with the CMP. However, after reconsidering the issue pertaining to produced water, EPA is now proposing to revise the permit to apply Ocean Plan objectives at the seaward boundary of the territorial seas of the State of California for the purpose of calculating effluent limitations. Since this change constitutes a modification of the permit conditions on which the CCC relied when it concurred with EPA's consistency certification in January 2001, EPA submitted the modified permit to the CCC for another CZMA consistency review. EPA recertified the modified permit to the CCC on December 10, 2003 pursuant to section 307(c)(1) of the CZMA, whereas in December 2000, EPA certified the permit pursuant to section 307(c)(3) of the CZMA. The recertification included a proposed permit, fact sheet, Ocean Discharge Criteria Evaluation (ODCE) prepared under section 403(c) of the CWA and various other documents in support of the recertification.

On March 17, 2004, the CCC objected to EPA's consistency certification of December 10, 2003 for the permit. In accordance with 15 CFR 930.31(d), EPA may still issue the permit, but the permit cannot become effective for a given discharger until the CCC concurs with an individual consistency certification submitted by the discharger, or the Secretary of Commerce overrides a CCC objection in accordance with 15 CFR part 930, subpart H. The effective date in today's proposed permit makes allowance for these regulatory requirements.

In addition, EPA is proposing to accelerate the schedule for produced water sampling for determining reasonable potential to exceed applicable water quality criteria. The revised permit would require a total of 12 samples taken during the first year of the permit rather than 10 samples taken during the first 2 ½ years, as was required by the proposed permit for which EPA published a Notice of Availability on July 20, 2000 (65 FR 45063). The revised permit also includes revised maximum discharge volumes for Platforms Harvest, Hermosa and Hidalgo, based on updated information from the operator. Furthermore, the revised permit uses EPA's revised CWA 304(a) water quality criteria found in "National Recommended Water Quality Criteria: 2002 (EPA–822–R–02–047) and 68 FR 75507 (December 31, 2003) for calculating effluent limitations based on dilution achieved at the 100-meter mixing zone. The revised permit also includes a number of minor editorial changes, clarifications and other revisions based on comments which have been received since the July 20, 2000 Notice of Availability was published. These revisions are explained in the Addendum to the Fact Sheet.

EPA is not reopening the entire permit for public comment at this time; public comment is only being requested regarding the proposed modifications noted above. The proposed modifications are discussed in more detail in the Addendum to the Fact Sheet.

The proposed general permit establishes effluent limitations, prohibitions, and other terms and conditions for discharges from facilities operating in the general permit area. The terms and conditions are based on the administrative record. Summary information concerning the terms and conditions of the general permit were provided in EPA's July 20, 2000 notice of proposed permit (65 FR 45063). Additional information is available in the Addendum to the Fact Sheet.

B. *Permit Appeal Procedures.* Within 120 days following notice of EPA's final decision for the general permit under 40 CFR 124.15, any interested person may appeal the permit in the Federal Court of Appeals in accordance with section 509(b)(1) of the Clean Water Act (CWA). Persons affected by a general permit may not challenge the conditions of a general permit as a right in further Agency proceedings. They may instead either challenge the general permit in court, or apply for an individual permit as specified at 40 CFR 122.21 (and authorized at 40 CFR 122.28), and then petition the Environmental Appeals Board to review any condition of the individual permit (40 CFR 124.19 as modified on May 15, 2000, 65 FR 30886).

C. *Executive Order 12866.* Under Executive Order 12866 (58 FR 51735 (October 4, 1993)) the Agency must determine whether the regulatory action is "significant'' and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Order defines "significant regulatory action'' as one that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health, or safety, or State, local, or Tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of 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. OMB has exempted review of NPDES general permits under the terms of Executive Order 12866.

D. *Regulatory Flexibility Act.* The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rule making requirements under the Administrative Procedure Act (APA) or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

Issuance of an NPDES general permit is not subject to rulemaking requirements, under APA section 553 or any other law, and is thus not subject to the RFA requirements. The APA defines two broad, mutually exclusive categories of agency action—"rules'' and "orders.'' Its definition of "rule'' encompasses "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency * * *'' APA section 551(4). Its definition of "order'' is residual: "a final disposition * * * of an agency in a matter other than rule making but including licensing'' APA section 551(6). The APA defines "license'' to "include * * * an agency permit * * *'' APA section 551(8). The APA thus categorizes a permit as an order, which by the APA's definition is not a rule. Section 553 of the APA establishes "rule making'' requirements. The APA defines "rule making'' as "the agency process for formulating, amending, or repealing a rule'' APA section 551(5). By its terms, then, section 553 applies only to "rules'' and not also to "orders,'' which include permits.

E. *Unfunded Mandates Reform Act.* Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their "regulatory actions'' on State, local, and tribal governments and the private sector. UMRA uses the term "regulatory actions'' to refer to regulations. ( *See, e.g.*, UMRA section 201, "Each agency shall * * * assess the effects of Federal regulatory actions * * * (other than to the extent that such regulations incorporate requirements specifically set forth in law)''). UMRA section 102 defines "regulation'' by reference to 2 U.S.C. 658 which in turn defines "regulation'' and "rule'' by reference to section 601(2) of the Regulatory Flexibility Act (RFA). That section of the RFA defines "rule'' as "any rule for which the agency publishes a notice of proposed rulemaking pursuant to section 553(b) of the Administrative Procedure Act (APA)[we only need parentheses around APA], or any other law * * *.''

As discussed in the RFA section of this notice, NPDES general permits are not "rules'' under the APA and thus not subject to the APA requirement to publish a notice of proposed rule making. NPDES general permits are also not subject to such a requirement under the CWA. While EPA publishes a notice to solicit public comment on draft general permits, it does so pursuant to the CWA section 402(a) requirement to provide "an opportunity for a hearing.'' Thus, NPDES general permits are not "rules'' for RFA or UMRA purposes.

F. *Paperwork Reduction Act.* The information collection required by this permit has been approved by Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et. seq., in submission made for the NPDES permit program and assigned OMB control numbers 2040–0086 (NPDES permit application) and 2040–0004 (discharge monitoring reports).

**Authority:** Clean Water Act, 33 U.S.C. 1251 *et seq.*

Dated: March 31, 2004.

**Alexis Strauss,**

*Director, Water Division, Region 9.*

[FR Doc. 04–7977 Filed 4–7–04; 8:45 am]

BILLING CODE 6560–50–P

## FEDERAL ELECTION COMMISSION

### Sunshine Act Notices

**DATE AND TIME:** Tuesday, April 13, 2004 at 10 a.m.

**PLACE:** 999 E Street, NW., Washington, DC.

**STATUS:** This meeting will be closed to the public.

**ITEMS TO BE DISCUSSED:**

Compliance matters pursuant to 2 U.S.C. § 437g.

Audits conducted pursuant to 2 U.S.C. § 437g, § 438(b), and Title 26, U.S.C.

Matters concerning participation in civil actions or proceedings or arbitration.

Internal personnel rules and procedures or matters affecting a particular employee.

**FOR FURTHER INFORMATION CONTACT:** Robert Biersack, Acting Press Officer, Telephone: (202) 694–1220.

**Mary W. Dove,**

*Secretary of the Commission.*

[FR Doc. 04–8124 Filed 4–6–04; 2:56 pm]

BILLING CODE 6715–01–M

## FEDERAL RESERVE SYSTEM

### Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

**AGENCY:** Board of Governors of the Federal Reserve System

**SUMMARY:** Notice is hereby given of the final approval of proposed information collections by the Board of Governors of the Federal Reserve System (Board) under OMB delegated authority, as per 5 CFR 1320.16 (OMB Regulations on Controlling Paperwork Burdens on the Public). Board–approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the OMB 83–I's and supporting statements and approved collection of information instrument(s) 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.

**FOR FURTHER INFORMATION CONTACT:** Acting Federal Reserve Clearance Officer–Michelle Long—Division of Research and Statistics, Board of Governors of the Federal Reserve System, Washington, DC 20551 (202–452–3829).

OMB Desk Officer–Joseph Lackey—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

**Final approval under OMB delegated authority of the extension for three years, without revision, of the following reports:**

*1. Report title:* Money Market Mutual Fund Asset Reports

*Agency form number:* FR 2051a, b

*OMB Control number:* 7100–0012

*Frequency:* Weekly and Monthly

*Reporters:* Money Market Mutual Funds

*Annual reporting hours:* 7,140 hours

*Estimated average hours per response:* 3 minutes (FR 2051a), 12 minutes (FR 2051b)

*Number of respondents:* 2,100 (FR 2051a), 700 (FR 2051b)

*General description of report:* This information collection is voluntary (12 U.S.C. 353 et. seq.) and is given confidential treatment (5 U.S.C. 552(b)(4)).

*Abstract:* The weekly FR 2051a collects data on total shares outstanding for money market mutual funds (MMMFs) and the monthly FR 2051b collects data on total net assets and portfolio holdings for MMMFs. The data are used to construct the monetary aggregates and for the analysis of current money market conditions and banking developments.

*2. Report title:* Uniform Application for Municipal Securities Principal or Municipal Securities Representative Associated with a Bank Municipal Securities Dealer; Uniform Termination Notice for Municipal Securities Principal or Municipal Securities Representative Associated with a Bank Municipal Securities Dealer

*Agency form number:* FR MSD–4, FR MSD–5

*OMB control number:* 7100–0100, 7100–0101

*Frequency:* On occasion

*Reporters:* State member banks, bank holding companies, and foreign dealer banks engaging in activities as municipal securities dealers.

*Annual reporting hours:* 30 (FR MSD–4), 18 (FR MSD–5)

*Estimated average hours per response:* 1.00 (FR MSD–4), 0.25 (FR MSD–5)

*Number of respondents:* 30 (FR MSD–4), 70 (FR MSD–5)

*General description of report:* These information collections are mandatory (15 U.S.C. §§ 78o–4, 78q and 78w) and are given confidential treatment (5 U.S.C. § 552(b)(6)).

*Abstract:* The FR MSD–4 collects information, such as personal history and professional qualifications, on an employee whom the bank wishes to assume the duties of a municipal securities principal or representative. The FR MSD–5 collects the date of, and reason for, termination of such an employee.

*3. Report title:* Notice By Financial Institutions of Government Securities Broker or Government Securities Dealer Activities; Notice By Financial Institutions of Termination of Activities as a Government Securities Broker or Government Securities Dealer.

*Agency form number:* FR G–FIN, FR G–FINW

*OMB control number:* 7100–0224

*Frequency:* On occasion

*Reporters:* State member banks, foreign banks, uninsured state branches or state agencies of foreign banks, commercial lending companies owned or controlled by foreign banks, and Edge corporations.

*Annual reporting hours:* (FR G–FIN), 1 (FR G–FINW)

*Estimated average hours per response:* 1.00 (FR G–FIN), 0.25 (FR G–FINW)

*Number of respondents:* 25 (FR G–FIN), 4 (FR G–FINW)

*General description of report:* These information collections are mandatory (15 U.S.C. 78o–5(a)(1)(B)) and are not given confidential treatment.

*Abstract:* The Government Securities Act of 1986 (the Act) requires financial institutions to notify their appropriate regulatory authority of their intent to engage in government securities broker or dealer activity, to amend information submitted previously, and to record their termination of such activity. The Federal Reserve uses the information in its supervisory capacity to measure compliance with the Act.

Board of Governors of the Federal Reserve System, April 2, 2004.

**Jennifer J. Johnson,**

*Secretary of the Board.*

[FR Doc. 04–7991 Filed 4–7–04; 8:45 am]

BILLING CODE 6210–01–S

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## FEDERAL RESERVE SYSTEM

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Board of Governors of the Federal Reserve System.

**SUMMARY:** 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–I's 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 Proposal**

The following information collection, which is being handled under this delegated authority, has received initial Board approval and are hereby published for comment. At the end of the comment period, the proposed information collection, 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 June 7, 2004.

**ADDRESSES:** Comments may be mailed to Ms. Jennifer J. Johnson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, N.W., Washington, DC 20551. However, because paper mail in the Washington area and at the Board of Governors is subject to delay, please consider submitting your comments by e–mail to "**03''regs.comments#64; federalreserve.gov**, or faxing them to the Office of the Secretary at 202–452–3819 or 202–452–3102. Members of the public may inspect comments in Room MP–500 between 9:00 a.m. and 5:00 p.m. on weekdays pursuant to 261.12, except as provided in 261.14, of the Board's Rules Regarding Availability of Information, 12 CFR 261.12 and 261.14.

A copy of the comments may also be submitted to the OMB desk officer for the Board: Joseph Lackey, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3208, Washington, DC 20503.

**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.

Acting Federal Reserve Clearance Officer – Michelle Long—(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, without revision, of the following report:**

*Report title:* Notice of Branch Closure
*Agency form number:* 4031
*OMB control number:* 7100–0264
*Frequency:* on occasion
*Reporters:* state member banks
*Annual reporting hours:* 783
*Estimated average hours per response:* 2 hours for reporting requirements; 1 hour for disclosure requirements; 8 hours for recordkeeping requirements
*Number of respondents:* 239
*General description of report:* This information collection is mandatory (12 U.S.C. 1831r–l(a)(1)) and may be given confidential treatment upon request (5 U.S.C. § 552(b)(4)).

*Abstract:* The mandatory reporting, recordkeeping, and disclosure requirements regarding the closing of any branch of an insured depository institution are imposed by section 228 of the Federal Deposit Insurance Corporation Improvement Act of 1991 (FDICIA). There is no reporting form associated with the reporting portion of this information collection; state member banks notify the Federal Reserve by letter prior to closing a branch. The Federal Reserve uses the information to fulfill its statutory obligation to supervise state member banks.

Board of Governors of the Federal Reserve System, April 2, 2004.

**Jennifer J. Johnson,**

*Secretary of the Board.*

[FR Doc. E4–783 Filed 4–7–04; 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 April 22, 2004.

**A. Federal Reserve Bank of St. Louis** (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166–2034:

*1. Ann L. Sharp Trust with J. Baxter Sharp III, as trustee*, both of Brinkley, Arkansas; to retain voting shares of Clarendon Holding Co., Clarendon, Arkansas, and thereby indirectly retain voting shares of The Merchants & Planters Bank, Clarendon, Arkansas.

Board of Governors of the Federal Reserve System, April 2, 2004.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. E4–785 Filed 4–7–04; 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 website 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 May 3, 2004.

**A. Federal Reserve Bank of New York** (Jay Bernstein, Bank Supervision Officer) 33 Liberty Street, New York, New York 10045–0001:

*1. First Bancorp*, San Juan, Puerto Rico; to acquire certain shares of common stock of PanAmerican Bancorp, Hollywood, Florida, and thereby indirectly acquire PanAmerican Bank, Hollywood, Florida.

**B. Federal Reserve Bank of St. Louis** (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166–2034:

*1. Harrodsburg First Financial Bancorp, Inc.*, Harrodsburg, Kentucky; to merge with Independence Bancorp, New Albany, Indiana, and thereby indirectly acquire Independence Bank, New Albany, Indiana.

Board of Governors of the Federal Reserve System, April 2, 2004.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. E4–784 Filed 4–7–04; 8:45 am]

BILLING CODE 6210–01–S

## FEDERAL RESERVE SYSTEM

### Notice of Proposals To Engage in Permissible Nonbanking Activities or To Acquire Companies That Are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y (12 CFR part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the

question whether the proposal complies with the standards of section 4 of the BHC Act. 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 the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than April 22, 2004.

**A. Federal Reserve Bank of New York** (Jay Bernstein, Bank Supervision Officer) 33 Liberty Street, New York, New York 10045–0001:

*1. National Australia Bank Limited*, Melbourne, Australia; to engage *de novo* indirectly through National Americas Investment, Inc., MSRA Holdings, Inc., both of Jacksonville, Florida, and National Americas Capital Investments LLC, New York, New York, in leasing personal or real property in connection with structured finance and special finance services to large corporate and institutional clients, pursuant to section 225.28(b)(3) of Regulation Y.

Board of Governors of the Federal Reserve System, April 2, 2004.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. E4–786 Filed 4–7–04; 8:45 am]

BILLING CODE 6210–01–S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

**[Document Identifier: OS–0990–0243]**

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* Revision of a Currently Approved Collection.

*Title of Information Collection:* OCR Pre-grant Data Request Package.

*Form/OMB No.:* OS–0990–0243.

*Use:* Health care providers who have requested certification to participate in the Medicare program must review their policies/practices and submit documents to demonstrate compliance with the civil rights requirements of Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973 and the Age Discrimination Act of 1975.

*Frequency:* Recordkeeping, Single time.

*Affected Public:* Business or other for profit; state, local or tribal government.

*Annual Number of Respondents:* 4,000.

*Total Annual Responses:* 4,000.

*Average Burden Per Response:* 16 hours.

*Total Annual Hours:* 64,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access the HHS Web site address at *http://www.hhs.gov/oirm/ infocollect/pending/* or e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *naomi.cook@hhs.gov,* or call the Reports Clearance Office on (202) 690–6162. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer at the address below: OMB Desk Officer: Brenda Aguilar, OMB Human Resources and Housing Branch, Attention: (OMB #0990–0243), New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: March 30, 2004.

**Robert E. Polson,**

*Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.*

[FR Doc. 04–7927 Filed 4–7–04; 8:45 am]

BILLING CODE 4168–17–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Toxic Substances and Disease Registry

### Program To Build Capacity To Conduct Environmental Medicine and Health Education Activities

*Announcement Type:* New.

*Funding Opportunity Number:* 04079.

*Catalog of Federal Domestic Assistance Number:* 93.161.

*Key Dates: Application Deadline:* June 7, 2004.

*Executive Summary:* This program announcement is intended to increase professional and lay health education services, and build environmental medicine capacity, to inform and educate national professional organizations engaged in clinical healthcare practice, their members and constituent stakeholders, and other Agency for Toxic Substances and Disease Registry (ATSDR) partners working to assist communities to cope with environmental contamination.

### I. Funding Opportunity Description

**Authority:** This program is authorized under Sections 104(i) (14) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA) [42 U.S.C. 9604(i) (14)].

*Purpose:* The purpose of the program is to provide professional and lay health education services, and build capacity for increased subject matter expertise, in environmental medicine among national professional organizations engaged in clinical healthcare practice, their members and constituent stakeholders, and other ATSDR partners working to assist communities to cope with environmental contamination. This program addresses the "Healthy People 2010'' focus area of Educational and Community-Based Programs, Environmental Health, and Age-Related Objectives for Children.

Measurable outcomes of the program will be in alignment with one or more of the following performance goals for the ATSDR: (1) Prevent ongoing and future exposures and resultant health effects from hazardous waste sites and releases; (2) mitigate the risks of human health effects at toxic waste sites with documented exposures; and (3) build and enhance effective partnerships.

*Activities:* Awardee activities for this project are as follows:

*Required Recipient Activities:*

- Assemble and communicate information on educational products, services, and capacity enhancements (*e.g.*, training, resource materials, practice aids, technical assistance, *etc.*) needed to improve the practice of environmental medicine and health education among the applicant's national organizational members and its constituent partners in environmental medicine.
- Develop, implement, and evaluate products, services, and capacity

enhancements provided to improve the practice of environmental medicine and health among the applicant's members and its constituent partners, including healthcare clinicians, environmental health educators, and other ATSDR constituents. Such activities should include information about the unique vulnerabilities and special needs of children where appropriate.

- Provide all educational products and, when appropriate, other services and capacity enhancements in an electronic format for distribution and use through the Internet and/or other technology-centered forms of information transfer.
- Evaluate the effectiveness and impact of the educational products, services, and capacity enhancements through the practices of environmental medicine and environmental health education.
- Attend and participate in the annual ATSDR Partners Meeting normally held in Atlanta, Georgia, including assisting in planning and presenting program activities and evaluation results.

*Optional Recipient Enhancement Activities:*

- Provide site-specific consultation and capacity building activities specific to environmental medicine and health education capabilities in ATSDR-served community sites that are concerned with chemical contamination.

In a cooperative agreement, ATSDR staff is substantially involved in the project activities, above and beyond routine grant monitoring.

*ATSDR Activities for this project are as follows:*

- Provide technical assistance in identifying the constituent and organizational member needs for environmental medicine and health education resources.
- Provide information, instructional resources, technical assistance and collaboration needed to work effectively in communities dealing with known contamination.
- Assist in the development of the evaluation plans that address the effectiveness and impact of the overall project.
- Provide assistance in establishing communication and resource networks between applicants and such partners as other federal agencies, state and local health departments, tribal governments, environmental and health professional non-governmental organizations, and academic, medical, and clinical associations.
- Provide technical assistance and collaboration in the dissemination of resource materials, including assistance to apply distance learning outreach, consultation, and training.
- Assist in providing training related to exposure assessment, health concerns response, and community involvement in contaminated sites.

## II. Award Information

*Type of Award:* Cooperative agreement.

ATSDR involvement in this program is listed in the Activities Section above.

*Fiscal Year Funds:* 2004.

*Approximate Total Funding:* $115,000.

*Approximate Number of Awards:* One-two.

*Approximate Average Award:* $115,000 (This amount is for the first 12-month budget period, and includes both direct and indirect costs.)

*Floor of Award Range:* $70,000.

*Ceiling of Award Range:* $115,000.

*Anticipated Award Date:* July 1, 2004.

*Budget Period Length:* 12 months.

*Project Period Length:* Up to five years.

Throughout the project period, ATSDR commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal Government.

## III. Eligibility Information

### *III.1. Eligible Applicants*

Applications may be submitted by public non-profit national member organizations of medical and allied healthcare professionals with subject matter expertise in environmental medicine, clinical practice, and medical consultation as well as experience in environmental health education. Applicants must demonstrate experience and expertise in providing educational products, services, and capacity enhancements (*e.g.* training, resource materials, practice aids, technical assistance, and education of professional and lay audiences) to their organizational members, their constituent partners, and community populations concerned with environmental contamination like those served by ATSDR and its partners.

*Justification for Limitation on Eligibility:* This project engages national expertise in environmental medical assistance to communities, families, and individuals who are threatened or affected by illness from exposures to hazardous substances. Through collaboration with national medical and clinical professional organizations, the field of environmental medicine is stimulated to grow at all levels of the health and medical care system. In addition, national organizations are capable of providing increased local capacity to respond quickly to concerns in contaminated communities across the nation.

### *III.2. Cost Sharing or Matching*

Matching funds are not required for this program.

### *III.3. Other Eligibility Requirements*

If the requested funding amount is greater than the ceiling of the award range, the application will be considered non-responsive and will not be entered into the review process. You will be notified that your application did not meet the submission requirements.

If your application is incomplete or non-responsive to the requirements listed, it will not be entered into the review process. You will be notified that your application did not meet the submission requirements.

**Note:** Title 2 of the United States Code section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, or loan.

## IV. Application and Submission Information

### *IV.1. Address To Request Application Package*

To apply for this funding opportunity use application form PHS 5161. Application forms and instructions are available on the CDC Web site, at the following Internet address: *http://www.cdc.gov/od/pgo/forminfo.htm.*

If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section (PGO–TIM) staff at: 770–488–2700. Application forms can be mailed to you.

### *IV.2. Content and Form of Submission*

*Application:* You must include a project narrative with your application forms. Your narrative must be submitted in the following format:

- Maximum number of pages: 25. If your narrative exceeds the page limit, only the first pages which are within the page limit will be reviewed.
- Font size: 12 point unreduced.
- Paper size: 8.5 by 11 inches.
- Page margin size: One inch.
- Printed only on one side of page.

• Held together only by rubber bands or metal clips; not bound in any other way.

• Double-spaced.

Your narrative should address work required to be conducted over the entire project period, and must include the following items in the order listed:

• Project Plan:

1. *Background:* A brief discussion demonstrating an understanding of issues of chemical and toxic contamination of communities in the United States (U.S.), including disproportionate risk to children and other vulnerable populations.

2. *Target Populations and Their Needs in Environmental Medicine and Health Education:* An explanation of populations (*e.g.*, organizational members, partners, and community residents) that can be reached by the national organization and the perceived needs these populations have for health education services and environmental medicine resources.

3. *Project Goals and Objectives:* This section should provide clearly stated project objectives that are realistic, measurable, and related to program requirements.

4. *Activities and Timeline:* The activities of the project should be clearly presented to demonstrate a sufficient time allocation, and chronology or sequence of events to be conducted. The activities should provide specificity and demonstrate feasibility of the proposed activities in the form of a plan of work and timeline for accomplishing the project activities.

5. *Plan for Collaboration:* The project plan should present the intent and scope of activities that the applicant intends to undertake within his/her membership organization and with key constituent groups as well as the level of interaction intended to occur with the partner networks of ATSDR.

• *Capacity to Influence Clinical Practice in Environmental Medicine and Health Education:* In this section, a discussion of past and present activities that demonstrate a capability to:

1. Plan, conduct, and evaluate clinical practice in environmental medicine and health education initiatives for professional and lay audiences.

2. Provide consultative services in the clinical practice of environmental medicine and health education activities for professional and lay audiences.

3. Develop and deliver resources that support clinical practice in environmental medicine and health education efforts for professional and lay audiences.

4. Demonstrates a history of collaborative environmental health work.

• *Personnel:* This section should address the qualification, experience, and responsibilities of each individual working on the project. Adequate time and effort necessary to provide effective leadership should be demonstrated by the project lead. Any new staffing requirements should be addressed with inclusion of a recruitment plan and position descriptions. Vitas or resumes should be provided for all existing staff.

• *Evaluation Plan:* The project evaluation plan should address the evaluation strategies and methods necessary to measure impacts and outcomes of the project interventions. It should present measures for the overall project and its impact and outcome, such as achievement of stated public health objectives and effect of the project on the stated population. Other project measures may be changes in the knowledge, attitudes, and behaviors or practices of the target population/audience, or professional/community-wide changes intended to occur in programs, policies, or the physical environment that influences the health of the target populations. To the extent possible, the evaluation measures must be objective and quantitative and relate to the performance goals stated in section "B. Purpose'' of this announcement.

• *Budget Justification:* A clearly justified budget narrative that is consistent with the purpose, relates directly to project activities, is clearly justified, and is consistent with intended use of funds is required.

Additional information may be included in the application appendices. The appendices will not be counted toward the narrative page limit. This additional information includes:

• Curriculum Vitas or Resumes.

• Organizational Charts.

• Letters of Support.

You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access *http://www.dunandbradstreet.com* or call 1–866–705–5711.

For more information, see the CDC Web site at: *http://www.cdc.gov/od/pgo/funding/pubcommt.htm.*

If your application form does not have a DUNS number field, please write your DUNS number at the top of the first page of your application, and/or include your DUNS number in your application cover letter.

You must submit a signed original and two copies of your application forms.

Additional requirements that may require you to submit additional documentation with your application are listed in section "VI.2. Administrative and National Policy Requirements.''

*IV.3. Submission Dates and Times*

*Application Deadline Date:* June 7, 2004.

*Explanation of Deadlines:* Applications must be received in the CDC Procurement and Grants Office by 4 p.m. eastern time on the deadline date. If you send your application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If CDC receives your application after closing due to: (1) Carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, you will be given the opportunity to submit documentation of the carriers guarantee. If the documentation verifies a carrier problem, CDC will consider the application as having been received by the deadline.

This program announcement is the definitive guide on application submission address and deadline. It supersedes information provided in the application instructions. If your application does not meet the deadline above, it will not be eligible for review, and will be discarded. You will be notified that your application did not meet the submission requirements.

CDC will not notify you upon receipt of your application. If you have a question about the receipt of your application, first contact your courier. If you still have a question, contact the PGO–TIM staff at: 770–488–2700. Before calling, please wait two to three days after the application deadline. This will allow time for applications to be processed and logged.

*IV.4. Intergovernmental Review of Applications*

Executive Order 12372 does not apply to his program.

*IV.5. Funding Restrictions*

Funding restrictions, which must be taken into account while writing your budget, are as follows:

• Funds may be expended for reasonable program purposes, such as personnel, travel, supplies and services, including contractual.

• ATSDR funding is generally not to be used for the purchase of furniture or equipment.

• The direct and primary recipient in a cooperative agreement program must perform a substantive role in carrying out project activities and not merely serve as a conduit for an award to another party or provider who is an ineligible party.

If you are requesting indirect costs in your budget, you must include a copy of your indirect cost rate agreement. If your indirect cost rate is a provisional rate, the agreement should be less than 12 months of age.

Awards will not allow reimbursement of pre-award costs.

Guidance for completing your budget can be found on the CDC Web site, at the following Internet address: *http://www.cdc.gov/od/pgo/funding/budgetguide.htm.*

*IV.6. Other Submission Requirements*

*Application Submission Address:* Submit the original and two hard copies of your application by mail or express delivery service to: Technical Information Management—PA# 04079, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

Applications may not be submitted electronically at this time.

**V. Application Review Information**

*V.1. Criteria*

You are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals stated in the "Purpose'' section of this announcement. Measures must be objective and quantitative, and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

Your application will be evaluated against the following criteria:

1. Proposed Project—40 Percent

a. Clearly stated understanding of environmental public health problems associated with communities and other locations affected with hazardous contaminations, including any special risks to children as a susceptible population.

b. Clear and reasonable public health goals and clearly stated project objectives that are realistic, measurable, and related to program requirements.

c. Identification of specific target audiences and their needs in clinical practice of environmental medicine and health education.

d. Specificity and feasibility of the proposed timeline for implementing project activities.

e. Appropriateness and thoroughness of the proposed activities for the proposed target groups.

f. Plans for collaborative efforts.

g. Appropriate letters of support.

2. Capability—20 Percent

a. Capability to develop and distribute national guidance in clinical practice of environmental medicine and health education initiatives and the supportive resource materials.

b. Demonstrated ability to plan, conduct, and evaluate clinical practice in environmental medicine and health education activities, including training.

c. Capability to prove consultative services nationally through the organization's membership.

d. Demonstrated ability to collaborate effectively with a variety of public health and clinical partners.

3. Proposed Personnel—20 Percent

a. Ability of the applicant to provide adequate program staff and support staff, including proposed consultants or contractors.

b. Experience and expertise of proposed staff in developing, distributing, implementing, and evaluating clinical guidance in environmental medicine and health education initiatives and the supporting intervention materials.

4. Evaluation Plan—20 Percent

a. Strategies and methods to measure impacts and outcomes of project interventions, such as changes in target population/audience knowledge, attitudes, and behaviors or practices, as well as environmental changes within a community or professional organization.

b. Specific evaluation plan to measure overall project impact and outcome, such as achievement of stated public health objectives and effect of the project on the stated population.

5. Proposed Budget—(Not Scored)

Is the budget reasonable, clearly justified with a budget narrative, and consistent with the intended use of cooperative agreement funds?

*V.2. Review and Selection Process*

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness by ATSDR. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

An objective review panel will evaluate complete and responsive applications according to the criteria listed in the "V.1. Criteria'' section above.

In addition, the following factors may affect the funding decision: Ability to provide site-specific consultation on environmental health concerns in locations where NCEH/ATSDR is assisting communities to cope with hazardous contamination.

*V.3. Anticipated Announcement Award Date: August 1, 2004.*

**VI. Award Administration Information**

*VI.1. Award Notices*

Successful applicants will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and ATSDR. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

*VI.2. Administrative and National Policy Requirements*

**45 CFR Part 74 and Part 92**

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: *http://www.access.gpo.gov/nara/cfr/cfr-table-search.html.*

The following additional requirements apply to this project:

- AR–1 Human Subjects Requirements
- AR–9 Paperwork Reduction Act Requirements
- AR–10 Smoke-Free Workplace Requirements
- AR–11 Healthy People 2010
- AR–12 Lobbying Restrictions
- AR–14 Accounting System Requirements
- AR–15 Proof of Non-Profit Status
- AR–18 Cost Recovery-ATSDR
- AR–19 Third Party Agreements-ATSDR
- *Materials Review:* All materials, including meeting agendas, course notebooks, and fact sheets, developed with cooperative agreement funding

must be reviewed by the ATSDR Project Officer in draft before they are finalized and disseminated. ATSDR will return draft materials with comments within two weeks of receipt. All materials developed with cooperative agreement must contain acknowledgement of funding as follows:

This material was developed under a cooperative agreement from the Agency for Toxic Substances and Disease Registry, U.S. Department of Health and Human Services, with funding from the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) of 1980 as amended by the Superfund Amendment and Reauthorization Act (SARA) of 1986.

All materials developed with cooperative agreement funds will not be copyrighted and will remain in the public domain to encourage wide distribution. ATSDR will receive final paper and electronic copies (electronic files are to be compatible with ATSDR software) of all materials developed by the awardee.

Additional information on these requirements can be found on the CDC Web site at the following Internet address: *http://www.cdc.gov/od/pgo/funding/ARs.htm.*

*VI.3. Reporting Requirements*

You must provide CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:
   a. Current Budget Period Objectives and Activities.
   b. Current Budget Period Financial Progress.
   c. New Budget Period Program Proposed Objectives and Activity.
   d. Detailed Line-Item Budget and Justification.
   e. Additional Requested Information.
   f. Measures of Effectiveness.
2. Financial status report and annual progress report are due 60 after the end of the budget period.
3. Final financial and performance reports, no more than 90 days after the end of the project period.

These reports must be sent to the Grants Management Specialist listed in the "Agency Contacts'' section of this announcement.

**VII. Agency Contacts**

For general questions about this announcement, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770–488–2700.

For program technical assistance, contact: Brenda L. Adams, Project Officer, CPET/PSB/DHEP/ATSDR, 1600 Clifton Road, NE., Mailstop E–33, Atlanta, Georgia 30333, Telephone: 404–498–0513, E-mail: *badams@cdc.gov.*

For budget assistance, contact: Edna Green, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770–488–2743, E-mail: *egreen@cdc.gov.*

Dated: April 2, 2004.

**William P. Nichols, MPA,**

*Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.*

[FR Doc. 04–7940 Filed 4–7–04; 8:45 am]

BILLING CODE 4163–70–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

**[30Day–47–04]**

### Proposed Data Collections Submitted for Public Comment and Recommendations

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) 498–1210. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

**Proposed Project**

Assessment Information about the National Center for Injury Prevention and Control (NCIPC) Publications—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

This project will collect information from Internet users after they order or download a publication from the Web site of the Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Injury Prevention and Control. CDC, National Center for Injury Prevention and Control produces a variety of publications about injury prevention for a range of audiences, from public health professionals to the general public. Publications include reports to Congress, fact books, brochures, research articles, tool kits, and books. Most of these publications are available to the general public, and the chief distribution method is through the CDC, NCIPC Web site, *www.cdc.gov/ncipc.* On the Web site, people can order printed copies or view electronic copies of the publications.

It is critical for CDC to obtain feedback from users of their NCIPC publications, so that the information can be used to identify who uses the publications and how. This will help guide the development of future publications, revisions of current ones, as well as distribution of publications. As part of the effort to gain understanding about the audiences of the CDC, NCIPC publications, information will be collected through a web-based form. CDC, NCIPC Web site users will have the opportunity to fill out the form after ordering, downloading, or reading online publications through the Web site. The form contains questions about the demographic background of the users, how they found the Web site, how they plan to use the publication, their need for publications in other languages, the degree to which the publication offerings were useful to them, and space for their general comments. The results of the forms will be compiled and studied so CDC can better consider the needs of people who use the publications in future publication development, revisions, and distribution plans. The estimated annualized burden is 17,026 hours.

| Respondents | Number of respondents | Number of responses per respondent | Average burden per response (in hrs.) |
|---|---|---|---|
| Form A | 200,000 | 1 | 5/60 |
| Form B | 21,600 | 1 | 1/60 |

Dated: April 1, 2004.

**Alvin Hall,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 04–7937 Filed 4–7–04; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

**[30Day–32–04]**

### Proposed Data Collections Submitted for Public Comment and Recommendations

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) 498–1210. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

**Proposed Project**

Final Evaluation of the Effectiveness of Targeted Lookback for Identifying Transfusion Recipients who receive Blood that may have been Contaminated with Hepatitis C Virus—New—National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC).

In 1998 the Food and Drug Administration (FDA) issued guidelines to blood collection establishments and transfusion services for the notification of persons who received blood or blood components from donors who subsequently tested positive for antibody to hepatitis C virus (anti-HCV) using a licensed multiantigen screening assay. Blood collection establishments were to identify potentially HCV-contaminated blood products and inform transfusion services of these units. The transfusion services made an attempt to notify the recipients of these products and encouraged recipients to be tested for HCV infection. Recently, the FDA revised their original guidance to extend the lookback period for these multiantigen screened donors, and include in the lookback process donors who tested anti-HCV positive using the earlier single-antigen screening assay.[1]

CDC, in collaboration with the FDA, has been charged with the responsibility of evaluating this nationwide notification process. An interim nationwide survey (Evaluation of the Effectiveness of Targeted Lookback for Identifying Transfusion Recipients who receive Blood that may have been Contaminated with Hepatitis C Virus, OMB No. 0920–0462) of blood collection establishments and transfusion services was conducted in December 1999 to determine the progress that had been made to date, and to summarize the lookback results. The objective of this currently proposed study is to resurvey the blood collection establishments and transfusion services to obtain final results and assess the overall effectiveness of the targeted lookback for identifying persons infected with HCV. The evaluation has two specific aims:

1. Determine the effectiveness of targeted lookback for identifying prior transfusion recipients with HCV infection, including the proportion of recipients identified who are still alive, the proportion of those alive who were successfully notified, the proportion of those notified who have already been tested, the proportion of those notified who get tested as a result of the notification, and the proportion of those tested who are HCV positive.
2. Determine the cost-effectiveness of targeted lookback, including resources (person-hours, costs of recipient notification and testing, etc.) utilized by blood collection establishments and transfusion services for implementation of the lookback protocol.

The evaluation will include the following components: (1) A nationwide survey of blood collection establishments; (2) A nationwide survey of transfusion services. The estimated annualized burden is 15,480 hours.

| Survey site | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hrs) |
|---|---|---|---|---|
| Blood Collection Establishment | HCV Targeted Lookback Blood Collection Establishment Final Questionnaire. | 160 | 1 | 3 |
| Transfusion Services | HCV Targeted Lookback Transfusion Service Final Questionnaire. | 5,000 | 1 | 3 |

Dated: April 1, 2004.

**Alvin Hall,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 04–7938 Filed 4–7–04; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Grants for Education Programs in Occupational Safety and Health; Notice of Availability of Funds

*Announcement Type:* New and Competing Continuation.

*Funding Opportunity Number:* RFA OH05–001.

*Catalog of Federal Domestic Assistance Number:* 93.263.

*Key Dates:*

*Letter of Intent Deadline:* None.

*Pre-Application Technical Assistance Conference Call:* May 13, 2004 (see Section VIII of this announcement).

*Application Deadline:* July 1, 2004.

*Executive Summary:* The Centers for Disease Control and Prevention (CDC)

[1] Food and Drug Administration. Guidance For Industry. "Lookback'' for Hepatitis C Virus (HCV): Product Quarantine, Consignee Notification, Further Testing, Product Disposition, and Notification of Transfusion Recipients Based on Donor Test Results Indicating Infection with HCV Rockville, MD: Center for Biologics Evaluation and Research (CBER), December 2001.

announces the availability of fiscal year (FY) 2005 funds for a grant program for institutional training grants in occupational safety and health. The National Institute for Occupational Safety and Health (NIOSH) is mandated to provide an adequate supply of qualified personnel to carry out the purposes of the Occupational Safety and Health Act. Projects are funded to support Occupational Safety and Health Education and Research Center Training Grants (ERCs) and Training Project Grants (TPGs). ERCs are academic institutions that provide interdisciplinary graduate training and continuing education in the industrial hygiene, occupational health nursing, occupational medicine, occupational safety, and closely related occupational safety and health fields. The ERCs also serve as regional resource centers for industry, labor, government, and the public. TPGs are academic institutions that primarily provide single-discipline graduate training in the industrial hygiene, occupational health nursing, occupational medicine, occupational safety, and closely related occupational safety and health fields.

## I. Funding Opportunity Description

**Authority:** This program is authorized under section 670(a) of the Occupational Safety and Health Act [29 U.S.C. 670(a)].

*Purpose:* The purpose of the program is to provide financial assistance to eligible applicants to assist in providing an adequate supply of qualified professional occupational safety and health personnel. This program addresses the "Healthy People 2010'' focus area of Occupational Safety and Health.

Measurable outcomes of the program will be in alignment with the following performance goal for the National Institute for Occupational Safety and Health: Ensure safer and healthier work environments for Americans through information dissemination, knowledge transfer, and training.

*Activities*

In conducting activities to achieve the purpose of this program, the awardee will be responsible for the following activities that define the ERC and TPG programs to be conducted:

1. *All Applicants* are required to provide Measures of Effectiveness that will demonstrate the accomplishment of the various objectives of the grant. Measures must be objective/quantitative and must measure the intended outcomes. These Measures of Effectiveness shall be submitted with the application and shall be an element of evaluation.

2. *ERC Applicants* shall be an identifiable organizational unit within the sponsoring organization. Applicants must plan to conduct the following activities in order to be considered for an award. If the activities are not proposed, the application will be considered non-responsive and will be returned to the applicant without a review.

a. Establish cooperative arrangements with a medical school or teaching hospital (with an established program in preventive or occupational medicine), a school of nursing or its equivalent, a school of public health or its equivalent, or a school of engineering or its equivalent. It is expected that other schools or departments with relevant disciplines and resources shall be represented and shall contribute as appropriate to the conduct of the total program, *e.g.*, epidemiology, toxicology, biostatistics, environmental health, law, business administration, and education. Specific mechanisms to implement the cooperative arrangements between departments, schools/colleges, universities, etc., shall be demonstrated in order to assure that the intended interdisciplinary training and education will be engendered.

b. Designate an ERC Director who possesses a demonstrated capacity for sustained productivity and leadership in occupational health and safety education and training. The Director shall oversee the general operation of the ERC Program and shall, to the extent possible, directly participate in training activities. A Deputy Director shall be responsible for managing the daily administrative duties of the ERC and to increase the ERC Director's availability to ERC staff and to the public.

c. Designate Program Directors who are full-time faculty and professional staff representing various disciplines and qualifications relevant to occupational safety and health that are capable of planning, establishing, and carrying out or administering training projects undertaken by the ERC. Each academic program, as well as the continuing education and outreach program, shall have a Program Director.

d. Designate faculty and staff with demonstrated training and research expertise, appropriate facilities and ongoing training and research activities in occupational safety and health areas.

e. Establish a program for conducting education and training for four core disciplines: Occupational physicians, occupational health nurses, industrial hygienists, and occupational safety personnel. ERC core academic programs are intended to provide multi-level practitioner and research training. Core academic programs should offer masters degrees and, in research institutions, doctoral degrees. There shall be a minimum of five full-time students or full-time equivalent students in each of the core programs and a minimum of three full-time students or full-time equivalent students in each of the component programs, with a goal of a minimum of 30 full-time students (total in all of core and component programs together). ERCs are encouraged to recruit and train minority students to help address the under-representation of minorities among the occupational safety and health professional workforce. Although it is desirable for an ERC to have the full range of core programs, an ERC with a minimum of three academic programs of which two are in the core disciplines is eligible for support providing it is demonstrated that students will be exposed to the principles and issues of all four core disciplines. In order to maximize the unique strengths and capabilities of institutions, consideration will be given to the development of new and innovative academic component programs that are relevant to the occupational safety and health field, *e.g.*, ergonomics, industrial toxicology, occupational injury prevention, occupational epidemiology, health services research, and agricultural safety and health; and to innovative technological approaches to training and education. ERCs must also document that the program covers an occupational safety and health discipline in critical need or meets a specific regional workforce need. Each core program curriculum shall include courses from non-core categories as well as appropriate clinical rotations and field experiences with public health and safety agencies and with labor-management health and safety groups. Where possible, field experience shall involve students representing other disciplines in a manner similar to that used in team surveys and other team approaches. ERCs should address the importance of providing training and education content related to special populations at risk, including minority workers and other sub-populations specified in the National Occupational Research Agenda (NORA) special populations at risk category. Further information regarding NORA may be found at the CDC/NIOSH Internet address: *http://www.cdc.gov/niosh/nora/.*

f. Establish a specific plan describing how trainees in core and component

academic programs will be exposed to the principles of all other occupational safety and health core and allied disciplines. ERCs that apply as a consortium (contracting with other institutional partners) generally have geographic, policy and other barriers to achieving this ERC characteristic and, therefore, must give special, innovative, attention to thoroughly describing the approach for fulfilling interdisciplinary interaction between students.

g. Demonstrate impact of the ERC on the curriculum taught by relevant medical specialties, including family practice, internal medicine, dermatology, orthopedics, pathology, radiology, neurology, perinatal medicine, psychiatry, *etc.,* and on the curriculum of undergraduate, graduate and continuing education of primary core disciplines as well as relevant medical specialties and the curriculum of other schools such as engineering, business, and law.

h. Establish an outreach program to interact with and help other institutions or agencies located within the region. Programs shall be designed to address regional needs and implement innovative strategies for meeting those needs. Partnerships and collaborative relationships shall be encouraged between ERCs and TPGs. Programs to address the under-representation of minorities among occupational safety and health professionals shall be encouraged. Specific efforts should be made to conduct outreach activities to develop collaborative training programs with academic institutions serving minority and other special populations, such as Tribal Colleges and Universities, Historically Black Colleges and Universities, and Hispanic-Serving Institutions. Examples of outreach activities might include: interaction with other colleges and schools within the ERC and with other universities or institutions in the region to integrate occupational safety and health principles and concepts within existing curricula (*e.g.,* Colleges of Business Administration, Engineering, Architecture, Law, and Arts and Sciences); exchange of occupational safety and health faculty among regional educational institutions; providing curriculum materials and consultation for curriculum/course development in other institutions; use of a visiting faculty program to involve labor and management leaders; cooperative and collaborative arrangements with professional societies, scientific associations, and boards of accreditation, certification, or licensure; and presentation of awareness seminars to undergraduate and secondary educational institutions (*e.g.,* high school science fairs and career days) as well as to labor, management and community associations.

i. Establish a specific plan for preparing, distributing and conducting courses, seminars and workshops to provide short-term and continuing education training courses for physicians, nurses, industrial hygienists, safety engineers and other occupational safety and health professionals, paraprofessionals and technicians, including personnel from labor-management health and safety committees, in the geographical region in which the ERC is located. The goal shall be that the training be made available to a minimum of 400 trainees per year representing all of the above categories of personnel, on an approximate proportional basis with emphasis given to providing occupational safety and health training to physicians in family practice, as well as industrial practice, industrial nurses, and safety engineers. Priority shall be given to establishing new and innovative training technologies, including distance learning programs and to short-term programs designed to prepare a cadre of practitioners in occupational safety and health. Where appropriate, it shall be professionally acceptable that Continuing Education Units (as approved by appropriate professional associations) may be awarded. These courses should be structured so that higher educational institutions, public health and safety agencies, professional societies or other appropriate agencies can utilize them to provide training at the local level to occupational health and safety personnel working in the workplace. Further, the ERC shall conduct periodic training needs assessments, shall develop a specific plan to meet these needs, and shall have demonstrated capability for implementing such training directly and through other institutions or agencies in the region. The ERC should establish and maintain cooperative efforts with labor unions, government agencies, and industry trade associations, where appropriate, thus serving as a regional resource for addressing the problems of occupational safety and health that are faced by State and local governments, labor and management.

j. Establish a Board of Advisors representing the user and affected population, including representatives of labor, industry, government agencies, academic institutions and professional associations, shall be established by the ERC. The Board should meet at least annually to advise an ERC Executive Committee and to provide periodic evaluation of ERC activities. The Executive Committee shall be composed of the ERC Director and Deputy Director, academic Program Directors, the Director for Continuing Education and Outreach and others whom the ERC Director may appoint to assist in governing the internal affairs of the ERC.

k. Establish a plan to incorporate research training into all aspects of training and, in research institutions, as documented by on-going funded research and faculty publications, a defined research training plan for training doctoral-level researchers in the occupational safety and health field. The plan will include how the ERC intends to strengthen existing research training efforts, how it will integrate research training activities into the curriculum, field and clinical experiences, how it will expand these research activities to have an impact on other primarily clinically-oriented disciplines, such as nursing and medicine, and how it will build on and utilize existing research opportunities in the institution. Each ERC is required to identify or develop a minimum of one, preferably more, areas of research focus related to work environment problems. Consideration should be given to the CDC/NIOSH priority research areas identified in the National Occupational Health Research Agenda (NORA). The research training plan will address how students will be instructed and instilled with critical research perspectives and skills. This training will emphasize the importance of developing and working on interdisciplinary teams appropriate for addressing a research issue. It should also prepare students with the skill necessary for developing research protocols, pilot studies, outreach efforts to transfer research findings into practice, and successful research proposals. Such components of research training will require the ERCs to strive toward developing the faculty composition and administrative infrastructure essential to being Centers of Excellence in Occupational Safety and Health Research Training that are required to train research leaders of the future. The plan should address the incremental growth of such elements and evaluation of the plan commensurate with funds available. In addition to the research training components, the plan will also include such items as specific strategies for obtaining student and faculty funding, plans for acquiring equipment, if appropriate, and a plan for developing research-oriented faculty.

l. Document evidence of support from other sources, including other Federal

grants, support from States and other public agencies, and support from the private sector including grants from foundations and corporate endowments, chairs, and gifts.

3. *TPG Applicants* must plan to conduct an academic program that covers an occupational safety and health discipline in critical need or meets a specific regional workforce need. There shall be a minimum of three full-time students or full-time equivalent students in each academic program. Applicants should address the importance of providing training and education content related to special populations at risk, including minority and disadvantaged workers. The types of training currently eligible for support are:

a. Graduate training for practice, teaching, and research careers in occupational safety and health. Priority will be given to programs producing graduates in areas of greatest occupational safety and health need. Strong consideration will be given to the establishment of innovative training technologies.

b. Undergraduate and other pre-baccalaureate training providing trainees with capabilities for positions in occupational safety and health professions.

c. Special technical or other programs for long-term training of occupational safety and health technicians or specialists.

## II. Award Information

*Type of Award:* Grant.

*Fiscal Year Funds:* 2005.

*Approximate Total Funding:* $6,500,000. See *Funding Preferences* below for a breakdown of funding and awards by category.

*Approximate Number of Awards:* 20.

*Approximate Average Award:* $656,000 for ERCs and $83,000 for TPGs. (This amount is for the first 12-month budget period, and includes both direct and indirect costs).

*Floor of Award Range:* None.

*Ceiling of Award Range:* None.

*Anticipated Award Date:* July 1, 2005.

*Budget Period Length:* 12 months.

*Project Period Length:* Maximum of 5 years. Throughout the project period, CDC's commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal Government.

*Funding Preferences:* These awards are intended to augment the scope, enrollment, and quality of training programs rather than to replace funds already available for current operations.

*Funding for ERCs:* Approximately $4,660,000 of the total funds available will be utilized as follows:

1. Approximately $3,250,000 is available to award five competing continuation or new ERC grants. This includes a total of $190,000 to augment the support of trainees in occupational medicine residency programs. Awards will range from $500,000 to $800,000 with the average award being $650,000.

2. Approximately $180,000 is available to award three competing continuation or new training grants; two of the awards are planned for $120,000 for Hazardous Substance Academic Training (HSAT) Programs and one of the awards is planned for $60,000 for a Hazardous Substance Training (HST) Program. The awards are to support the development and presentation of continuing education and short courses (HST Programs), and academic curricula (HSAT Programs) for trainees and professionals engaged in the management of hazardous substances. Program support is available for faculty and staff salaries, trainee costs, and other costs to provide training and education for occupational safety and health and other professional personnel engaged in the evaluation, management, and handling of hazardous substances.

3. Approximately $70,000 is available to award one competing continuation or new grant to support the enhancement of the ERC research training mission through the support of pilot project research training programs.

4. Approximately $1,160,000 is available to award five competing continuation or new grants to support the enhancement of the ERC research training mission through the support of National Occupational Research Agenda (NORA) research support programs. The ERCs represent a variety of strengths and approaches that are required in order to promote high quality research in occupational safety and health, and are a major vehicle for the development of future leaders in occupational safety and health research. They are structured to foster development of interdisciplinary research skills that are needed to effectively address the NORA priority areas and are a critical link to practicing occupational safety and health professionals and others to translate research findings into interventions that prevent illness and injury in the workplace. Examples of activities that support the implementation of the National Occupational Research Agenda include: Assessing regional needs for research and research training in NORA areas; providing administrative and technical support for conducting research, including the administrative support of Pilot Project Research Training Programs; coordinating interdisciplinary research among graduate students; training graduate students in research principles, including students whose theses are in NORA priority areas, and training students who become occupational safety and health professionals to implement NORA findings in evidence-based practice; and, administering outreach and continuing education activities that bring NORA-related research findings to those who can effect changes that will reduce worker illness and injury.

*Funding for TPGs:* Approximately $1,200,000 is available to fund fourteen competing continuation or new TPG grants. Awards will range from $40,000 to $250,000, with the average award being $85,000. This includes a total of $75,000 to augment the support of trainees in occupational medicine residency programs. These awards will support academic programs in the core disciplines (*i.e.*, industrial hygiene, occupational health nursing, occupational medicine, and occupational safety and ergonomics) and relevant component programs (*e.g.*, occupational injury prevention, industrial toxicology, and ergonomics).

*Funding for ERCs and TPGs:* Approximately $750,000 is available to fund three competing continuation or new grants for occupational health services research training programs. Awards will range from $200,000 to $290,000, with the average award being $250,000. This program is intended to encourage new occupational health services research training programs and will only support doctoral-level training and trainees.

## III. Eligibility Information

### *III.1. Eligible applicants*

Any public or private non-profit university, college, educational or training institution that has demonstrated competency in the occupational safety and health field and is located in a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, Guam, the Trust Territory of the Pacific Islands, Wake Island, Outer Continental Shelf lands defined in the Outer Continental Shelf Lands Act, Johnston Island, and any other U.S. Territory or Trust Territory not named herein are eligible to apply for an institutional training grant.

*III.2. Cost Sharing or Matching*

Matching funds are not required for this program.

*III.3. Other*

If your application is incomplete or non-responsive to the requirements listed in this section, it will not be entered into the review process. You will be notified that your application did not meet submission requirements.

Applicants must demonstrate competency by providing within the grant application, documentation of faculty training and experience in the occupational safety and health field being proposed, and an approved curriculum with course work in the occupational safety and health field.

**Note:** Title 2 of the United States Code section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, or loan.

## IV. Application and Submission Information

*IV.1. Address To Request Application Package*

To apply for this funding opportunity use application form CDC 2.145A (OMB Number 0920–0261). Application forms and instructions are available on the CDC Web site, at the following Internet address: *http://www.cdc.gov/od/pgo/forminfo.htm.*

If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section (PGO–TIM) staff at: 770–488–2700. Application forms can be mailed to you.

*IV.2. Content and Form of Submission*

*Application:* You must submit a project narrative with your application forms. The narrative must be submitted in the following format:

- Maximum number of pages: 15 pages single-spaced per program. If your narrative exceeds the page limit, only the first pages which are within the page limit will be reviewed.
- Font size: 12 point unreduced.
- Paper size: 8.5 by 11 inches.
- Page margin size: One inch.
- Printed only on one side of page.
- Held together only by rubber bands or metal clips; not bound in any other way.
- Use standard size, black letters that can be clearly copied. Do not use photo reduction. Prepare all graphs, diagrams, tables, and charts in black ink. The application must contain only material that can be photocopied. Do not include course catalogue and course brochures. When additional space is needed to complete any of the items, use plain white paper (8.5 x 11 inches), leave one inch margins on each side, identify each item by its title, and type the name of the program director and the grant number (if the application is a competitive renewal) in the upper right corner of each page. All pages, including Appendices should be numbered consecutively at least one-half inch from the bottom edge.

Your narrative should address activities to be conducted over the entire project period, and must include the items specified in the "Recommended Outline for Preparation of Competing New/Renewal Training Grant Applications (CDC 2.145A)'' available at the CDC Internet address listed in Section IV.1. The budget and budget justification pages will not be counted in the stated page limit. Additional information may be included in the application appendices. The appendices will not be counted toward the narrative page limit.

You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access *http://www.dunandbradstreet.com* or call 1–866–705–5711.

For more information, see the CDC Web site at: *http://www.cdc.gov/od/pgo/funding/pubcommt.htm.*

If your application form does not have a DUNS number field, please write your DUNS number at the top of the first page of your application, and/or include your DUNS number in your application cover letter.

Additional requirements that may require you to submit additional documentation with your application are listed in section *VI.2. Administrative and National Policy Requirements.*

*IV.3. Submission Dates and Times*

*Application Deadline Date:* July 1, 2004.

*Explanation of Deadlines:* Applications must be received in the CDC Procurement and Grants Office by 4 p.m. eastern time on the deadline date. If you send your application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If CDC receives your application after closing due to: (1) Carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, you will be given the opportunity to submit documentation of the carriers guarantee. If the documentation verifies a carrier problem, CDC will consider the application as having been received by the deadline.

This announcement is the definitive guide on application submission address and deadline. It supersedes information provided in the application instructions. If your application does not meet the deadline above, it will not be eligible for review, and will be discarded. You will be notified that your application did not meet the submission requirements.

CDC will not notify you upon receipt of your application. If you have a question about the receipt of your application, first contact your courier. If you still have a question, contact the PGO–TIM staff at: 770–488–2700. Before calling, please wait two to three days after the application deadline. This will allow time for applications to be processed and logged.

*IV.4. Intergovernmental Review of Applications*

Executive Order 12372 does not apply to this program.

*IV.5. Funding Restrictions*

Restrictions, which must be taken into account while writing your budget, are as follows:

- At least 50 percent of the funds awarded for each grant must be used for direct trainee expenses. Post-doctoral trainee support is discouraged with the exception of occupational medicine residents. Under this announcement, only one award will be made to any single institution or organization.
- Trainee appointments for support can only be made for students enrolled in academic programs that have been recommended for approval by NIOSH, as noted in the Summary Statement.
- Indirect costs under the training grant program will be reimbursed at 8 percent of total allowable direct costs exclusive of tuition and related fees, and equipment, or at the actual indirect cost rate, whichever results in a lesser dollar amount.
- Awards will not allow reimbursement of pre-award costs.

Guidance for completing your budget can be found on the CDC Web site, at the following Internet address: *http://www.cdc.gov/od/pgo/funding/budgetguide.htm.*

*IV.6. Other Submission Requirements*

*Application Submission Address:* Submit the original and two hard copies of your application by mail or express delivery service to: Technical Information Management—RFA OH05–001, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

Applications may not be submitted electronically at this time.

**V. Application Review Information**

*V.1. Criteria*

You are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the grant. Measures of effectiveness must relate to the performance goals stated in the "Purpose'' section of this announcement. Measures must be objective and quantitative, and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

Your application will be evaluated against the following criteria:

The Special Emphasis Panel will evaluate each application against the following criteria:

1. *ERC Comprehensive Evaluation Criteria* are as follows:

a. Plans to satisfy the regional needs for training in the areas outlined by the application, including projected enrollment, recruitment and current workforce populations. Special consideration should be given to the development of programs addressing the under-representation of minorities among occupational safety and health professionals. Indicators of regional need should include measures utilized by the ERC such as previous record of training and placement of graduates. The need for supporting students in allied disciplines must be specifically justified in terms of user community requirements.

b. Are plans proposed for day-to-day management, allocation of funds and cooperative arrangements designed to effectively achieve the Characteristics of an Education and Research Center (see Activities: 2. ERC Applicants).

c. The establishment of new and innovative programs and approaches to training and education relevant to the occupational safety and health field and based on documentation that the program meets specific regional workforce needs. In reviewing such proposed programs, consideration should be given to the developing nature of the program and its capability to produce graduates who will meet such workforce needs.

d. Does the curriculum content and design include formalized training objectives, minimal course content to achieve degree, course descriptions, course sequence, additional related courses open to occupational safety and health students, time devoted to lecture, laboratory and field experience, and the nature of specific field and clinical experiences including their relationships with didactic programs in the educational process?

e. Academic training including the number of full-time and part-time students and graduates for each core and component program, the placement of graduates, employment history, and their current location by type of institution (academic, industry, labor, *etc.*). Previous continuing education training in each discipline and outreach activity and assistance to groups within the ERC region.

f. Methods in use or proposed methods for evaluating the effectiveness of training and outreach including the use of placement services and feedback mechanisms from graduates as well as employers, innovative strategies for meeting regional needs, critiques from continuing education courses, and reports from consultations and cooperative activities with other universities, professional associations, and other outside agencies.

g. Competence, experience and training of the ERC Director, the Deputy ERC Director, the Program Directors and other professional staff in relation to the type and scope of training and education involved.

h. Institutional commitment to ERC goals. An example of institutional commitment to the long-term stability of ERC programs is the commitment of tenured or tenure-track faculty positions to each participating academic program.

i. Academic and physical environment in which the training will be conducted, including access to appropriate occupational settings.

j. Is the budget adequate, justified, and consistent with the intended use of the grant funds? This includes a separate budget for the academic staff's time and effort in continuing education and outreach.

k. Evidence of the integration of research experience into the curriculum, and field and clinical experiences. In institutions seeking funds for doctoral level research training, evidence of a plan describing the research and research training the ERC proposes. This should include goals, elements of the program, research faculty and amount of effort, support faculty, facilities and equipment available and needed, and methods for implementing and evaluating the program.

l. Evidence of success in attaining outside support to supplement the ERC grant funds including other Federal grants, support from States and other public agencies, and support from the private sector including grants from foundations and corporate endowments, chairs, and gifts.

m. Evidence of a strategy to evaluate the impact that the ERC and its programs have had on the region served by the Center. Examples could include a continuing education needs assessment and action plan, a workforce needs survey and action plan, consultation and research programs provided to address regional occupational safety and health problems, the impact on primary care practice and training, a program graduate data base to track the employment history and contributions of graduates to the occupational safety and health field, and the cost effectiveness of the program.

n. Past performance based on evaluation of the most recent CDC/NIOSH Peer Review Summary Statement and the grant application Progress Report (Competing Continuation applications only).

2. *ERC Specialty Program Evaluation Criteria are as follows:*

a. Hazardous Substance Training Program in Education and Research Centers:

(1) Relevance of the proposed project to each element of the characteristics of a hazardous substance training program.

(2) Comprehensiveness and soundness of the training plan developed to carry out the proposed activities. This is based on a documented need for the training and evidence to support the approach used to provide the required training. It includes descriptions of the scope and magnitude of the hazardous substance problem in the region served by the ERC and current activities and training efforts.

(3) Education and experience of the Project Director, faculty, and staff assigned to this project with respect to handling, managing or evaluating hazardous substance sites and to the training of professionals in this field.

(4) Creativity and innovation of the project leadership with respect to marketing the courses, structure in attracting trainees and/or providing incentives for training.

(5) Has the applicant considered the work of relevant agencies involved in hazardous substance activities, including EPA, and cooperated with

these agencies in developing and implementing this training program?

(6) Suitability of facilities and equipment available for this project.

(7) Is the budget adequate, justified, and consistent with the intended use of the grant funds?

b. Hazardous Substance Academic Training Program in Education and Research Centers:

(1) Evidence of a needs assessment directed to the overall contribution of the proposed training program toward meeting the needs of the job market, especially within the applicant's region. The needs assessment should consider the regional requirements for hazardous substance training, information dissemination and special industrial, labor or community training needs that may be peculiar to the region.

(2) Evidence of a plan to satisfy regional needs for training in the areas outlined by the application, including Program projected enrollment and recruitment and current workforce populations.

(3) Does the HSAT curriculum content and design include: formalized training objectives; minimal course content to achieve a degree or successful completion of the specialty area requirements; course descriptions; course sequence; additional related courses open to occupational safety and health students; time devoted to lecture, laboratory, and field experience; and the nature of specific field and clinical experiences including their relationships with didactic programs in the educational process?

(4) Evidence that all trainees supported in the HSAT program have successfully completed a 40-hour Hazardous Waste Operations training course, or equivalent, to meet the requirements of 29 CFR 1910.120 (e)(3)(i). This training requirement may be accomplished prior to enrollment in the HSAT program of study.

(5) Previous record of academic and/or short course training delivered in the hazardous substances field, including the number and type of students trained. Previous record of hazardous substances outreach activity and assistance to hazardous substance groups within the ERCs region.

(6) Methods in use or proposed for evaluating the effectiveness of training and services including the use of placement services and feedback mechanisms from graduates as well as employers, student evaluations from academic and continuing education courses, and reports from consultations and cooperative activities with other universities, professional associations, and other outside agencies.

(7) The competence, experience and training of the Program Director and other professional staff in relation to the type and scope of training and education involved.

(8) Institutional commitment to HSAT Program goals.

(9) Academic and physical environment in which the training will be conducted.

(10) Is the budget adequate, justified, and consistent with the intended use of the grant funds? This includes the budget required to support the training courses developed, as well as accounting for the academic staff's time.

(11) Evidence of a plan describing the hazardous substances academic training the Center proposes. This should include goals, elements of the program, faculty and amount of effort, support faculty, facilities and equipment available and needed, and methods for implementing and evaluating the program.

(12) Evidence of success in attaining outside support to supplement the ERC grant funds including other federal grants, support from states and other public agencies, and support from the private sector including grants from foundations and corporate endowments, chairs, and gifts.

(13) Has the applicant collaborated with state and federal agencies having hazardous substance management functions, including the U.S. Environmental Protection Agency, and has the applicant cooperated with the agencies in developing and implementing this program?

c. ERC Pilot Project Research Training Programs:

(1) Relevance of the proposed program, including objectives that are specific and consistent.

(2) Adequacy of the plan proposed to conduct the pilot projects program, including procedures for reviewing and funding projects, the scientific review mechanism, and program quality assurance.

(3) Does the applicant demonstrate collaboration with other research training institutions in the region, including NIOSH Training Project Grantees?

(4) Education and experience of the proposed Research Training Program Director and faculty in the occupational safety and health field, including the utilization of pilot projects as a research training mechanism.

(5) Is the budget adequate, justified, and consistent with the intended use of the grant funds?

(6) Adequacy of the plan to evaluate the effectiveness of the proposed pilot projects program.

(7) Gender and minority issues—Are plans to include women, ethnic, and racial groups adequately developed (as appropriate for the scientific goals of the pilot projects)? (See AR–2, Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research.)

d. ERC NORA Research Support Programs:

(1) Adequacy of a detailed plan at the ERC level that will promote high quality NORA research and research training activities within the ERC and the region.

(2) Does the plan outline the approaches and mechanisms that will be used by the ERC to carry out interdisciplinary research and research training activities?

(3) Education and experience of the proposed Program Director, faculty, and staff in the occupational safety and health research training field.

(4) Academic and physical environment, including laboratories and equipment, in which research training will be conducted.

(5) Is the budget adequate, justified, and consistent with the intended use of the grant funds? Training grant funds may not be used to fund research projects. Some examples of how funds may be used for NORA-related research project technical support include laboratory supplies, training-related equipment, data entry/analysis, and technicians who work on multiple projects and thus enhance faculty ability to carry out training.

3. *TPG Evaluation Criteria* are as follows:

a. Need for training in the program area outlined by the application. This should include documentation of a plan for student recruitment, projected enrollment, job opportunities, regional need both in quality and quantity, and for programs addressing the under-representation of minorities in the profession of occupational safety and health.

b. Potential contribution of the project toward meeting the needs for graduate or specialized training in occupational safety and health.

c. The establishment of new and innovative programs and approaches to training and education relevant to the occupational safety and health field and based on documentation that the program meets specific regional workforce needs. In reviewing such proposed programs, consideration should be given to the developing nature of the program and its capability to produce graduates who will meet such workforce needs.

d. Curriculum content and design which should include formalized

program objectives, minimal course content to achieve degree, course sequence, related courses open to students, time devoted to lecture, laboratory and field experience, nature and the interrelationship of these educational approaches. There should also be evidence of integration of research experience into the curriculum, and field and clinical experiences.

e. Previous records of training in this or related areas, including placement of graduates.

f. Methods proposed to evaluate effectiveness of the training.

g. Degree of institutional commitment: Is grant support necessary for program initiation or continuation? Will support gradually be assumed? Is there related instruction that will go on with or without the grant? An example of institutional commitment to the long-term stability of TPG programs is the commitment of tenured or tenure-track faculty positions to each academic program.

h. Adequacy of facilities (classrooms, laboratories, library services, books, and journal holdings relevant to the program, and access to appropriate occupational settings).

i. Competence, experience, training, time commitment to the program and availability of faculty to advise students, faculty/student ratio, and teaching loads of the program director and teaching faculty in relation to the type and scope of training involved. The program director must be a full-time faculty member.

j. Admission Requirements: Student selection standards and procedures, student performance standards and student counseling services.

k. Advisory Committee: Membership, industries and labor groups represented; how often they meet; who they advise, role in designing curriculum and establishing program need. The Committee should meet at least annually to provide advice and periodic evaluation of TPG activities.

l. Evidence of a strategy to evaluate the impact that the program has had on the region. Examples could include a workforce needs survey and action plan, consultation and research programs provided to address regional occupational safety and health problems, a program graduate data base to track the employment history and contributions of graduates to the occupational safety and health field, and the cost effectiveness of the program.

m. Past performance based on evaluation of the most recent CDC/NIOSH Peer Review Summary Statement and the grant application Progress Report (Competing Continuation applications only).

n. Is the budget adequate, justified, and consistent with the intended use of the grant funds?

4. *ERC and TPG Evaluation Criteria for Occupational Health Services Research Training Programs* are as follows:

a. Evidence of a plan to satisfy the need for training in the area outlined by the application, including projected enrollment, recruitment and job opportunities. Indicators of need may include measures utilized by the Program such as previous record of training and placement of graduates. Indicate the potential contribution of the project toward meeting the need for this specialized training.

b. Are plans included for day-to-day management, allocation of funds and cooperative arrangements designed to effectively achieve the program requirements.

c. Evidence of a plan describing the academic and research training the program proposes. This should include goals, elements of the program, research faculty and amount of effort, support faculty, facilities and equipment available and needed, and methods for implementing and evaluating the program.

d. Does the curriculum content and design include formalized training objectives, minimal course content to achieve degree, course descriptions, course sequence, additional related courses open to students, time devoted to lecture, and clinical and research experience addressing the relationship with didactic programs in the educational process?

e. Is the program effort capable of supporting the number and type of students proposed?

f. Has the program initiated collaborative relationships with external agencies and institutions to expand and strengthen its research capabilities by providing student and faculty research opportunities?

g. Evidence of previous record of training in health services research and occupational safety and health, including placement of graduates and employment history.

h. Does the program document methods in use or proposed methods for evaluating the effectiveness of the training, including the use of feedback mechanisms from graduates and employers, placement of graduates in research positions, research accomplishments of graduates and reports from consultations and cooperative activities with other universities, professional associations, and other outside agencies?

i. Competence, experience and training of the Program Director, faculty and advisors in relation to the type and scope of research training and education involved.

j. Degree of institutional commitment to Program goals.

k. Adequacy of the academic and physical environment in which the training will be conducted, including access to appropriate occupational health research resources.

l. Is the budget reasonable, adequately justified, and consistent with the intended use of the grant funds?

m. Evidence of a plan for establishment of an Advisory Committee, including meeting times, roles and responsibilities.

*V.2. Review and Selection Process*

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness by the National Institute for Occupational Safety and Health. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

The initial peer review will be conducted by a Special Emphasis Panel (SEP) appointed by CDC. SEP members are extramural peer reviewers with occupational safety and health expertise in the program areas under review. An application will be considered a complete document for review purposes. Thus, there will not be any other form of communication between the applicant and the reviewers. In special circumstances, site visits may be made by a SEP for all applications of a given type, but such site visits are not routine or anticipated and will only be conducted where it is essential to observe activities of the applicants that NIOSH determines are necessary for an adequate review. Such site visits would not be for the applicants to add new information or clarify issues in their applications. Each of the review criteria will be addressed and considered by the peer reviewers in assigning the overall priority score, weighting them as appropriate for each application. If an application is deemed responsive, a priority score will be assigned using a range of 100–500 representing adjectival equivalents from outstanding (100) to acceptable (500). Note that an application does not need to be strong in all categories to be judged likely to have a major scientific impact and receive a good priority score.

The secondary peer review will be conducted by the NIOSH Secondary Review Committee which evaluates how the applications will contribute to the purpose for this program as stated at the beginning of this announcement.

*V.3. Anticipated Announcement and Award Dates*

Award notification dates are expected to be June 1, 2005 with award start dates of July 1, 2005.

**VI. Award Administration Information**

*VI.1. Award Notices*

Successful applicants will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

*VI.2. Administrative and National Policy Requirements*

**45 CFR Part 74 and Part 92**

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: *http://www.access.gpo.gov/nara/cfr/cfr-table-search.html.*

The following additional requirements apply to this project:

- AR–1* Human Subjects Requirements
- AR–2* Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR–3* Animal Subjects Requirements
- AR–10 Smoke-Free Workplace Requirements
- AR–11 Healthy People 2010
- AR–12 Lobbying Restrictions

*Applies only to ERC Pilot Project Research Training Program.

Additional information on these requirements can be found on the CDC Web site at the following Internet address: *http://www.cdc.gov/od/pgo/funding/ARs.htm.*

*VI.3. Reporting Requirements*

You must provide CDC with an original, plus two hard copies of the following reports:

1. Initial interim progress report is due December 1, 2004. This report is required on December 1, on an annual basis. The progress report will serve as your non-competing continuation application, and must contain the following elements:

a. Current Budget Period Activities Objectives.

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Budget and justification.

e. Additional Requested Information.

f. Measures of Effectiveness.

2. Financial status report, no more than 90 days after the end of each budget period. The initial report is due September 30, 2006.

3. Final financial and performance reports, no more than 90 days after the end of the project period. These reports must be mailed to the Grants Management or Contract Specialist listed in the "Agency Contacts'' section of this announcement.

**VII. Agency Contacts**

For general questions about this announcement, contact:

Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770–488–2700.

For program technical assistance, contact:

John T. Talty, Program Officer, Office of Extramural Programs, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 4676 Columbia Parkway, Mailstop C–7, Cincinnati, OH 45226–1998, Telephone: (513) 533–8241, E-mail: *jtt2@cdc.gov.*

For financial, grants management, or budget assistance, contact: Cynthia Y. Mitchell, Grants Management Specialist, CDC Procurement and Grants Office, 626 Cochrans Mill Rd., Mailstop P05, Pittsburgh, PA 15236, Telephone: (412) 386–6434, E-mail: *CMitchell@cdc.gov.*

**VIII. Other Information**

A pre-application technical assistance conference call will be held from 2 to 3 p.m. (eastern time) on May 13, 2004, to allow potential applicants the opportunity to ask questions about this announcement. The call in number is 1–866–524–1250, and the participant passcode is 469181.

Dated: April 2, 2004.

**William P. Nichols,**

*Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.*

[FR Doc. 04–7936 Filed 4–7–04; 8:45 am]

BILLING CODE 4163–19–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2004N–0093]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution

**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 requirements governing the registration of producers of drugs and listing of drugs in commercial distribution.

**DATES:** Submit written or electronic comments on the collection of information by June 7, 2004.

**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:** Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

**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 1320.39(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.

**Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution—(21 CFR Part 207)—(OMB Control Number 0910–0045—Extension)**

Under section 510 of the Federal Food, Drug, and Cosmetic Act (the act), (21 U.S.C. 360), FDA is authorized to establish a system for registration of producers of drugs and for listing of drugs in commercial distribution. To implement section 510 of the act, FDA issued part 207 (21 CFR part 207). Under § 207.20, manufacturers, repackers, and relabelers that engage in the manufacture, preparation, propagation, compounding, or processing of human or veterinary drugs and biological products, including bulk drug substances and bulk drug substances for prescription compounding, and drug premixes as well as finished dosage forms, whether prescription or over-the-counter, are required to register their establishment. In addition, manufacturers, repackers, and relabelers are required to submit a listing of every drug or biological product in commercial distribution. Owners or operators of establishments that distribute, under their own label or trade name, a drug product manufactured by a registered establishment are not required to either register or list. However, distributors may elect to submit drug listing information in lieu of the registered establishment that manufactures the drug product. Foreign drug establishments must also comply with the establishment registration and product listing requirements if they import or offer for import their products into the United States.

Under §§ 207.21 and 207.22, establishments, both domestic and foreign, must register with FDA by submitting Form FDA–2656 (Registration of Drug Establishment) within 5 days after beginning the manufacture of drugs or biologicals, or within 5 days after the submission of a drug application or biological license application. In addition, establishments must register annually by returning, within 30 days of receipt from FDA, Form FDA–2656e (Annual Update of Drug Establishment). (Note: This form is no longer mailed to registrants by FDA; updating registration information is estimated in table 1 of this document by the information submitted annually on Form FDA–2656). Changes in individual ownership, corporate or partnership structure location, or drug-handling activity must be submitted as amendments to registration under § 207.26 within 5 days of such changes. Distributors that elect to submit drug listing information must submit Form FDA–2656 to FDA and a copy of the completed form to the registered establishment that manufactured the product to obtain a labeler code. Establishments must, within 5 days of beginning the manufacture of drugs or biologicals, submit to FDA a listing for every drug or biological product in commercial distribution at that time by using Form FDA–2657 (Drug Product Listing). Private label distributors may elect to submit to FDA a listing of every drug product they place in commercial distribution. Registered establishments must submit to FDA drug product listing for those private label distributors who do not elect to submit listing information by using Form FDA–2658 (Registered Establishments' Report of Private Label Distributors).

Under § 207.25, product listing information submitted to FDA by domestic and foreign manufacturers must, depending on the type of product being listed, include any new drug application number or biological establishment license number, copies of current labeling and a sampling of advertisements, a quantitative listing of the active ingredient for each drug or biological product not subject to an approved application or license, the National Drug Code number, and any drug imprinting information.

In addition to the product listing information required on Form FDA–2657, FDA may also require, under § 207.31, a copy of all advertisements and a quantitative listing of all ingredients for each listed drug or biological product not subject to an approved application or license; the basis for a determination, by the establishment, that a listed drug or biological product is not subject to marketing or licensing approval requirements; and a list of certain drugs or biological products containing a particular ingredient. FDA may also request, but not require, the submission of a qualitative listing of the inactive ingredients for all listed drugs or biological products, and a quantitative listing of the active ingredients for all listed drugs or biological products subject to an approved application or license.

Under § 207.30, establishments must update their product listing information by using Form FDA–2657 and/or Form FDA–2658 every June and December or, at the discretion of the establishment, when any change occurs. These updates must include the following information: (1) A listing of all drug or biological products introduced for commercial distribution that have not been included in any previously submitted list, (2) all drug or biological products formerly listed for which commercial distribution has been discontinued, (3) all drug or biological products for which a notice of discontinuance was submitted and for which commercial distribution has been resumed, and (4) any material change in any information previously submitted. No update is required if no changes have occurred since the previously submitted list.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| 21 CFR Section/Form No. | No. of Respondents | Number of Responses per Respondent | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| FDA–2656<br>(Registration of Drug Establishment)<br>207.21<br>207.22<br>207.25<br>207.26<br>207.40 | 18,430 | .36 | 6,700 | 2.50 | 16,750 |
| FDA–2656<br>(Annual Update of Drug Establishment)<br>207.21<br>207.22<br>207.25<br>207.26<br>207.40 | 8,382 | .82 | 6,859 | 2.50 | 17,147.50 |
| FDA–2657<br>(Drug Product Listing)<br>207.21<br>207.22<br>207.25<br>207.30<br>207.31<br>207.40 | 15,530 | 3 | 46,713 | 2.50 | 116,782.50 |
| FDA–2658<br>(Registered Establishments' Report of Private Label Distributors)<br>207.21<br>207.22<br>207.25<br>207.30<br>207.31 | 7,216 | 2.14 | 15,415 | 2.50 | 38,537.50 |
| Total Reporting Burden | | | | | 189,217.50 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: March 29, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–7907 Filed 4–7–04; 8:45 am]

BILLING CODE 4160–01–S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2003N–0463]**

### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Infant Formula Requirements

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Infant Formula Requirements'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 13, 2004 (69 FR 1985), 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 0910–0256. The approval expires on March 31, 2007.

A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: April 2, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–8024 Filed 4–7–04; 8:45 am]

BILLING CODE 4160–01–S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2003N–0507]**

### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Experimental Study of Trans Fat Claims on Food

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Experimental Study of Trans Fat Claims on Food'' has been approved by the Office of Management and Budget

(OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of November 10, 2003 (68 FR 63799), 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 0910–0533. The approval expires on September 30, 2004. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: April 2, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–8025 Filed 4–7–04; 8:45 am]

**BILLING CODE 4160–01–S**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2004N–0133]**

### Electronic Record; Electronic Signatures; Public Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting to discuss various topics concerning our regulations on electronic records and electronic signatures in part 11 (21 CFR part 11). FDA has begun to re-examine part 11 as it applies to all FDA-regulated products. We will consider the input from the public meeting and comments on the topics presented in this document as we evaluate potential changes to part 11.

**DATES:** The public meeting will be held on June 11, 2004, from 8 a.m. to 4:30 p.m. Submit written or electronic requests to speak plus a presentation abstract by May 12, 2004. Although written or electronic comments on the issues presented in this document will be accepted until July 9, 2004, to have your comments considered at the meeting, submit them by May 12, 2004.

**ADDRESSES:** The public meeting will be held at the National Transportation Safety Board Boardroom and Conference Center, 429 L'Enfant Plaza, SW., Washington, DC 20594, 202–314–6421. The center may be reached by Metro, using the L'Enfant Plaza Station on the green, yellow, blue, and orange lines; for further information see *http://www.ntsb.gov/events/newlocation.htm*. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

You may submit comments, identified by Docket No. 2004N–0133, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.
- E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 2004N–0133 in the subject line of your e-mail message.
- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

*Instructions*: All submissions received must include the agency name and Docket No. for this rulemaking. All comments received will be posted without change to *http://www.fda.gov/dockets/ecomments*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Request for Comments'' heading in the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket*: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/dockets/ecomments* and/or the Division of Dockets Management, 5630 Fishers Lane,rm. 1061, Rockville, MD 20852.

Transcripts of the public meeting will be available for review at the Division of Dockets Management (see **ADDRESSES**) and on the Internet at *http://www.fda.gov/ohrms/dockets*.

**FOR FURTHER INFORMATION CONTACT:**

*For General Information*: Joseph C. Famulare, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 301–827–8940, *part11@cder.fda.gov*; or David Doleski, Center for Biologics Evaluation and Research (HFM–676), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3031, *doleski@cber.fda.gov*; or John Murray, Center for Devices and Radiological Health (HFZ–340), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–4659, *jfm@cdrh.fda.gov*; or Vernon D. Toelle, Center for Veterinary Medicine (HFV–234), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0312, *vtoelle@cvm.fda.gov*; or JoAnn Ziyad, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 202–418–3116, *jziyad@cfsan.fda.gov*; or Scott MacIntire, Office of Regulatory Affairs (HFC–240), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857–1706, 301–827–0386, *smacinti@ora.fda.gov*.

*For Registration Information*: Anne M. Henig, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5576, *heniga@cder.fda.gov*.

**SUPPLEMENTARY INFORMATION:**

### I. Background

Part 11 provides the criteria under which FDA considers electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records, and handwritten signatures executed on paper (62 FR 13430, March 20, 1997). These regulations, which apply to all FDA program areas, were intended to permit the widest possible use of electronic technology, consistent with FDA's responsibility to protect the public health.

After part 11 became effective in August 1997, significant discussions ensued among industry, contractors, and the agency concerning the scope, interpretation, and implementation of the regulations. Concerns were raised that some interpretations of the part 11 requirements would do the following: (1) Unnecessarily restrict the use of electronic technology in a manner inconsistent with FDA's stated intent in issuing the rule, (2) significantly increase the costs of compliance to an extent that was not contemplated at the time the rule was drafted, and (3) discourage innovation and technological advances without providing a

significant public health benefit. In particular, concerns were raised regarding part 11 requirements for validation, audit trails, record retention, record copying, and legacy systems.

As an outgrowth of our current good manufacturing practice (CGMP) initiative for human and animal drugs and biologics, we have begun to re-examine part 11 as it applies to all FDA regulated products. We recently articulated our current thinking on part 11 in the guidance for industry entitled "Part 11, Electronic Records; Electronic Signatures—Scope and Application'' (part 11 guidance) issued on September 5, 2003 (68 FR 52779). We explained in the part 11 guidance that we anticipate rulemaking to change part 11 as a result of our re-examination and that while we are re-examining part 11, we will narrowly interpret the scope of the regulation. By narrowly interpreting the scope of part 11, we mean that fewer records will be considered to be subject to part 11. For those records that remain subject to part 11, we intend to exercise enforcement discretion with regard to part 11 requirements for validation, audit trails, record retention and record copying in the manner described in the part 11 guidance and with regard to all part 11 requirements for systems that were operational before the effective date of part 11 under the circumstances described in the part 11 guidance. As noted in the part 11 guidance, we will enforce all predicate rule requirements[1].

## II. Purpose of Public Meeting

The purpose of the public meeting is to obtain input from the regulated industry and other stakeholders on the topics outlined in this document. Stakeholders include, but are not limited to, manufacturers of products regulated by FDA, suppliers of software products, consultants to regulated industries, and consumer groups.

## III. FDA's Objectives in Re-Examining Part 11

FDA's re-examination of part 11 includes the following objectives:

- To prevent unnecessary controls and costs, yet retain the objectives of the rule.
- To clarify the scope of part 11 (e.g., how it relates to other FDA regulations).
- To ensure that part 11 provides an adequate level of record security, authenticity, and integrity, and encourages innovation and technological advances.
- To further these objectives, we are seeking to accomplish the following:
- Identify areas where part 11 could be less prescriptive and detailed, and
- Clarify the relationship between part 11 and other FDA regulations (predicate rules) with respect to record and recordkeeping requirements.

## IV. Topics for Discussion and Comment

FDA would like public input to assist with our re-examination of part 11. We invite discussion on the scope of part 11, risk-based approaches, validation, audit trails, record retention, record copying, and legacy systems. We present the following specific issues and questions for comment in the public meeting.

### *A. Part 11 Subpart A—General Provisions*

Within the context of subpart A of part 11, we would like interested parties to address the following:

1. In the part 11 guidance document, we clarified that only certain records would fall within the scope of part 11. For example, we stated that under the narrow interpretation of its scope, part 11 would apply where records are required to be maintained under predicate rules or submitted to FDA, and when persons choose to used records in electronic format in place of paper format. On the other hand, when persons use computers to generate paper printouts of electronic records, those paper records meet all the requirements of the applicable predicate rules, and persons rely on the paper records to perform their regulated activities, FDA would generally not consider persons to be "using electronic records in lieu of paper records'' under § 11.2(a) and (b). In these instances, the use of computer systems in the generation of paper records would not trigger part 11. We are interested in comments on FDA's interpretation of the narrow scope of part 11 as discussed in the part 11 guidance and whether part 11 should be revised to implement the narrow interpretation described in the guidance.

2. We are interested in comments on whether revisions to definitions in part 11 would help clarify a narrow approach and suggestions for any such revisions.

3. In the part 11 guidance we announced that we did not intend to take enforcement action to enforce compliance with the validation, audit trail, record retention, and record copying requirements of part 11 in the manner described in the part 11 guidance. We emphasized that records must still be maintained or submitted in accordance with the underlying predicate rules, and the agency could take regulatory action for noncompliance with such predicate rules. We are interested in comments on the need for clarification in part 11 regarding which records are required by predicate rules and are therefore required to be part 11 compliant?

### *B. Part 11 Subpart B—Electronic Records*

Within the context of subpart B, the agency wants to solicit ideas on how to ensure that controls to safeguard records are appropriate and reasonable. There may be instances where persons believe that there are acceptable alternative approaches for implementing controls, with appropriate justification. We want to solicit ideas about how decisions for using alternative controls should be made, such as using a risk assessment. We would like interested parties to address the following:

1. As mentioned previously, the part 11 guidance identified four areas where we do not intend to take enforcement action under the circumstances described in the part 11 guidance, including the validation, audit trail, record retention, and record copying requirements of part 11. The part 11 guidance further recommends that decisions on whether or not to implement part 11 requirements on validation, audit trail, record retention, and record copying should be based on a justified and documented risk assessment and a determination of the potential of the system to affect product quality and safety, and record integrity. We are interested in comments on whether there are other areas of part 11 that should incorporate the concept of a risk-based approach, detailed in the part 11 guidance (e.g., those that require operational system and device checks).

2. Is additional clarity needed regarding how predicate rule requirements related to subpart B can be fulfilled?

3. Under the current part 11, the controls that apply to electronic records that are maintained also apply to electronic records that are submitted to FDA. Should the requirements for electronic records submitted to FDA be separate from electronic records maintained to satisfy predicate rule requirements?

4. The controls for electronic records in subpart B distinguish between open systems (an environment where system access is not controlled by persons who are responsible for the content of electronic records that are on the system) and closed systems (an environment where system access is

[1] As noted in the part 11 guidance, the underlying requirements set forth in the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and FDA regulations (other than part 11) are referred to as "predicate rules.''

controlled by persons who are responsible for the content of electronic records that are on the system). Should part 11 continue to differentiate between open systems and closed systems?

For individual controls in subpart B, we request comments on the following:

1. The part 11 guidance identified validation as one of the four areas where we intend to exercise enforcement discretion in the manner described in the guidance. Should we retain the validation provision under § 11.10(b) required to ensure that a system meets predicate rule requirements for validation?

2. The part 11 guidance identified record retention and record copying requirements as areas where we plan to exercise enforcement discretion in the manner described in the part 11 guidance. Are there any related predicate rule requirements that you believe are necessary to preserve the content and meaning of records with respect to record copying and record retention? What requirements would preserve record security and integrity and ensure that records are suitable for inspection, review, and copying by the agency?

3. Should audit trail requirements include safeguards designed and implemented to deter, prevent, and document unauthorized record creation, modification, and deletion?

4. Section 11.10(k) requires appropriate controls over systems documentation. In light of how technology has developed since part 11 became effective, should part 11 be modified to incorporate concepts, such as configuration and document management, for all of a system's software and hardware?

*C. Part 11 Subpart C—Electronic Signatures*

Within the context of subpart C, we would like interested parties to address the following: Section 11.10(d) requires that system access be limited to authorized individuals, but it does not address the handling of security breaches where an unauthorized individual accesses the system. Should part 11 address investigations and followup when these security breaches occur?

*D. Additional Questions for Comment*

In addition, we invite comment on the following questions:

1. What are the economic ramifications of modifying part 11 based on the issues raised in this document?

2. Is there a need to clarify in part 11 which records are required by predicate rules where those records are not specifically identified in predicate rules? If so, how could this distinction be made?

3. In what ways can part 11 discourage innovation?

4. What potential changes to part 11 would encourage innovation and technical advances consistent with the agency's need to safeguard public health?

5. What risk-based approaches would help to ensure that electronic records have the appropriate levels of integrity and authenticity elements and that electronic signatures are legally binding and authentic?

6. The part 11 guidance announced that the agency would exercise enforcement discretion (during our re-examination of part 11) with respect to all part 11 requirements for systems that otherwise were operational prior to August 20, 1997 (legacy systems), the effective date of part 11. What are stakeholder concerns in regards to modifications made to legacy systems in use as of August 1997?

Can the use of risk mitigation and appropriate controls eliminate concerns regarding legacy systems?

7. Should part 11 address record conversion?

8. Are there provisions of part 11 that should be augmented, modified, or deleted as a result of new technologies that have become available since part 11 was issued?

## V. Registration and Requests for Oral Presentations

Preregistration is not necessary if you are not speaking and plan only to attend. However, seating is limited and will be available on a first-come first-served basis.

To speak at the public meeting, you must preregister by May 12, 2004. Requests must be submitted electronically or in writing (see **ADDRESSES**). In your request to speak, you should provide the following information: (1) Specific issue that you intend to address; (2) names and addresses of all individuals that plan to participate; and (3) presentation abstract. Presentations should be limited to the topics addressed in this document. We will accept requests to speak based on the number of requests we receive, time constraints, and subjects covered. We will notify speakers of the scheduled time for their presentation before the meeting. Depending on the number of speakers, we may need to limit the time allotted for each presentation; at this point speakers should plan to limit their oral presentations to no more than 15 minutes. Speakers must submit two copies of each presentation by June 11, 2004. If you need special accommodations due to a disability, please inform the registration contact person at least 7 days in advance of the meeting.

## VI. Request for Comments

Regardless of attendance at the public meeting, interested persons may submit written or electronic comments on the topics presented in this document by July 9, 2004, to the Division of Dockets Management (see **ADDRESSES**). You should annotate and organize your comments to identify the specific sections of part 11 and/or topics to which they refer. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The received comments may be seen at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Transcripts of the public meeting also will be available for review at the Division of Dockets Management.

Dated: April 2, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–7942 Filed 4–7–04; 8:45 am]

BILLING CODE 4160–01–S

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Use of Radiolabeled Platelets for Assessment of In Vivo Viability of Platelet Products; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Use of Radiolabeled Platelets for Assessment of the In Vivo Viability of Platelet Products''. The goal of the workshop is to orient the transfusion community to a new approach for assessing the quality of platelet products through radiolabeling studies in healthy human volunteers.

*Date and Time*: The public workshop will be held on May 3, 2004, from 8 a.m. to 5 p.m.

*Location*: The public workshop will be held at Lister Hill Auditorium, Building 38A, National Institutes of Health, 8600 Rockville Pike, Bethesda, MD 20894.

*Contact Person*: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM–302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6129, FAX: 301–827–2843, e-mail: *wilczek@cber.fda.gov*.

*Registration*: Send registration information (including name, title, firm name, address, telephone, and fax number) to the contact person by April 23, 2004. Early registration is recommended because seating is limited to 176 participants. Registration will be done on a space available basis on the day of the workshop, beginning at 7:15 a.m. There is no registration fee.

If you need special accommodations due to a disability, please contact Joseph Wilczek (see *Contact Person*) at least 7 days in advance.

**SUPPLEMENTARY INFORMATION:** FDA, in co-sponsorship with the Hitchcock Foundation, is sponsoring a public workshop on the development of a new standard for assessing the in vivo quality of platelet products through radiolabeling studies. The workshop objectives are to review current methods in radiolabeling studies, to propose a new approach that will set the performance of fresh platelets as a gold standard, to present data on application of a new standard, and to discuss the development of a novel experimental protocol. The public workshop agenda is posted on FDA's Internet at *http://www.fda.gov/cber/meetings/radioplt0504.htm*.

*Transcripts*: Transcripts of the workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. In addition, the transcript will be placed on FDA's Internet at *http://www.fda.gov/cber/minutes/workshop-min.htm*.

Dated: April 2, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–8023 Filed 4–7–04; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2004D–0160]**

### Guidance for Industry: Use of Unapproved Hormone Implants in Veal Calves; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (#172) entitled "Use of Unapproved Hormone Implants in Veal Calves.'' This guidance outlines special measures to ensure the safety of veal in response to the identified illegal use of unapproved hormone implants in veal calves.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written comments on the guidance 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*. Comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the document.

Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

**FOR FURTHER INFORMATION CONTACT:** Gloria J. Dunnavan, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–1168, e-mail: *gloria.dunnavan@fda.gov*.

**SUPPLEMENTARY INFORMATION:**

#### I. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation in § 10.115 (21 CFR 10.115). It is being implemented immediately without prior public comment, under § 10.115(g)(2), because of the agency's urgent need to provide guidance concerning veal that has been implanted with unapproved hormones. However, under GGPs, FDA requests comments on the guidance and will revise the document, if appropriate. Comments will be considered by the agency in the development of future policy.

This guidance represents the agency's current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statutes and regulations.

#### II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### III. Electronic Access

Copies of this guidance document may be obtained from the CVM home page (*http://www.fda.gov/cvm*) and from the Division of Dockets Management Web site (*http://www.fda.gov/ohrms/dockets/default.htm*).

Dated: April 5, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–8075 Filed 4–6–04; 2:25 pm]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Center for Research Resources; Notice of 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 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 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:* National Center for Research Resources Initial Review Group; Comparative Medicine Review Committee.
*Date:* June 2–3, 2004.
*Open:* June 2, 2004, 8 a.m. to 8:30 a.m.
*Agenda:* To discuss program planning and other issues.
*Place:* Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.
*Closed:* June 2, 2004, 8:30 a.m. to adjournment.
*Agenda:* To review and evaluate grant applications.
*Place:* Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.
*Contact Person:* Guo Zhang, MD, PhD, Scientific Review Administrator, Office of Review, National Center for Research Resources, National Institutes of Health, One Democracy Plaza, 6701 Democracy Blvd., Room WS–1064, 10th Floor, Bethesda, MD 20814–9692, (301) 435–0812, *zhanggu@mail.nih.gov.*

*Name of Committee:* Scientific and Technical Review Board on Biomedical and Behavioral Research Facilities.
*Date:* June 8–11, 2004.
*Open:* June 8, 2004, 8 a.m. to 9 p.m.
*Agenda:* To discuss planning and other issues.
*Place:* Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.
*Closed:* June 8, 2004, 9 a.m. to adjournment.
*Agenda:* To review and evaluate grant applications.
*Place:* Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.
*Contact Person:* Sheryl K. Brining, PhD, Director, Office of Review, National Center for Research Resources, National Institutes of Health, 6701 Democracy Blvd., Rm. 1074, MSC 4874, Bethesda, MD 20892–4874, (301) 435–0809, *sb44k@nih.gov.*

*Name of Committee:* National Center for Research Resources Initial Review Group; Clinical Research Review Committee.
*Date:* June 9–10, 2004.
*Open:* June 9, 2004, 8 a.m. to 8:30 a.m.
*Agenda:* To discuss program planning and other issues.
*Place:* Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.
*Closed:* June 9, 2004, 8:30 a.m. to adjournment.
*Agenda:* To review and evaluate grant applications.
*Place:* Holiday Inn Select Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814.
*Contact Person:* Mohan Viswanathan, PhD, Deputy Director, Office of Review, NCRR, National Institutes of Health, 6701 Democracy Blvd., Room 1084, MSC 4874, 1 Democracy Plaza, Bethesda, MD 20892–4874, 301–435–0829, *mv10f@nih.gov.*

*Name of Committee:* National Center for Research Resources Initial Review Group; Research Centers In Minority Institutions Review Committee.
*Date:* June 23–24, 2004.
*Open:* June 23, 2004, 8 a.m. to 9 a.m.
*Agenda:* To discuss program planning and other issues.
*Place:* Doubletree Rockville Hotel, 1750 Rockville Pike, Rockville, MD 20892.
*Closed:* June 23, 2004, 9 a.m. to addjournment.
*Agenda:* To review and evaluate grant applications.
*Place:* Doubletree Rockville Hotel, 1750 Rockville Pike, Rockville, MD 20892.
*Contact Person:* Eric H. Brown, PhD, Scientific Review Administrator, Office of Review, National Center for Research Resources, National Institutes of Health, 6701 Democracy Boulevard, Room 1068, Bethesda, MD 20892–4874, 301–435–0815, *browne@ncrr.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: April 1, 2004.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04–7986 Filed 4–7–04; 8:45 am]

BILLING CODE 4140–01–M

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Heart, Lung, and Blood Institute; 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/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:* National Heart, Lung, and Blood Institute Special Emphasis Panel, Topical Thalidomide for Aphthous Stomatitis—HIV/AIDS.
*Date:* April 21, 2004.
*Time:* 9 a.m. to 3 p.m.
*Agenda:* To review and evaluate contract proposals.
*Place:* Sheraton Columbia Hotel, 10207 Wincopin Circle, Columbia, MD 21044.
*Contact Person:* David A Wilson, PhD, Scientific Review Administrator, Review Branch, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7204, MSC 7924, Bethesda, MD 20892, 301/435–0929.

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 Heart, Lung, and Blood Institute Special Emphasis Panel, Clinical Trial Nitric Oxide Synthase Inhibition in Cardiogenic Shock.
*Date:* May 3, 2004.
*Time:* 8 a.m. to 5 p.m.
*Agenda:* To review and evaluate grant applications.
*Place:* Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.
*Contact Person:* Judy S Hannah, PhD, Scientific Review Administrator, Review Branch, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7190, Bethesda, MD 20892, 301/435–0287.

(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: March 31, 2004.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04–7924 Filed 4–7–04; 8:45 am]

BILLING CODE 4140–01–M

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## 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 Comprehensive International Program of Research on AIDS (CIPRA).

*Date:* April 20, 2004.

*Time:* 10 a.m. to 2 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:* Roberta Binder, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, NIAID/NIH, 6700B Rockledge Drive, Rm 2155, Bethesda, MD 20892–7616, 301–496–2550, *rb169n@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: March 31, 2004.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04–7916 Filed 4–7–04; 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 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:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel Biodefense and Emerging Infectious Diseases Research Opportunities.

*Date:* April 23, 2004.

*Time:* 10 a.m. to 2 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:* Vassil St. Georgiev, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, Room 2102, 6700–B Rockledge Drive, MSC 7616, Bethesda, MD 20892, (301) 496–2550, *vg8q@nih.gov.*

*Name of Committee:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel Unsolicited Program Project Applications (P01s).

*Date:* June 10, 2004.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

*Contact Person:* Geetha P. Bansal, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, Room 3145, 6700–B Rockledge Drive, MSC 7616, Bethesda, MD 20892, (301) 402–5658, *gbansal@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: March 31, 2004.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04–7917 Filed 4–7–04; 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 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 of Allergy and Infectious Diseases Special Emphasis Panel Large Scale Antibody and T Cell Epitope Discovery Program.

*Date:* May 3–4, 2004.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Kenneth E. Sentora, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, (301) 496–2550, *ks216i@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: March 31, 2004.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04–7919 Filed 4–7–04; 8:45 am]

**BILLING CODE 4140–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Biomedical Imaging and Bioengineering; 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 Biomedical Imaging and Bioengineering Special Emphasis Panel NIBIB Program Project Grants.

*Date:* April 13, 2004.

*Time:* 9 a.m. to 1 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Four Points by Sheraton Bethesda, 8400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Prabha L. Atreya, PhD, Scientific Review Administrator, Office of Scientific Review, National Institute of Biomedical Imaging, and Bioengineering, Bethesda, MD 20892, (301) 496–8633, *atreyap@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.

Dated: March 31, 2004.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04–7920 Filed 4–7–04; 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 Unsolicited Program Project Application.

*Date:* April 26, 2004.

*Time:* 1 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health/NIAID, 6700B Rockledge Drive, Bethesda, MD 20895, (Telephone Conference Call).

*Contact Person:* Edward W. Schroder, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, (301) 435–8537.

(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: March 31, 2004.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04–7921 Filed 4–7–04; 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 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 of Allergy and Infectious Diseases Special Emphasis Panel, TB Vaccine Testing and Research Materials.

*Date:* April 29, 2004.

*Time:* 9 a.m. to 1 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* National Institutes of Health/NIAID, Scientific Review Program, 6700 B Rockledge Drive, Room 3129, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Eleazar Cohen, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, Room 3129, 6700 B Rockledge Drive, Bethesda, MD 20892, (301) 435–3564, *ec17w@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: April 1, 2004.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04–7987 Filed 4–7–04; 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 552(b)(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 cleraly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel, Bioinformatics Integration Support Contract (BISC).

*Date:* April 29–30, 2004.

*Time:* 8 a.m. to 6 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* 6700 B Rockledge Drive, Room 1205, Bethesda, MD 20817.

*Contact Person:* Robert C. Goldman, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, NIAID, NIH, DHHS, Room 3124, 6700–B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, (301) 496–8424, *rg159w@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transportation Reserach; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: April 1, 2004.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04–7988 Filed 4–7–04; 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 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 Mental Health Special Emphasis Panel Translational Approaches to Bipolar Research.

*Date:* May 7, 2004.

*Time:* 9 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:* Benjamin Xu, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Boulevard, Room 6143, MSC 9608, Bethesda, MD 20892–9608. 301–443–1178. *benxu1@mail.nih.gov*.

(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: April 2, 2004.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04–7989 Filed 4–7–04; 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 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 Alcohol Abuse and Alcoholism Special Emphasis Panel; ZAA1 CC (12) L30 Application Reviews.

*Date:* April 20, 2004.

*Time:* 10 a.m. to 12 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, NIAAA/Fisher's Building, 5635 Fishers Lane, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Mahadev Murthy, PhD, Scientific Review Administrator, Extramural Project Review Branch, Office of Scientific Affairs, National Institute on Alcohol Abuse and Alcoholism, 6000 Executive Blvd., Suite 409, Bethesda, MD 20892–7003, (301) 443–2860.

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 Alcohol Abuse and Alcoholism Special Emphasis Panel; Review of R01 Application.

*Date:* April 22, 2004.

*Time:* 12 p.m. to 1 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Dorita Sewell, PhD, Scientific Review Administrator, Extramural Project Review Branch, Office of Scientific Affairs, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 6000 Executive Blvd., Suite 409, Bethesda, MD 20892–7003, 301–443–2890, *dsewell@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. 93.271, 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: April 2, 2004.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04–7990 Filed 4–7–04; 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:* National Library of Medicine Special Emphasis Panel, LRP Review.

*Date:* April 27, 2004.

*Time:* 1 p.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Library of Medicine, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20817 (Telephone Conference Call).

*Contact Person:* Hua-Chuan Sim, MD, Health Science Administrator, National Library of Medicine, Extramural Programs, Bethesda, MD 20892–796.

(Catalogue of Federal Domestic Assistance Program Nos. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: March 31, 2004.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04–7922 Filed 4–7–04; 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:* National Library of Medicine Special emphasis Panel, P41 Review.

*Date:* April 22, 2004.

*Time:* 1 p.m. to 2 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

*Contact Person:* Hua-Chuan Sim, MD, Health Science Administrator, National Library of Medicine, Extramural Programs, Bethesda, MD 20892.

(Catalogue of Federal Domestic Assistance Program Nos. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: March 31, 2004.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04–7923 Filed 4–7–04; 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 Antibody Engineering.

*Date:* April 1, 2004.

*Time:* 9:15 a.m. to 10 a.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Cathleen L. Cooper, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, Department of Health and Human Services, 6701 Rockledge Drive, Room 4208, MSC 7812, Bethesda, MD 20892, (301) 435–3566, *cooperc@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 Biomaterial Engineering Panel.

*Date:* April 7, 2004.

*Time:* 3:30 p.m. to 4:30 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:* Sally Ann Amero, PhD, Scientific Review Administrator, Center for Scientific Review, Genetic Sciences Integrated Review Group, National Institutes of Health, 6701 Rockledge Drive, Room 4190, MSC 7826, Bethesda, MD 20892, (301) 435–1159, *ameros@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 Medical Devices SBIR.

*Date:* April 8, 2004.

*Time:* 11 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:* Jerome R. Wujek, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892, (301) 435–2507, *wujekjer@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 CTLA4 Inhibition and Autoimmunity in Melanoma.

*Date:* April 9, 2004.

*Time:* 3 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:* Mary Bell, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6188, MSC 7804, Bethesda, MD 20892, (301) 451–8754, *bellmar@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 Exploratory/Development (R21) Bioengineering Research Grant.

*Date:* April 14, 2004.

*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:* Marcia Steinberg, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5140, MSC 7840, Bethesda, MD 20892, (301) 435–1023, *steinberm@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 Mitochondria Biology.

*Date:* April 14, 2004.

*Time:* 1:15 p.m. to 2:15 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:* Toby Behar, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4136, MSC 7850, Bethesda, MD 20892, (301) 435–4433, *behart@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 MDCN Member Conflict on Mitochondria.

*Date:* April 14, 2004.

*Time:* 2:15 p.m. to 3:15 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:* 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.*

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 SEP AARR E(05) To Review Member Conflict Application.

*Date:* April 21, 2004.

*Time:* 10 a.m. to 11 a.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Kenneth A Roebuck, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5214, MSC 7852, Bethesda, MD 20892, (301) 435–1166, *roebuckk@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: March 31, 2004.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04–7918 Filed 4–7–04; 8:45 am]

**BILLING CODE 4140–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Prospective Grant of Exclusive License: Dengue Tetravalent Vaccine Containing a Common 30 Nucleotide Deletion in The 3′-UTR of Dengue Types 1,2,3, And 4

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the following invention as embodied in the following patent applications: (1) E–120–2001, Whitehead *et al.,* "Development of Mutations Useful for Attenuating Dengue Viruses and Chimeric Dengue Viruses'', U.S. Provisional Patent Application 60/293,049, filed May 22, 2001, PCT/US02/16308, filed May 22, 2002, U.S. Patent Application 10/719,547, filed November 21, 2003, European Patent Application 02739358.6, filed May 22, 2002, Canadian Patent Application 2448329, filed May 22, 2002, Indian Patent Application 2814DELNP2003, filed May 22, 2002, Australian Patent Application 2002312011, filed May 22, 2002, and Brazilian Patent Application PI0209943.8, filed May 22, 2002, and (2) E–089–2002, "Dengue Tetravalent Vaccine Containing a Common 30 Nucleotide Deletion in The 3′-UTR of Dengue Types 1,2,3, And 4, or Antigenic Chimeric Dengue Viruses 1,2,3, And 4'', U.S. Provisional Applications 60/377,860, filed May 3, 2002, 60/436,500, filed December 23, 2002, PCT/US03/13279, filed April 25, 2003 to MacroGenics, Inc., having a place of business in Rockville, Maryland. The patent rights in this invention have been assigned to the United States of America.

**DATES:** Only written comments and/or application for a license which are received by the NIH Office of Technology Transfer on or before June 7, 2004, will be considered.

**ADDRESSES:** Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Peter Soukas, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; E-mail: *ps193c@nih.gov*; Telephone: (301) 435–4646; Facsimile: (301) 402–0220.

**SUPPLEMENTARY INFORMATION:** The global prevalence of dengue has grown dramatically in recent decades. The disease is now endemic in more than 100 countries in Africa, North and South America, the Eastern Mediterranean, Southeast Asia and the Western Pacific. Southeast Asia and the Western Pacific are most seriously affected. Before 1970 only nine countries had experienced Dengue Hemorrhagic Fever (DHF) epidemics, a number that had increased more than four-fold by 1995. WHO currently estimates there may be 50 million cases of dengue infection worldwide every year.

The methods and compositions of this invention provide a means for prevention of dengue infection and dengue hemorrhagic fever (DHF) by immunization with attenuated, immunogenic viral vaccines against dengue. The vaccine is further described in Blaney JE *et al.,* "Mutations which enhance the replication of dengue virus type 4 and an antigenic chimeric dengue virus type 2/4 vaccine candidate in Vero cells.'' *Vaccine* 2003 Oct 1;21(27–30):4317–27 and Whitehead SS *et al.,* "A live, attenuated dengue virus type 1 vaccine candidate with a 30-nucleotide deletion in the 3′ untranslated region is highly attenuated and immunogenic in monkeys.'' *J. Virol.* 2003 Jan;77(2):1653–7.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within 60 days from the date of this published Notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

The field of use may be limited to live attenuated vaccines against dengue infections in humans. The Licensed Territory may be limited to the United States, the European Union, Japan, and Canada.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: March 31, 2004.

**Steven M. Ferguson,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.*

[FR Doc. 04–7926 Filed 4–7–04; 8:45 am]

BILLING CODE 4140–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

### Notice of Request for Applications for Cooperative Agreements for Ecstasy and Other Club Drugs Prevention Services (SP 04–004)

**Authority:** Section 506B of the Public Health Service Act.

**AGENCY:** Substance Abuse and Mental Health Services Administration, HHS.

**ACTION:** Notice of request for applications for Cooperative Agreements for Ecstasy and Other Club Drugs Prevention Services (SP 04–004).

**SUMMARY:** The United States Department of Health and Human Services (HHS), Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention (CSAP) is accepting applications for fiscal year (FY) 2004 Cooperative Agreements for Agreements for Ecstasy and Other Club Drugs Prevention Services (SP 04–004). These cooperative agreements will expand and strengthen effective, culturally appropriate ecstasy and other club drugs prevention services at the State and local levels. The services implemented through these grants must incorporate the best objective information available regarding effectiveness and acceptability. SAMHSA/CSAP expects that the services funded through these grants will be sustained by the grantee beyond the term of the grant.

**DATES:** Applications are due on June 18, 2004.

**FOR FURTHER INFORMATION CONTACT:** For questions on program issues, contact: Tom DeLoe, Ph.D., SAMHSA/CSAP, 5600 Fishers Lane, Rockwall II, Suite 1075, Rockville, MD 20857, 301–443–9110, E-mail: *tdeloe@samhsa.gov.*

For questions on grants management issues, contact: Edna Frazier, Office of Program Services, Division of Grants Management, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockwall II, Suite 630, Rockville, MD 20857, (301) 443–6816, *efrazier@samhsa.gov.*

**SUPPLEMENTARY INFORMATION:**

Cooperative Agreement for Ecstasy and Other Club Drugs Prevention Services (Short Title: Ecstasy and Other Club Drugs Cooperative Agreements), SP 04–004 (Initial Announcement), Catalogue of Federal Domestic Assistance (CFDA) No.: 93.243

KEY DATES

| | |
|---|---|
| Application Deadline | Applications must be submitted by June 18, 2004. |
| Intergovernmental Review (E.O. 12372) | Letters from State Single Point of Contact (SPOC) are due no later than 60 days after application deadline. |
| Public Health System Impact Statement (PHSIS)/Single State Agency Coordination. | Applicants must send the PHSIS to appropriate State and local health agencies by application deadline. Comments from Single State Agency are due no later than 60 days after application deadline. |

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## I. Funding Opportunity Description

### *1. Introduction and Background*

As authorized by Section 506B of the Public Health Service Act, the Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Prevention (CSAP) announces the availability of funds for Cooperative Agreements for Ecstasy and Other Club Drugs Prevention Services. These grants will expand and strengthen effective, culturally appropriate ecstasy and other club drugs prevention services at the State and local levels. The services implemented through these grants must incorporate the best objective information available regarding effectiveness and acceptability. SAMHSA/CSAP expects that the services funded through these grants will be sustained by the grantee beyond the term of the grant.

Ecstasy and Other Club Drugs are substances whose use can lead to serious health and behavioral problems, including memory loss, aggression, violence, psychotic behavior, and potential heart and/or neurological damage. Their use also contributes to increased transmission of infectious diseases, especially hepatitis and HIV/AIDS. Use is increasing among the general adolescent population as well as the following populations: men who have sex with men and use other drugs; young adults who attend "raves'' or private clubs; homeless and runaway youth; and male and female commercial sex workers.

### *2. Expectations*

The Ecstasy and Other Club Drugs Cooperative Agreements program are one of SAMHSA/CSAP's Services Grants programs. Grantees must use the funds to expand and strengthen effective, culturally appropriate Ecstasy and Other Club Drugs prevention services at the State and local levels, and SAMHSA/CSAP expects that the services will be sustained beyond the term of the grant.

SAMHSA/CSAP intends that its Services Grants, including the Ecstasy and Other Club Drugs Cooperative Agreements, will result in the delivery of services as soon as possible and encourages grantees to begin service delivery within 4 months of receiving the grant award. However, SAMHSA/CSAP recognizes that grantees may need to enhance their prevention system infrastructure in order to enhance/expand Ecstasy and Other Club Drugs prevention services. Therefore, grantees may propose an infrastructure development phase in year one of their grant projects. If a community is ready to provide services at the time of the award, service delivery may be implemented without this planning phase.

These Ecstasy and Other Drugs Cooperative Agreements will be implemented over a project period of up to five years. During this same time period, SAMHSA/CSAP will be working with the States to conduct comprehensive needs assessments in order to develop strategic plans to prevent/reduce the use of alcohol, tobacco and other drugs through a new SAMHSA/CSAP initiative called the Strategic Prevention Framework (SPF). SAMHSA/CSAP recognizes that Ecstasy and Other Drugs Cooperative Agreements grantees may need to adjust their plans as their SPF plans unfold. Therefore, amendments to the Ecstasy and Other Drugs Cooperative Agreements may be made in Years 3, 4 or 5 in order to bring the Ecstasy and Other Drugs Cooperative Agreements project into alignment with the SPF plans.

#### 2.1 Documenting the Evidence-Base for Services To Be Implemented

The services implemented through the Ecstasy and Other Club Drugs Cooperative Agreements must incorporate the best objective information available regarding the effectiveness and acceptability of the services to be implemented. In general, the services implemented through the Ecstasy and Other Club Drugs Cooperative Agreements must have strong evidence of effectiveness. However, because the evidence base for Ecstasy and Other Club Drugs prevention is limited, SAMHSA/CSAP may fund services for which the evidence of effectiveness is based on formal consensus among recognized experts in the field and/or evaluation studies that have not been published in the peer reviewed literature.

Applicants must document in their applications that the services/practices they propose to implement are evidence-based services/practices. In addition, applicants must justify use of the proposed services/practices for the target population along with any adaptations or modifications necessary to meet the unique needs of the target population or otherwise increase the likelihood of achieving positive outcomes. Further guidance on each of these requirements is provided below.

Documenting the Evidence-Based Practice/Service

SAMHSA/CSAP has already determined that certain services/practices are solidly evidence-based services/practices. These include practices in SAMHSA/CSAP's National Registry of Effective Programs (NREP), and SAMHSA/CSAP encourages applicants to select services/practices from NREP.

None of the models listed in NREP specifically addresses prevention of Ecstasy and Other Club Drug use. However, many of the NREP models do address similar risk and protective factors associated with the prevention of Ecstasy and Other Club Drug use. SAMHSA/CSAP encourages applicants to adapt/replicate a NREP model that is culturally and developmentally appropriate for the target population to be served. To review the NREP models, go to *http://www.modelprograms.samhsa.gov/template.cfm.*

Applicants may propose other services/practices not listed in NREP, but the applicant must demonstrate evidence of effectiveness in order to receive funding. Such applicants must provide a narrative justification that summarizes the evidence for effectiveness and acceptability of the proposed service/practice. The preferred evidence of effectiveness and acceptability will include the findings from clinical trials, efficacy and/or effectiveness studies published in the peer-reviewed literature.

If little or no research specific to the proposed target population or service delivery setting has been published in the peer-reviewed scientific literature, applicants may present evidence involving studies that have not been published in the peer-reviewed research literature and/or documents describing formal consensus among recognized experts. If consensus documents are presented, they must describe consensus among multiple experts whose work is recognized and respected by others in the field. Local recognition of an individual as a respected or influential person at the community level is not considered a "recognized expert'' for this purpose.

In presenting evidence in support of the proposed service/practice, applicants must show that the evidence presented is the best objective information available.

Justifying Selection of the Service/Practice for the Target Population

Regardless of the strength of the evidence-base for the service/practice, all applicants must show that the proposed service/practice is appropriate for the proposed target population. Ideally, this evidence will include research findings on effectiveness and acceptability specific to the proposed target population. However, if such evidence is not available, the applicant should provide a justification for using the proposed service/practice with the target population. This justification might involve, for example, a description of adaptations to the proposed service/practice based on other research involving the target population.

Justifying Adaptations/Modifications of the Proposed Service/Practice

SAMHSA/CSAP has found that a high degree of faithfulness or "fidelity'' (see Glossary) to the original model for an evidence-based service/practice increases the likelihood that positive outcomes will be achieved when the model is used by others. Therefore, SAMHSA/CSAP encourages fidelity to the original evidence-based service/practice to be implemented.

However, SAMHSA/CSAP recognizes that adaptations or modifications to the original model may be necessary for a variety of reasons:

- To allow implementers to use resources efficiently.
- To adjust for specific needs of the client population.
- To address unique characteristics of the local community where the service/practice will be implemented.

All applicants must describe and justify any adaptations or modifications to the proposed service/practice that will be made.

2.2 Services Delivery

SAMHSA/CSAP's Ecstasy and Other Club Drug Cooperative Agreement funds must be used primarily to support direct services, including the following types of activities:

■ Conducting outreach and pre-service strategies to expand access to prevention services to underserved populations. If you propose to provide only outreach and pre-service strategies, you must show that your organization is an effective and integral part of a network of service providers.

■ Purchasing or providing prevention services for populations at risk.

■ Purchasing or providing "wrap-around'' services (see Glossary) (*e.g.*, child care, transportation services) designed to improve access and retention.

■ Collecting data using specified tools to measure program effectiveness and standards to measure and monitor prevention services and costs. (No more than 20% of the total grant award may be used for data collection and evaluation.)

2.3 Infrastructure Development

Although SAMHSA/CSAP expects that its Ecstasy and Other Club Drug Cooperative Agreement funds will be used primarily for direct services, SAMHSA/CSAP recognizes that applicants may need to enhance their prevention system infrastructure in order to enhance/expand Ecstasy and Other Club Drug prevention services. Therefore, applicants may (but are not required to) propose an infrastructure development phase in year one of their projects. Infrastructure development activities may include:

■ Planning.

■ Building partnerships to ensure the success of the project and entering into service delivery and other agreements.

■ Developing or changing the infrastructure to expand prevention services.

- Training of State and local law enforcement officials, prevention and education officials, members of anti-drug coalitions, and parents.

Regardless of the infrastructure development activities proposed by the applicant, the infrastructure development phase must result in the development of a service implementation plan by the end of the first year of the project. This plan must be approved by CSAP before services may be implemented.

After the infrastructure development phase is complete, infrastructure development activities necessary to support service expansion will be limited to 15% of the total grant award.

2.4 Data and Performance Measurement

The Government Performance and Results Act of 1993 (Pub. L. 103–62, or "GPRA'') requires all Federal agencies to set program performance targets and report annually on the degree to which the previous year's targets were met. Agencies are expected to evaluate their programs regularly and to use results of these evaluations to explain their successes and failures and justify requests for funding.

To meet the GPRA requirements, SAMHSA/CSAP must collect performance data (*i.e.*, "GPRA data'') from grantees. Grantees are required to report these GPRA data to SAMHSA/CSAP on a timely basis. In your application, you must demonstrate your ability to collect and report on these measures, and you may be required to

provide some baseline data. The terms and conditions of the grant award also will specify the data to be submitted and the schedule for submission. Grantees will be required to adhere to these terms and conditions of award.

GPRA Requirements for the Infrastructure Development Phase

Grantees with an infrastructure development phase will be required to report on the following systems outcome indicators as appropriate:

—Needs assessment
—Community awareness
—Relationship building, and
—Capacity building.

CSAP is currently developing these systems outcome indicators and will seek the Office of Management and Budget approval for use of these indicators by the grantees. CSAP will then work with each grantee to determine appropriate indicators based on the activities being implemented.

GPRA Requirements for Service Delivery

For all grantees, once service delivery begins, data must be collected for those ages 12 and older using CSAP's GPRA data tool. The CSAP GPRA data tool is posted with this Request for Applications (RFA) on SAMHSA/CSAP's Web site at *http://www.samhsa.gov/grants.* A hard copy of the CSAP GPRA data tool will be included in application kits distributed by the National Clearinghouse for Alcohol and Drug Information (NCADI).

If services are being provided for individuals age 9–11, applicants must propose an approach and instrument for collecting data from these participants that is comparable to CSAP's GPRA data tool.

In addition, if grantees are targeting any of the five domains of prevention-related human behaviors and attitudes [Alcohol, Tobacco, and Other Drug Use (ATOD); Individual/Peer; Family; School; or Community], they must use additional performance measures selected from CSAP's Core Measures. All applicants must: (1) Identify which core measures the applicant proposes to collect for their program, and (2) describe their ability to collect and report data on these measures. The grantee and the CSAP project officer will jointly finalize the selection of core measures based on the nature of the program model selected and the domain within which the program will be implemented. This will be accomplished following the notice of award.

CSAP's Core Measures will be posted with this RFA on SAMHSA's Web site, *http://www.SAMHSA.gov/grants.* Applicants unable to access the document on-line should contact Beverlie Fallik at (301) 443–5827 or *bfallik@samhsa.gov;* or Sue Fialkoff at (301)443–1248 or *sfialkof@samhsa.gov.*

The following documents should be consulted when planning for data collection and reporting:

| Document | Purpose | Where it can be found |
|---|---|---|
| CSAP GPRA Data Collection Tool. | Required data for programs providing direct services to individuals age 12 and over. Youth and adult versions in English and Spanish available. | Posted with this RFA on SAMHSA's Web site at *http://www.SAMHSA.gov/grants* and included in the application kit distributed by SAMHSA/CSAP's clearinghouse. |
| Core Measures Guidance .... | Describes how to use CSAP Core Measures ..... | Posted with this RFA on SAMHSA's Web site at *http://www.samhsa.gov/grants* and included in the application kit distributed by SAMHSA's clearinghouse. |
| CSAP Core Measures Notebook. | Full description of CSAP Core Measures (200+pages) | Posted with this RFA on SAMHSA's Web site at *http://www.samhsa.gov/grants* If you are unable to access this document, contact Beverlie Fallik at (301) 443–5827 or *bfallik@samhsa.gov*; or Sue Fialkoff at (301) 443–1248 or *sfialkof@samhsa.gov.* |

Applicants should be aware that SAMHSA/CSAP is working to develop a set of required core performance measures for four types of grants (*i.e.*, Services Grants, Infrastructure Grants, Best Practices Planning and Implementation Grants, and Service-to-Science Grants). As this effort proceeds, some of the data collection and reporting requirements for this program may change. All grantees will be expected to comply with any changes in data collection requirements that occur during the grantee's project period.

2.5 Grantee Meetings

You must plan to send a minimum of two people (including the Project Director) to at least one joint grantee meeting in each year of the grant, and you must include funding for this travel in your budget. At these meetings, grantees will present the results of their projects and Federal staff will provide technical assistance. Each meeting will be 3 days. These meetings will usually be held in the Washington, DC, area, and attendance is mandatory.

2.6 Evaluation

Grantees must evaluate their projects, and you are required to describe your evaluation plans in your application. The evaluation should be designed to provide regular feedback to the project to improve services. The evaluation must include both process and outcome components. Process and outcome evaluations must measure change relating to project goals and objectives over time compared to baseline information. Control or comparison groups are not required. You must consider your evaluation plan when preparing the project budget.

An ongoing goal for SAMHSA/CSAP is to assure that effective program models are developed and added to CSAP's National Registry of Effective Programs (NREP). Therefore, grantees will be strongly encouraged to adapt/replicate and evaluate their program models and submit them to NREP for review as the programs generate statistically significant findings in Years 3, 4, and 5.

*Process components* should address issues such as:

☐ How closely did implementation match the plan?

☐ What types of deviation from the plan occurred?

☐ What led to the deviations?

☐ What effect did the deviations have on the planned intervention and evaluation?

☐ Who provided (program, staff) what services (modality, type, intensity, duration), to whom (individual characteristics), in what context (system, community), and at what cost (facilities, personnel, dollars)?

*Outcome components* should address issues such as:

☐ What was the effect of intervention on participants?

☐ What program/contextual factors were associated with outcomes?

☐ What individual factors were associated with outcomes?

☐ How durable were the effects?

No more than 20% of the total grant award may be used for evaluation and data collection, including GPRA.

## II. Award Information

*1. Award Amount*

It is expected that $4.5 million will be available to fund up to 15 Ecstasy and Other Club Drug Prevention Services awards in FY 2004. The awards will be up to $300,000 in total costs (direct and indirect) per year. The actual amount available for the awards may vary, depending on unanticipated program requirements and the number and quality of the applications received.

Awards will be made for project periods of up to five years. Proposed budgets cannot exceed $300,000 in any year of the proposed project. Annual continuations will depend on the availability of funds, grantee progress in meeting program goals and objectives, and timely submission of required data and reports. Applicants proposing an infrastructure development phase in year one must have their service implementation plan approved before service delivery may begin.

*2. Funding Mechanism*

The Ecstasy and Other Club Drug Prevention Services awards will be made as cooperative agreements.

*Role of Federal Agency:* The CSAP project officer will actively participate in the program planning and program decision-making processes throughout the length of the Cooperative Agreement. In addition to the provision of program monitoring and technical assistance to the awardee, the CSAP project officer, in cooperation with the awardee, will: (1) Approve the development and selection of the service model and the services implementation plan; (2) assist with development/refinement of infrastructure development activities, if appropriate; (3) select system outcome and core measure outcomes based on the services model selected and; (4) approve the program services sustainability plan.

*Role of the Awardee:* Awardees will: (1) Collaborate with CSAP staff in the implementation, monitoring of all aspects of the cooperative agreement and; (2) provide CSAP (and its Program Coordinating Center) with required reporting data.

## III. Eligibility Information

*1. Eligible Applicants*

Eligible applicants are States, Territories, the District of Columbia, and Native American Tribal Governments. Eligibility is limited to these entities for two reasons: (1) To facilitate State and community planning and coordination, and assure that program infrastructure development and selection of ecstasy and other club drug service models are consistent with the State/Territory Strategic Prevention Framework for substance abuse prevention, and (2) to enhance program sustainability.

Although eligibility is limited to these governmental entities, these governmental entities must partner with local community organizations (public or private) in developing and implementing the grant project. Eligible applicants may submit more than one application, but only one community may be targeted in each application. States, tribes, and territories may retain up to 10% per year of the total grant award for costs associated with the administration and management of each grant submitted. At least 90% of the total grant award each year must be allocated to the community partner for implementation of services/infrastructure development at the community level.

*2. Cost Sharing*

Cost sharing (see Glossary) is not required in this program, and applications will not be screened out on the basis of cost sharing. However, you may include cash or in-kind contributions (see Glossary) in your proposal as evidence of commitment to the proposed project.

*3. Other*

3.1 Additional Eligibility Requirements

*Applications must comply with the following requirements, or they will be screened out and will not be reviewed:* Use of the PHS 5161–1 application; application submission requirements in Section IV–3 of this document; and formatting requirements provided in Section IV–2.3 of this document.

3.2 Evidence of Experience and Credentials

SAMHSA/CSAP believes that only existing, experienced, and appropriately credentialed organizations with demonstrated infrastructure and expertise will be able to provide required services quickly and effectively. Therefore, in addition to the basic eligibility requirements specified in this announcement, applicants must meet three additional requirements related to the provision of prevention services.

The three requirements are:

- A provider organization for direct client services (e.g., substance abuse prevention services) appropriate to the grant must be involved in each application. More than one provider organization may be involved;
- Each direct service provider organization must have at least 2 years experience providing services in the geographic area(s) covered by the application, as of the due date of the application; and
- Each direct service provider organization must comply with all applicable local (city, county) and State/tribal licensing, accreditation, and certification requirements, as of the due date of the application.

**Note:** The above requirements apply to all service provider organizations. A license from an individual clinician will not be accepted in lieu of a provider organization's license.

In Appendix 1 of the application, you must: (1) Identify at least one experienced, licensed service provider organization; (2) include a list of all direct service provider organizations that have agreed to participate in the proposed project, including the applicant agency if the applicant is a treatment or prevention service provider organization; and (3) include the Statement of Assurance (provided in Appendix F of this announcement), signed by the authorized representative of the applicant organization identified on the face-page of the application, that all participating service provider organizations:

- Meet the 2-year experience requirement
- Meet applicable licensing, accreditation, and certification requirements, and,
- If the application is within the funding range, will provide the Government Project Officer (GPO) with the required documentation within the time specified.

If Appendix 1 of the application does not contain items (1)–(3), the application will be considered ineligible and will not be reviewed.

In addition, if, following application review, an application's score is within the fundable range for a grant award, the GPO will call the applicant and request that the following documentation be sent by overnight mail:

- A letter of commitment that specifies the nature of the participation and what service(s) will be provided from every service provider organization

that has agreed to participate in the project;

• Official documentation that all participating organizations have been providing relevant services for a minimum of 2 years before the date of the application in the area(s) in which the services are to be provided; and

• Official documentation that all participating service provider organizations comply with all applicable local (city, county) and State/tribal requirements for licensing, accreditation, and certification or official documentation from the appropriate agency of the applicable State/tribal, county, or other governmental unit that licensing, accreditation, and certification requirements do not exist.

If the GPO does not receive this documentation within the time specified, the application will be removed from consideration for an award and the funds will be provided to another applicant meeting these requirements.

## IV. Application and Submission Information

To ensure that you have met all submission requirements, a checklist is provided for your use in Appendix A of this document.

### *1. Address To Request Application Package*

You may request a complete application kit by calling the National Clearinghouse for Alcohol and Drug Information (NCADI) at 1–800–729–6686.

You also may download the required documents from the SAMHSA/CSAP Web site at *http://www.samhsa.gov.* Click on "grant opportunities.''

Additional materials available on this Web site include:

• A technical assistance manual for potential applicants;

• Standard terms and conditions for SAMHSA grants;

• Guidelines and policies that relate to SAMHSA grants (*e.g.*, guidelines on cultural competence, consumer and family participation, and evaluation); and

• Enhanced instructions for completing the PHS 5161–1 application.

### *2. Content and Form of Application Submission*

2.1 Required Documents

SAMHSA application kits include the following documents:

□ PHS 5161–1 (revised July 2000)—Includes the face page, budget forms, assurances, certification, and checklist. Applications that are not submitted on the 5161–1 application form will be screened out and will not be reviewed.

□ Request for Applications (RFA)—Includes instructions for the grant application. This document is the RFA.

You must use all of the above documents in completing your application.

2.2 Required Application Components

To ensure equitable treatment of all applications, applications must be complete. In order for your application to be complete, it must include the required ten application components (Face Page, Abstract, Table of Contents, Budget Form, Project Narrative and Supporting Documentation, Appendices, Assurances, Certifications, Disclosure of Lobbying Activities, and Checklist).

□ *Face Page*—Use Standard Form (SF) 424, which is part of the PHS 5161–1. [**Note:** Beginning October 1, 2003, applicants will need to provide a Dun and Bradstreet (DUNS) number to apply for a grant or cooperative agreement from the Federal Government. SAMHSA applicants will be required to provide their DUNS number on the face page of the application. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access the Dun and Bradstreet Web site at *http.www.dunandbradstreet.com* or call 1–866–705–5711. To expedite the process, let Dun and Bradstreet know that you are a public/private nonprofit organization getting ready to submit a Federal grant application.]

□ *Abstract*—Your total abstract should not be longer than 35 lines. In the first five lines or less of your abstract, write a summary of your project that can be used, if your project is funded, in publications, reporting to Congress, or press releases.

□ *Table of Contents*—Include page numbers for each of the major sections of your application and for each appendix.

□ *Budget Form*—Use SF 424A, which is part of the PHS 5161–1. Fill out Sections B, C, and E of the SF 424A.

□ *Project Narrative and Supporting Documentation*—The Project Narrative describes your project. It consists of Sections A through E. Sections A-E together may not be longer than 30 pages. More detailed instructions for completing each section of the Project Narrative are provided in "Section V—Application Review Information'' of this document.

The Supporting Documentation provides additional information necessary for the review of your application. This supporting documentation should be provided immediately following your Project Narrative in Sections F through I. There are no page limits for these sections, except for Section H, the Biographical Sketches/Job Descriptions.

□ Section F—Literature Citations. This section must contain complete citations, including titles and all authors, for any literature you cite in your application.

□ Section G—Budget Justification, Existing Resources, Other Support. You must provide a narrative justification of the items included in your proposed budget, as well as a description of existing resources and other support you expect to receive for the proposed project. Be sure to show that:

○ No more than 10% of the total award is retained by the applicant to cover costs of administering the grant;

○ At least 90% of the total grant award is allocated to the community partner to implement the project;

○ No more than 15% of the total grant award will be used for infrastructure development, except during the allowable infrastructure development phase in the first year of the project; and

○ more than 20% of the total grant award will be used for data collection and evaluation (including GPRA).

The infrastructure development, data collection and evaluation costs may be shared by the State and the community partner.

■ Section H—Biographical Sketches and Job Descriptions.

○ Include a biographical sketch for the Project Director and other key positions. Each sketch should be 2 pages or less. If the person has not been hired, include a letter of commitment from the individual with a current biographical sketch.

○ Include job descriptions for key personnel. Job descriptions should be no longer than 1 page each.

○ Sample sketches and job descriptions are listed on page 22, Item 6 in the Program Narrative section of the PHS 5161–1.

■ Section I—Confidentiality and SAMHSA Participant Protection/Human Subjects. Section IV–2.4 of this document describes requirements for the protection of the confidentiality, rights and safety of participants in SAMHSA/CSAP-funded activities. This section also includes guidelines for completing this part of your application.

□ *Appendices 1 through 3*—Use only the appendices listed below. Do not use more than 30 pages for Appendices 1 and 3. There is no page limit for Appendix 2. Do not use appendices to extend or replace any of the sections of

the Project Narrative. Reviewers will not consider them if you do.

■ Appendix 1: Letters of commitment/support. Identification of at least one experienced, licensed service provider organization. A list of all direct service provider organizations that have agreed to participate in the proposed project, including the applicant agency, if it is a treatment or prevention service provider organization. The Statement of Assurance (provided in Appendix F of this announcement) signed by the authorized representative of the applicant organization identified on the face page of the application, that assures SAMHSA that all listed providers meet the 2-year experience requirement, are appropriately licensed, accredited, and certified, and that if the application is within the funding range for an award, the applicant will send the GPO the required documentation within the specified time.

■ Appendix 2: Data Collection Instruments/Interview Protocols

■ Appendix 3: Sample Consent Forms

□ *Assurances*—Non-Construction Programs. Use Standard Form 424B found in PHS 5161–1. Applicants are required to complete the Assurance of Compliance with SAMHSA Charitable Choice Statutes and Regulations, Form SMA 170. This form will be posted on SAMHSA's Web site with the RFA and provided in the application kits available at NCADI.

□ *Certifications*—Use the "Certifications'' forms found in PHS 5161–1.

□ *Disclosure of Lobbying Activities*—Use Standard Form LLL found in the PHS 5161–1. Federal law prohibits the use of appropriated funds for publicity or propaganda purposes, or for the preparation, distribution, or use of the information designed to support or defeat legislation pending before the Congress or State legislatures. This includes "grass roots'' lobbying, which consists of appeals to members of the public suggesting that they contact their elected representatives to indicate their support for or opposition to pending legislation or to urge those representatives to vote in a particular way.

□ *Checklist*—Use the Checklist found in PHS 5161–1. The Checklist ensures that you have obtained the proper signatures, assurances and certifications and is the last page of your application.

*2.3 Application Formatting Requirements*

Applicants also must comply with the following basic application requirements. Applications that do not comply with these requirements will be screened out and will not be reviewed.

□ Information provided must be sufficient for review.

□ Text must be legible.

• Type size in the Project Narrative cannot exceed an average of 15 characters per inch, as measured on the physical page. (Type size in charts, tables, graphs, and footnotes will not be considered in determining compliance.)

• Text in the Project Narrative cannot exceed 6 lines per vertical inch.

□ Paper must be white paper and 8.5 inches by 11.0 inches in size.

□ To ensure equity among applications, the amount of space allowed for the Project Narrative cannot be exceeded.

• Applications would meet this requirement by using all margins (left, right, top, bottom) of at least one inch each, and adhering to the 30-page limit for the Project Narrative.

• Should an application not conform to these margin or page limits, SAMHSA will use the following method to determine compliance: The total area of the Project Narrative (excluding margins, but including charts, tables, graphs and footnotes) cannot exceed 58.5 square inches multiplied by 30. This number represents the full page less margins, multiplied by the total number of allowed pages.

• Space will be measured on the physical page. Space left blank within the Project Narrative (excluding margins) is considered part of the Project Narrative, in determining compliance.

□ The 30-page limit for Appendices 1 and 3.

To facilitate review of your application, follow these additional guidelines. Failure to adhere to the following guidelines will not, in itself, result in your application being screened out and returned without review. However, following these guidelines will help reviewers to consider your application.

□ Pages should be typed single-spaced with one column per page.

□ Pages should not have printing on both sides.

□ Please use black ink and number pages consecutively from beginning to end so that information can be located easily during review of the application. The cover page should be page 1, the abstract page should be page 2, and the table of contents page should be page 3. Appendices should be labeled and separated from the Project Narrative and budget section, and the pages should be numbered to continue the sequence.

□ Send the original application and two copies to the mailing address in Section IV–6.1 of this document. Please do not use staples, paper clips, and fasteners. Nothing should be attached, stapled, folded, or pasted. Do not use heavy or lightweight paper or any material that cannot be copied using automatic copying machines. Odd-sized and oversized attachments such as posters will not be copied or sent to reviewers. Do not include videotapes, audiotapes, or CD-ROMs.

*2.4 SAMHSA Confidentiality and Participant Protection Requirements and Protection of Human Subjects Regulations*

Applicants must describe procedures relating to Confidentiality, Participant Protection and the Protection of Human Subjects Regulations in Section I of the application, using the guidelines provided below. Problems with confidentiality, participant protection, and protection of human subjects identified during peer review of the application may result in the delay of funding.

*Confidentiality and Participant Protection:* All applicants *must* describe how they will address requirements for each of the following elements relating to confidentiality and participant protection.

1. Protect Clients and Staff from Potential Risks

■ Identify and describe any foreseeable physical, medical, psychological, social and legal risks or potential adverse effects as a result of the project itself or any data collection activity.

■ Describe the procedures you will follow to minimize or protect participants against potential risks, including risks to confidentiality.

■ Identify plans to provide guidance and assistance in the event there are adverse effects to participants.

■ Where appropriate, describe alternative treatments and procedures that may be beneficial to the participants. If you choose not to use these other beneficial treatments, provide the reasons for not using them.

2. Fair Selection of Participants

■ Describe the target population(s) for the proposed project. Include age, gender, and racial/ethnic background and note if the population includes homeless youth, foster children, children of substance abusers, pregnant women, or other targeted groups.

■ Explain the reasons for including groups of pregnant women, children, people with mental disabilities, people

in institutions, prisoners, and individuals who are likely to be particularly vulnerable to HIV/AIDS.

■ Explain the reasons for including or excluding participants.

■ Explain how you will recruit and select participants. Identify who will select participants.

3. Absence of Coercion

■ Explain if participation in the project is voluntary or required. Identify possible reasons why participation is required, for example, court orders requiring people to participate in a program.

■ If you plan to compensate participants, state how participants will be awarded incentives (*e.g.*, money, gifts, *etc.*).

■ State how volunteer participants will be told that they may receive services intervention even if they do not participate in or complete the data collection component of the project.

4. Data Collection

■ Identify from whom you will collect data (*e.g.*, from participants themselves, family members, teachers, others). Describe the data collection procedures and specify the sources for obtaining data (*e.g.*, school records, interviews, psychological assessments, questionnaires, observation, or other sources). Where data are to be collected through observational techniques, questionnaires, interviews, or other direct means, describe the data collection setting.

■ Identify what type of specimens (*e.g.*, urine, blood) will be used, if any. State if the material will be used just for evaluation or if other use(s) will be made. Also, if needed, describe how the material will be monitored to ensure the safety of participants.

■ Provide in Appendix 2, "Data Collection Instruments/Interview Protocols,'' copies of all available data collection instruments and interview protocols that you plan to use.

5. Privacy and Confidentiality

■ Explain how you will ensure privacy and confidentiality. Include who will collect data and how it will be collected.

■ Describe:

○ How you will use data collection instruments.

○ Where data will be stored.

○ Who will or will not have access to information.

○ How the identity of participants will be kept private, for example, through the use of a coding system on data records, limiting access to records, or storing identifiers separately from data.

**Note:** If applicable, grantees must agree to maintain the confidentiality of alcohol and drug abuse client records according to the provisions of Title 42 of the Code of Federal Regulations, Part II.

6. Adequate Consent Procedures

■ List what information will be given to people who participate in the project. Include the type and purpose of their participation. Identify the data that will be collected, how the data will be used and how you will keep the data private.

■ State:

○ Whether or not their participation is voluntary.

○ Their right to leave the project at any time without problems.

○ Possible risks from participation in the project.

○ Plans to protect clients from these risks.

■ Explain how you will get consent for youth, the elderly, people with limited reading skills, and people who do not use English as their first language.

**Note:** If the project poses potential physical, medical, psychological, legal, social or other risks, you must obtain written informed consent.

■ Indicate if you will obtain informed consent from participants or assent from minors along with consent from their parents or legal guardians. Describe how the consent will be documented. For example: Will you read the consent forms? Will you ask prospective participants questions to be sure they understand the forms? Will you give them copies of what they sign?

■ Include, as appropriate, sample consent forms that provide for: (1) Informed consent for participation in service intervention; (2) informed consent for participation in the data collection component of the project; and (3) informed consent for the exchange (releasing or requesting) of confidential information. The sample forms must be included in Appendix 3, "Sample Consent Forms'', of your application. If needed, give English translations.

**Note:** Never imply that the participant waives or appears to waive any legal rights, may not end involvement with the project, or releases your project or its agents from liability for negligence.

■ Describe if separate consents will be obtained for different stages or parts of the project. For example, will they be needed for both participant protection in treatment intervention and for the collection and use of data?

■ Additionally, if other consents (*e.g.*, consents to release information to others or gather information from others) will be used in your project, provide a description of the consents. Will individuals who do not consent to having individually identifiable data collected for evaluation purposes be allowed to participate in the project?

7. Risk/Benefit Discussion

Discuss why the risks are reasonable compared to expected benefits and importance of the knowledge from the project.

*Protection of Human Subjects Regulations:* Depending on the evaluation design you propose in your application, you may have to comply with the Protection of Human Subjects Regulations (45 CFR part 46).

Applicants whose projects must comply with the Protection of Human Subjects Regulations must describe the process for obtaining Institutional Review Board (IRB) approval fully in their applications. While IRB approval is not required at the time of grant award, these applicants will be required, as a condition of award, to provide the documentation that an Assurance of Compliance is on file with the Office for Human Research Protections (OHRP) and the IRB approval has been received prior to enrolling any clients in the proposed project.

Additional information about Protection of Human Subjects Regulations can be obtained on the web at *http://ohrp.osophs.dhhs.gov.* You may also contact OHRP by e-mail (*ohrp@osophs.dhhs.gov*) or by phone (301/496–7005).

*3. Submission Dates and Times*

Applications are due by June 18, 2004.

Your application must be received by the application deadline. Applications received after this date must have a proof-of-mailing date from the carrier dated at least 1 week prior to the due date. Private metered postmarks are not acceptable as proof of timely mailing.

You will be notified by postal mail that your application has been received.

Applications not received by the application deadline or not postmarked by a week prior to the application deadline will be screened out and will not be reviewed.

*4. Intergovernmental Review (E.O. 12372) Requirements*

Executive Order 12372, as implemented through Department of Health and Human Services (DHHS) regulation at 45 CFR Part 100, sets up a system for State and local review of applications for Federal financial assistance. A current listing of State Single Points of Contact (SPOCs) is

included in the application kit and can be downloaded from the Office of Management and Budget (OMB) Web site at *http://www.whitehouse.gov/omb/grants/spoc.html.*

■ Check the list to determine whether your State participates in this program. You do not need to do this if you are a federally recognized Indian tribal government.

■ If your State participates, contact your SPOC as early as possible to alert him/her to the prospective application(s) and to receive any necessary instructions on the State's review process.

■ For proposed projects serving more than one State, you are advised to contact the SPOC of each affiliated State.

■ The SPOC should send any State review process recommendations to the following address within 60 days of the application deadline: Substance Abuse and Mental Health Services Administration, Office of Program Services, Review Branch, 5600 Fishers Lane, Room 17–89, Rockville, Maryland, 20857, ATTN: SPOC—Funding Announcement No. SP–04–004.

*5. Funding Limitations/Restrictions*

Cost principles describing allowable and unallowable expenditures for Federal grantees, including SAMHSA grantees, are provided in the following documents:

■ Institutions of Higher Education: OMB Circular A–21

■ State and Local Governments: OMB Circular A–87

■ Nonprofit Organizations: OMB Circular A–122

■ Appendix E Hospitals: 45 CFR Part 74

In addition, SAMHSA Services Grant recipients must comply with the following funding restrictions:

■ No more than 15% of the total grant award may be used for developing the infrastructure necessary for expansion of services, except during the allowable infrastructure development phase in year one of the project. (There is no limit on expenditure for infrastructure development during this phase of the project.)

■ No more than 20% of the total grant award may be used for evaluation and data collection (including GPRA). These costs may be shared by the applicant and the community partner.

■ No more than 10% of the total grant award may be retained by the applicant for costs associated with the administration and management of the grant.

■ At least 90% of the total grant award must be allocated to the community partner for implementation of services/infrastructure development at the community level.

Grant funds must be used for purposes supported by the program and may not be used to:

■ Pay for any lease beyond the project period.

■ Provide services to incarcerated populations (defined as those persons in jail, prison, detention facilities, or in custody where they are not free to move about in the community).

■ Pay for the purchase or construction of any building or structure to house any part of the program. (Applicants may request up to $75,000 for renovations and alterations of existing facilities, if necessary and appropriate to the project.)

■ Pay for incentives to induce individuals to enter services. However, a grantee or service provider may provide up to $20 or equivalent (coupons, bus tokens, gifts, child care, and vouchers) to individuals as incentives to participate in required data collection follow-up. This amount may be paid for participation in each required interview.

■ Implement syringe exchange programs, such as the purchase and distribution of syringes and/or needles.

■ Pay for pharmacologies for HIV antiretroviral therapy, sexually transmitted diseases (STD)/sexually transmitted illnesses (STI), TB, and hepatitis B and C, or for psychotropic drugs.

*6. Other Submission Requirements*

6.1 Where To Send Applications

Send applications to the following address: Substance Abuse and Mental Health Services Administration, Office of Program Services, Review Branch, 5600 Fishers Lane, Room 17–89, Rockville, Maryland, 20857.

Be sure to include the funding announcement number (SP 04–004) in item number 10 on the face page of the application. If you require a phone number for delivery, you may use (301) 443–4266.

6.2 How To Send Applications

Mail an original application and 2 copies (including appendices) to the mailing address provided above. The original and copies must not be bound. Do not use staples, paper clips, or fasteners. Nothing should be attached, stapled, folded, or pasted.

You must use a recognized commercial or governmental carrier. Hand carried applications will not be accepted. Faxed or e-mailed applications will not be accepted.

**V. Application Review Information**

*1. Evaluation Criteria*

Your application will be reviewed and scored according to the quality of your response to the requirements listed below for developing the Project Narrative (Sections A–E). These sections describe what you intend to do with your project.

■ In developing the Project Narrative section of your application, use these instructions, which have been tailored to this program. These are to be used instead of the "Program Narrative'' instructions found in the PHS 5161–1.

■ The Project Narrative (Sections A–E) together may be no longer than 30 pages.

■ You must use the five sections/headings listed below in developing your Project Narrative. Be sure to place the required information in the correct section, or it will not be considered. Your application will be scored according to how well you address the requirements for each section of the Project Narrative.

■ Reviewers will be looking for evidence of cultural competence in each section of the Project Narrative. Points will be assigned based on how well you address the cultural competence aspects of the evaluation criteria. SAMHSA guidelines for cultural competence can be found on the SAMHSA Web site at *http://www.samhsa.gov/grants.*

■ The Supporting Documentation you provide in Sections F–I and Appendices 1–5 will be considered by reviewers in assessing your response, along with the material in the Project Narrative.

■ The number of points after each heading is the maximum number of points a review committee may assign to that section of your Project Narrative. Bullet statements in each section do not have points assigned to them. They are provided to invite the attention of applicants and reviewers to important areas within the criterion.

Section A: Statement of Need (10 Points)

■ Describe the target population (see Glossary) as well as the geographic area to be served, and justify the selection of both. Include the numbers to be served and demographic information. Clearly identify the target community that is partnering with the applicant organization in developing and implement the proposed project. Discuss the target population's language, beliefs, norms and values, as well as socioeconomic factors that must be considered in delivering programs to this population.

■ Describe the nature of the problem and extent of the need for the target population based on data. The statement of need should include a clearly established baseline for the project. Documentation of need may come from a variety of qualitative and quantitative sources. The quantitative data could come from local data or trend analyses, State data (*e.g.*, from State Needs Assessments), and/or national data (*e.g.*, from SAMHSA's National Household Survey on Drug Abuse and Health or from National Center for Health Statistics/Centers for Disease Control reports). For data sources that are not well known, provide sufficient information on how the data were collected so reviewers can assess the reliability and validity of the data.

■ Describe how the proposed project is guided by the Drug Enforcement Agency's (DEA) assessment of the incidence, disposition, and prevalence of ecstasy and other club drug use within the State, Tribal area, or Territory. (Information in the DEA assessments is available on the DEA Web site at *www.dea.gov/pubs/state_factsheets.html.)*

■ Applicants proposing an infrastructure development phase must document the need for infrastructure development to improve effective Ecstasy and Other Club Drug Use prevention services implementation in the target community. This documentation should include a description of the service gaps, barriers and other problems related to need for infrastructure development and how they will be overcome.

Section B: Proposed Evidence-Based Service/Practice (30 Points)

■ Clearly state the purpose, goals and objectives of your proposed project. Describe how achievement of goals will produce meaningful and relevant results (*e.g.*, increase access, availability, prevention, outreach, pre-services, and/or intervention).

■ Identify the evidenced based service/practice that you propose to implement. Describe the evidence-base for the proposed service/practice and show that it incorporates the best objective information available regarding effectiveness and acceptability. Follow the instructions provided in #1, #2 or #3 below, as appropriate:

1. *If you are proposing to implement a service/practice included in NREP (see Appendix C)*, simply identify the practice and state the source from which it was selected. You do not need to provide further evidence of effectiveness.

2. *If you are providing evidence that includes scientific studies published in the peer-reviewed literature or other studies that have not been published, describe the extent to which:*

—The service/practice has been evaluated and the quality of the evaluation studies (*e.g.*, whether they are descriptive, quasi-experimental studies, or experimental studies)
—The services/practice has demonstrated positive outcomes and for what populations the positive outcomes have been demonstrated
—The service/practice has been documented (*e.g.*, through development of guidelines, tool kits, treatment protocols, and/or manuals) and replicated
—Fidelity measures have been developed (*e.g.*, no measures developed, key components identified, or fidelity measures developed)

3. *If you are providing evidence based on a formal consensus process involving recognized experts in the field, describe:*

—The experts involved in developing consensus on the proposed service/practice (*e.g.*, members of an expert panel formally convened by SAMHSA, NIH, the Institute of Medicine or other nationally recognized organization). The consensus must have been developed by a group of experts whose work is recognized and respected by others in the field. Local recognition of an individual as a respected or influential person at the community level is not considered a "recognized expert'' for this purpose.
—The nature of the consensus that has been reached and the process used to reach consensus
—The extent to which the consensus has been documented (*e.g.*, in a consensus panel report, meeting minutes, or an accepted standard practice in the field)
—Any empirical evidence (whether formally published or not) supporting the effectiveness of the proposed service/practice
—The rationale for concluding that further empirical evidence does not exist to support the effectiveness of the proposed service/practice

■ Justify the use of the proposed service/practice for the target population. Describe and justify any adaptations necessary to meet the needs of the target population as well as evidence that such adaptations will be effective for the target population.

■ Identify and justify any additional adaptations or modifications to the proposed service/practice.

■ Describe how the proposed project will address issues of age, race, ethnicity, culture, language, sexual orientation, disability, literacy, and gender in the target population, while retaining fidelity to the chosen practice.

■ Demonstrate how the proposed service/practice will meet your goals and objectives. Provide a logic model (see Glossary) that links need, the services or practice to be implemented, and outcomes.

Section C: Proposed Implementation Approach (25 Points)

■ Describe how the proposed service or practice will be implemented. Provide a realistic time line for the project (chart or graph) showing key activities, milestones, and responsible staff. [**Note:** The time line should be part of the Project Narrative. It should not be placed in an appendix.]

■ If applicable, describe the infrastructure development phase and how it will be implemented. Discuss how the infrastructure development phase will lay the groundwork for implementation of the proposed service or practice. Show that the infrastructure development phase will be completed by the end of the first year of the project.

■ Describe how the community partner has been involved in developing the grant project and how it will be involved in implementing the evidence-based practice and infrastructure development activity(ies), if appropriate.

■ Clearly state the unduplicated number of individuals you propose to serve (annually and over the entire project period) with grant funds, including the types and numbers of services to be provided and anticipated outcomes. Describe how the target population will be identified, recruited, and retained.

■ Describe how members of the target population helped prepare the application, and how they will help plan, implement, and evaluate the project.

■ Describe how the project components will be embedded within the existing service delivery system, including other SAMHSA-funded projects, if applicable. Identify any other organizations that will participate in the proposed project. Describe their roles and responsibilities and demonstrate their commitment to the project. Include letters of commitment from community organizations supporting the project in Appendix 1. Identify any cash or in-kind contributions that will be made to the project by the applicant or other partnering organizations.

■ For applicants that are not proposing an infrastructure development phase, show that the necessary groundwork (*e.g.*, planning, consensus development, development of memoranda of agreement, identification of potential facilities) has been completed or is near completion so that the project can be implemented and service delivery can begin as soon as possible and no later than 4 months after grant award.

■ Describe the potential barriers to successful conduct of the proposed project and how you will overcome them.

■ Provide a plan to secure resources to sustain the proposed project when Federal funding ends.

Section D: Staff and Organizational Experience (20 Points)

■ Discuss the capability and experience of the applicant organization and other participating organizations with similar projects and populations, including experience in providing culturally appropriate/competent services and implementing effective prevention interventions.

■ Provide a list of staff who will participate in the project, showing the role of each and their level of effort and qualifications. Include the Project Director and other key personnel, such as the evaluator and treatment/prevention personnel.

■ Describe the racial/ethnic characteristics of key staff and indicate if any are members of the target population/community. If the target population is multi-linguistic, indicate if the staffing pattern includes bilingual and bicultural individuals.

■ Describe the resources available for the proposed project (*e.g.*, facilities, equipment), and provide evidence that services will be provided in a location that is adequate, accessible, compliant with the Americans with Disabilities Act (ADA), and amenable to the target population.

■ Describe how the applicant has worked with local communities to plan, coordinate and implement effective prevention activities.

■ Describe the applicant's ability to utilize data to monitor services and costs.

Section E: Evaluation and Data (15 Points)

■ Document your ability to collect and report on the required performance measures.

■ Identify and justify the Core Measures appropriate to your project and document your ability to collect and report those measures.

■ Describe plans for data collection, management, analysis, interpretation and reporting. Describe the existing approach to the collection of data, along with any necessary modifications. Be sure to include data collection instruments/interview protocols in Appendix 2.

■ Discuss the reliability and validity of evaluation methods and instrument(s) in terms of the gender/age/culture of the target population.

■ Describe the process and outcome evaluation, including assessments of implementation and individual outcomes. Show how the evaluation will be integrated with requirements for collection and reporting of performance data, including data required by SAMHSA to meet GPRA requirements.

■ Describe how the evaluation will be used to ensure the fidelity to the practice.

■ Provide a per-person or unit cost of the project to be implemented, based on the applicant's actual costs and projected costs over the life of the project.

**Note:** Although the budget for the proposed project is not a review criterion, the Review Group will be asked to comment on the appropriateness of the budget after the merits of the application have been considered.

*2. Review and Selection Process*

SAMHSA applications are peer-reviewed according to the review criteria listed above. For those programs where the individual award is over $100,000, applications must also be reviewed by the appropriate National Advisory Council.

Decisions to fund a grant are based on:

■ The strengths and weaknesses of the application as identified by peer reviewers and, when applicable, approved by the appropriate National Advisory Council;

■ Availability of funds;

■ Equitable distribution of awards in terms of geography (including urban, rural and remote settings) and balance among target populations and program size; and

■ After applying the aforementioned criteria, the following method for breaking ties: When funds are not available to fund all applications with identical scores, SAMHSA will make award decisions based on the application(s) that received the greatest number of points by peer reviewers on the evaluation criterion in Section V–1 with the highest number of possible points (Proposed Evidence-Based Service/Practice—30 points). Should a tie still exist, the evaluation criterion with the next highest possible point value will be used, continuing sequentially to the evaluation criterion with the lowest possible point value, should that be necessary to break all ties. If an evaluation criterion to be used for this purpose has the same number of possible points as another evaluation criterion, the criterion listed first in Section V–1 will be used first.

## VI. Award Administration Information

*1. Award Notices*

After your application has been reviewed, you will receive a letter from SAMHSA through postal mail that describes the general results of the review, including the score that your application received.

If you are approved for funding, you will receive an additional notice, the Notice of Grant Award, signed by SAMHSA's Grants Management Officer. The Notice of Grant Award is the sole obligating document that allows the grantee to receive Federal funding for work on the grant project. It is sent by postal mail and is addressed to the contact person listed on the face page of the application.

If you are not funded, you can re-apply if there is another receipt date for the program.

*2. Administrative and National Policy Requirements*

■ You must comply with all terms and conditions of the grant award. SAMHSA's standard terms and conditions are available on the SAMHSA Web site at *www.samhsa.gov/grants/2004/useful_info.asp.*

■ Depending on the nature of the specific funding opportunity and/or the proposed project as identified during review, additional terms and conditions may be identified negotiated with the grantee prior to grant award. These may include, for example:

○ Actions required to be in compliance with human subjects requirements;

○ Requirements relating to additional data collection and reporting;

○ Requirements relating to participation in a cross-site evaluation; or

○ Requirements to address problems identified in review of the application.

■ You will be held accountable for the information provided in the application relating to performance targets. SAMHSA program officials will consider your progress in meeting goals and objectives, as well as your failures and strategies for overcoming them, when making an annual recommendation to continue the grant

and the amount of any continuation award. Failure to meet stated goals and objectives may result in suspension or termination of the grant award, or in reduction or withholding of continuation awards.

■ In an effort to improve access to funding opportunities for applicants, SAMHSA is participating in the U.S. Department of Health and Human Services "Survey on Ensuring Equal Opportunity for Applicants.'' This survey is included in the application kit for SAMHSA grants. Applicants are encouraged to complete the survey and return it, using the instructions provided on the survey form.

*3. Reporting Requirements*

3.1 Progress and Financial Reports

■ Grantees must provide annual and final progress reports. The final report must summarize information from the annual reports, describe the accomplishments of the project, and describe next steps for implementing plans developed during the grant period.

■ Grantees must provide annual and final financial status reports. These reports may be included as separate sections of annual and final progress reports or can be separate documents. Because SAMHSA is extremely interested in ensuring that treatment or prevention services can be sustained, your financial reports should explain plans to ensure the sustainability (see Glossary) of efforts initiated under this grant. Initial plans for sustainability should be described in year 01. In each subsequent year, you should describe the status of your project, as well as the successes achieved and obstacles encountered in that year.

■ SAMHSA will provide guidelines and requirements for these reports to grantees at the time of award and at the initial grantee orientation meeting after award. SAMHSA staff will use the information contained in the reports to determine the grantee's progress toward meeting its goals.

3.2 Government Performance and Results Act (GPRA)

The Government Performance and Results Act (GPRA) mandates accountability and performance-based management by Federal agencies. To meet the GPRA requirements, SAMHSA must collect performance data (*i.e.*, "GPRA data'') from grantees. These requirements are specified in Section I–2.4 (Data and Performance Measurement) of this document.

3.3 Publications

If you are funded under this grant program, you are required to notify the Government Project Officer (GPO) and SAMHSA's Publications Clearance Officer (301–443–8596) of any materials based on the SAMHSA-funded grant project that are accepted for publication.

In addition, SAMHSA requests that grantees:

■ Provide the GPO and SAMHSA Publications Clearance Officer with advance copies of publications.

■ Include acknowledgment of the SAMHSA grant program as the source of funding for the project.

■ Include a disclaimer stating that the views and opinions contained in the publication do not necessarily reflect those of SAMHSA or the U.S. Department of Health and Human Services, and should not be construed as such.

SAMHSA reserves the right to issue a press release about any publication deemed by SAMHSA to contain information of program or policy significance to the substance abuse treatment/substance abuse prevention/mental health services community.

## VII. Agency Contacts

For questions about program issues, contact: Tom DeLoe, Ph.D., SAMHSA/CSAP, 5600 Fishers Lane, Rockwall II, Suite 1075, Rockville, MD 20857, 301–443–9110, E-mail: *tdeloe@samhsa.gov.*

For questions on grants management issues, contact: Edna Frazier, Office of Program Services, Division of Grants Management, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockwall II, Suite 630, Rockville, MD 20857, (301) 443–6816, *efrazier@samhsa.gov.*

## Appendix A—Checklist for Formatting Requirements and Screenout Criteria for SAMHSA Grant Applications

SAMHSA's goal is to review all applications submitted for grant funding. However, this goal must be balanced against SAMHSA's obligation to ensure equitable treatment of applications. For this reason, SAMHSA has established certain formatting requirements for its applications. If you do not adhere to these requirements, your application will be screened out and returned to you without review. In addition to these formatting requirements, programmatic requirements (*e.g.*, relating to eligibility) may be stated in the specific funding announcement. Please check the entire funding announcement before preparing your application.

☐ Use the PHS 5161–1 application.

☐ Applications must be received by the application deadline. Applications received after this date must have a proof of mailing date from the carrier dated at least 1 week prior to the due date. Private metered postmarks are not acceptable as proof of timely mailing. Applications not received by the application deadline or not postmarked at least 1 week prior to the application deadline will not be reviewed.

☐ Information provided must be sufficient for review.

☐ Text must be legible.

• Type size in the Project Narrative cannot exceed an average of 15 characters per inch, as measured on the physical page. (Type size in charts, tables, graphs, and footnotes will not be considered in determining compliance.)

• Text in the Project Narrative cannot exceed 6 lines per vertical inch.

☐ Paper must be white paper and 8.5 inches by 11.0 inches in size.

☐ To ensure equity among applications, the amount of space allowed for the Project Narrative cannot be exceeded.

• Applications would meet this requirement by using all margins (left, right, top, bottom) of at least one inch each, and adhering to the page limit for the Project Narrative stated in the specific funding announcement.

• Should an application not conform to these margin or page limits, SAMHSA will use the following method to determine compliance: The total area of the Project Narrative (excluding margins, but including charts, tables, graphs and footnotes) cannot exceed 58.5 square inches multiplied by the page limit. This number represents the full page less margins, multiplied by the total number of allowed pages.

• Space will be measured on the physical page. Space left blank within the Project Narrative (excluding margins) is considered part of the Project Narrative, in determining compliance.

☐ The page limit for Appendices stated in the specific funding announcement cannot be exceeded.

To facilitate review of your application, follow these additional guidelines. Failure to adhere to the following guidelines will not, in itself, result in your application being screened out and returned without review. However, the information provided in your application must be sufficient for review. Following these guidelines will help ensure your application is complete, and will help reviewers to consider your application.

☐ The 10 application components required for SAMHSA applications should be included. These are:

• Face Page (Standard Form 424, which is in PHS 5161–1).

• Abstract.

• Table of Contents.

• Budget Form (Standard Form 424A, which is in PHS 5161–1).

• Project Narrative and Supporting Documentation.

• Appendices.

• Assurances (Standard Form 424B, which is in PHS 5161–1).

• Certifications (a form within PHS 5161–1).

• Disclosure of Lobbying Activities (Standard Form LLL, which is in PHS 5161–1).

• Checklist (a form in PHS 5161–1).

☐ Applications should comply with the following requirements:

• Provisions relating to confidentiality, participant protection and the protection of human subjects specified in Section IV–2.4 of the FY 2004 standard funding announcements.

• Budgetary limitations as specified in Section I, II, and IV–5 of the FY 2004 standard funding announcements.

• Documentation of nonprofit status as required in the PHS 5161–1.

☐ Pages should be typed single-spaced with one column per page.

☐ Pages should not have printing on both sides.

☐ Please use black ink and number pages consecutively from beginning to end so that information can be located easily during review of the application. The cover page should be page 1, the abstract page should be page 2, and the table of contents page should be page 3. Appendices should be labeled and separated from the Project Narrative and budget section, and the pages should be numbered to continue the sequence.

☐ Send the original application and two copies to the mailing address in the funding announcement. Please do not use staples, paper clips, and fasteners. Nothing should be attached, stapled, folded, or pasted. Do not use heavy or lightweight paper or any material that cannot be copied using automatic copying machines. Odd-sized and oversized attachments such as posters will not be copied or sent to reviewers. Do not include videotapes, audiotapes, or CD–ROMs.

## Appendix B—Glossary

*Best Practice:* Best practices are practices that incorporate the best objective information currently available regarding effectiveness and acceptability.

*Catchment Area:* A catchment area is the geographic area from which the target population to be served by a program will be drawn.

*Cooperative Agreement:* A cooperative agreement is a form of Federal grant. Cooperative agreements are distinguished from other grants in that, under a cooperative agreement, substantial involvement is anticipated between the awarding office and the recipient during performance of the funded activity. This involvement may include collaboration, participation, or intervention in the activity. HHS awarding offices use grants or cooperative agreements (rather than contracts) when the principal purpose of the transaction is the transfer of money, property, services, or anything of value to accomplish a public purpose of support or stimulation authorized by Federal statute. The primary beneficiary under a grant or cooperative agreement is the public, as opposed to the Federal Government.

*Cost Sharing or Matching:* Cost sharing refers to the value of allowable non-Federal contributions toward the allowable costs of a Federal grant project or program. Such contributions may be cash or in-kind contributions. For SAMHSA grants, cost sharing or matching is not required, and applications will not be screened out on the basis of cost sharing. However, applicants often include cash or in-kind contributions in their proposals as evidence of commitment to the proposed project. This is allowed, and this information may be considered by reviewers in evaluating the quality of the application.

*Fidelity:* Fidelity is the degree to which a specific implementation of a program or practice resembles, adheres to, or is faithful to the evidence-based model on which it is based. Fidelity is formally assessed using rating scales of the major elements of the evidence-based model. A toolkit on how to develop and use fidelity instruments is available from the SAMHSA-funded Evaluation Technical Assistance Center at http://tecathsri.org or by calling (617) 876–0426.

*Grant:* A grant is the funding mechanism used by the Federal Government when the principal purpose of the transaction is the transfer of money, property, services, or anything of value to accomplish a public purpose of support or stimulation authorized by Federal statute. The primary beneficiary under a grant or cooperative agreement is the public, as opposed to the Federal Government.

*In-Kind Contribution:* In-kind contributions toward a grant project are non-cash contributions (*e.g.*, facilities, space, services) that are derived from non-Federal sources, such as State or sub-State non-Federal revenues, foundation grants, or contributions from other non-Federal public or private entities.

*Logic Model:* A logic model is a diagrammatic representation of a theoretical framework. A logic model describes the logical linkages among program resources, conditions, strategies, short-term outcomes, and long-term impact. More information on how to develop logics models and examples can be found through the resources listed in Appendix G.

*Practice:* A practice is any activity, or collective set of activities, intended to improve outcomes for people with or at risk for substance abuse and/or mental illness. Such activities may include direct service provision, or they may be supportive activities, such as efforts to improve access to and retention in services, organizational efficiency or effectiveness, community readiness, collaboration among stakeholder groups, education, awareness, training, or any other activity that is designed to improve outcomes for people with or at risk for substance abuse or mental illness.

*Practice Support System:* This term refers to contextual factors that affect practice delivery and effectiveness in the pre-adoption phase, delivery phase, and post-delivery phase, such as (a) community collaboration and consensus building, (b) training and overall readiness of those implementing the practice, and (c) sufficient ongoing supervision for those implementing the practice.

*Stakeholder:* A stakeholder is an individual, organization, constituent group, or other entity that has an interest in and will be affected by a proposed grant project.

*Strategic Prevention Framework:* This term refers to a SAMHSA/CSAP initiative to encourage States to develop strategic plans to prevent/reduce the use of alcohol, tobacco and other drugs. This process will include needs assessment, capacity building, planning, implementation, and evaluation.

*Sustainability:* Sustainability is the ability to continue a program or practice after SAMHSA grant funding has ended.

*Target Population:* The target population is the specific population of people whom a particular program or practice is designed to serve or reach.

*Wraparound Service:* Wraparound services are non-clinical supportive services—such as child care, vocational, educational, and transportation services—that are designed to improve the individual's access to and retention in the proposed project.

## Appendix C—National Registry of Effective Programs

To help SAMHSA's constituents learn more about science-based programs, SAMHSA's Center for Substance Abuse Prevention (CSAP) created a National Registry of Effective Programs (NREP) to review and identify effective programs. NREP seeks candidates from the practice community and the scientific literature. While the initial focus of NREP was substance abuse prevention programming, NREP has expanded its scope and now includes prevention and treatment of substance abuse and of co-occurring substance abuse and mental disorders, and psychopharmacological programs and workplace programs.

NREP includes three categories of programs: Effective Programs, Promising Programs, and Model Programs. Programs defined as Effective have the option of becoming Model Programs if their developers choose to take part in SAMHSA dissemination efforts. The conditions for making that choice, together with definitions of the three major criteria, are as follows.

*Promising Programs* have been implemented and evaluated sufficiently and are scientifically defensible. They have positive outcomes in preventing substance abuse and related behaviors. However, they have not yet been shown to have sufficient rigor and/or consistently positive outcomes required for Effective Program status. Nonetheless, Promising Programs are eligible to be elevated to Effective/Model status after review of additional documentation regarding program effectiveness. Originated from a range of settings and spanning target populations, Promising Programs can guide prevention, treatment, and rehabilitation.

*Effective Programs* are well-implemented, well-evaluated programs that produce consistently positive pattern of results (across domains and/or replications). Developers of Effective Programs have yet to help SAMHSA/CSAP disseminate their programs, but may do so themselves.

*Model Programs* are also well-implemented, well-evaluated programs, meaning they have been reviewed by NREP according to rigorous standards of research. Their developers have agreed with SAMHSA/CSAP to provide materials, training, and technical assistance for nationwide implementation. That helps ensure the program is carefully implemented and likely to succeed.

Programs that have met the NREP standards for each category can be identified by accessing the NREP Model Programs Web site at *www.modelprograms.samhsa.gov.*

## Appendix F—Statement Of Assurance

As the authorized representative of the applicant organization, I assure SAMHSA that if {insert name of organization} application is within the funding range for a grant award, the organization will provide the SAMHSA Government Project Officer (GPO) with the following documents. I understand that if this documentation is not received by the GPO within the specified timeframe, the application will be removed from consideration for an award and the funds will be provided to another applicant meeting these requirements.

- A letter of commitment that specifies the nature of the participation and what service(s) will be provided from every service provider organization, listed in Appendix 1 of the application, that has agreed to participate in the project;
- Official documentation that all service provider organizations participating in the project have been providing relevant services for a minimum of 2 years prior to the date of the application in the area(s) in which services are to be provided. Official documents must definitively establish that the organization has provided relevant services for the last 2 years; and
- Official documentation that all participating service provider organizations are in compliance with all local (city, county) and State/tribal requirements for licensing, accreditation, and certification or official documentation from the appropriate agency of the applicable State/tribal, county, or other governmental unit that licensing, accreditation, and certification requirements do not exist. (Official documentation is a copy of each service provider organization's license, accreditation, and certification. Documentation of accreditation will not be accepted in lieu of an organization's license. A statement by, or letter from, the applicant organization or from a provider organization attesting to compliance with licensing, accreditation and certification or that no licensing, accreditation, certification requirements exist *does not* constitute adequate documentation.)

## Appendix G—Logic Model Resources


Chen, W.W., Cato, B.M., & Rainford, N. (1998–9). Using a logic model to plan and evaluate a community intervention program: A case study. International Quarterly of Community Health Education, 18(4), 449–458.

Edwards, E.D., Seaman, J.R., Drews, J., & Edwards, M.E. (1995). A community approach for Native American drug and alcohol prevention programs: A logic model framework. Alcoholism Treatment Quarterly, 13(2), 43–62.

Hernandez, M. & Hodges, S. (2003). Crafting Logic Models for Systems of Care: Ideas into Action. [Making children's mental health services successful series, volume 1]. Tampa, FL: University of South Florida, The Louis de la Parte Florida Mental Health Institute, Department of Child & Family Studies. *http://cfs.fmhi.usf.edu* or phone (813) 974–4651.

Hernandez, M. & Hodges, S. (2001). Theory-based accountability. In M. Hernandez & S. Hodges (Eds.), Developing Outcome Strategies in Children's Mental Health, pp. 21–40. Baltimore: Brookes.

Julian, D.A. (1997). Utilization of the logic model as a system level planning and evaluation device. Evaluation and Planning, 20(3), 251–257.

Julian, D.A., Jones, A., & Deyo, D. (1995). Open systems evaluation and the logic model: Program planning and evaluation tools. Evaluation and Program Planning, 18(4), 333–341.

Patton, M.Q. (1997). Utilization-Focused Evaluation (3rd Ed.), pp. 19, 22, 241. Thousand Oaks, CA: Sage.

Wholey, J.S., Hatry, H.P., Newcome, K.E. (Eds.) (1994). Handbook of Practical Program Evaluation. San Francisco, CA: Jossey-Bass Inc.


Dated: April 2, 2004.

**Daryl Kade,**

*Director, Office of Policy, Planning and Budget, Substance Abuse and Mental Health Services Administration.*

[FR Doc. 04–7908 Filed 4–7–04; 8:45 am]

BILLING CODE 4162–20–P

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Substance Abuse and Mental Health Services Administration

## Funding Opportunity Title: Notice of Funding Availability (NOFA) for the National Center for Child Traumatic Stress of the National Child Traumatic Stress Initiative (Short Title: NCTSI—National Center)

*Announcement Type:* Initial.

*Funding Opportunity Number:* SM 04–008.

*Catalog of Federal Domestic Assistance (CFDA) Number:* 93.243.

*Due Date for Application:* June 10, 2004.

**Note:** Letters from State Single Point of Contact (SPOC) in response to E.O. 12372 are due August 9, 2004.

**SUMMARY:** The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Mental Health Services (CMHS), announces the availability of FY 2004 funds for the National Center for Child Traumatic Stress of the National Child Traumatic Stress Initiative. A synopsis of this funding opportunity, as well as many other Federal Government funding opportunities, are also available at the Internet site: *http://www.grants.gov.*

For complete instructions, potential applicants must obtain a copy of SAMHSA's standard Infrastructure Grant Program Announcement (INF–04 PA [MOD]), and the PHS 5161–1 (Rev. 7/00) application form before preparing and submitting an application. The INF–04 PA (MOD) describes the general program design and provides instructions for applying for all SAMHSA Infrastructure Grants, including the National Center for Child Traumatic Stress of the National Child Traumatic Stress Initiative. Additional instructions and specific requirements for this funding opportunity are described below.

## I. Funding Opportunity Description

**Authority:** Section 582 of the Public Health Service Act, as amended and subject to the availability of funds.

The National Center for Child Traumatic Stress of National Child Traumatic Stress Initiative (NCTSI—National Center) is one of SAMHSA's Infrastructure Grants. SAMHSA's Infrastructure Grants provide funds to increase the capacity of mental health and/or substance abuse services systems to support effective programs and services. The purpose of the NCTSI—National Center grant is to support funding of a national coordinating center for the NCTSI network that will provide leadership, coordination, and support for collaboration of the NCTSI centers. The national coordinating center will develop and implement a framework and organizational procedures for communication and collaboration among Network centers to promote and sustain a comprehensive approach to identifying, improving, developing, and/or evaluating child trauma treatment interventions and services approaches. The national coordinating center will further develop the national capacity for training in implementing effective treatment and service delivery and develop and disseminate informational resources and other products on child and adolescent traumatic stress to professionals, policy makers, and the public.

In providing leadership for the national Network, the national coordinating center will implement the framework and organizational procedures for communication and collaboration among Network centers. This program will also enable the national coordinating center to coordinate and integrate centers funded subsequent to the original cohort into the Network. The functions of the national coordinating center are to:

- Provide leadership to the Network and strengthen the Network's ability to support high-priority, results-oriented collaborative projects that are essential for the success of the Initiative;

• Oversee and coordinate the core activities of the Network (Data, Learning from Research and Clinical Practice, Service Systems, Training and Policy) to collect, organize, screen, review, and disseminate existing or new resource materials on child and adolescent traumatic stress for professionals, policy makers, and the public;

• Coordinate the Steering Committee for the Network;

• Promote, facilitate, and support targeted collaborative activities among all centers, by building incentives for Network centers to achieve productive collaboration on high-priority projects, and creating management structures that makes it easier for Network members to work with one another;

• Provide technical assistance to Network members, policy makers and the public, utilizing intra-Network expertise as well as external consultants;

• Work in partnership to help CMHS monitor and evaluate all internal and external Network collaborative activities for relevance, efficiency, effectiveness, and impact on the main goals of the Initiative;

• Develop customized training materials, organize training events, and disseminate training curricula developed by Network members; and

• Communicate and market Network activities through the use of multiple media, including Web-based technology, and develop a national media strategy and global marketing plan that reaches out to other professional and government constituent organizations.

*Background:* In recognition of the serious impact that trauma can have on children, Congress in FY2001 authorized CMHS to develop a grant program focusing on improving treatment and services for psychological trauma in children and youth through development of knowledge and evidence-based practices for treating trauma-related psychiatric disorders. To develop a grant program that would adequately address the Congressional intent, CMHS established the National Child Traumatic Stress Initiative (NCTSI) consisting of a network of three types of centers: (1) A national coordinating center, the National Center for Child Traumatic Stress (NCCTS) that provides the vision, national leadership, and overall organizing and coordinating expertise for the NCTSI; (2) Intervention Development and Evaluation Centers (IDECs) that develop and assess interventions for different types of trauma and for different populations of children and adolescents who have experienced trauma; and (3) Community Treatment and Services Centers (CTSCs) that provide community-based treatment for trauma. This network of centers works collaboratively to address the most important issues in treatment and service delivery for traumatized children and adolescents. The collaborative activities implemented under this novel structure permit improvement in treatment and services to traumatized children on a national scale, beyond the individual reach of each of the grantees.

## II. Award Information

*1. Estimated Funding Available/ Number of Awards:* It is expected that up to $5 million will be available to fund one award in FY 2004. This will be a Category I-Comprehensive Infrastructure Grant award, as described in the INF–04 PA (MOD). This Category I award will be up to $5 million in total costs (direct and indirect) for one year, rather than the funding amount and funding period specified in the INF–04 PA (MOD). The proposed budget cannot exceed the allowable amount. The actual amount available for the award may vary, depending on unanticipated program requirements.

*2. Funding Instrument:* Cooperative Agreement

*Role of Federal Staff:*

• Consult with the National Center Directors on all phases of the project to ensure accomplishment of the goals of the Initiative;

• Review critical project activities for conformity to the mission of the NCTSI;

• Assume overall responsibility for monitoring the conduct and progress of the NCTSI programs;

• Make recommendations regarding continued funding;

• Provide guidance on project design and components;

• Participate in policy and steering groups or related work groups;

• Review quarterly reports and conduct site visits, if warranted;

• Oversee development and implementation of multi-site evaluation in partnership with evaluation contractors, NCCTS staff and other NCTSI grantees;

• Approve data collection plans and institute policies regarding data collection;

• Submit required clearance packages to the Office of Management and Budget (OMB) using information and materials provided by the grantee;

• Recommend outside consultants for training, site-specific evaluation, and data collection, if needed;

• Author or co-author publications on program findings; and

• Provide technical assistance on ways to help disseminate and apply study results.

*Role of Awardee:*

• Comply with the terms of the award and satisfactorily perform activities to achieve the NCTSI goals;

• Consult with and accept guidance from CMHS staff on performance of activities to achieve NCTSI goals;

• Consult with SAMHSA staff and outside consultants on evaluation plans. Assist in evaluation of network activities and program outcome evaluation;

• Provide SAMHSA with justifications and materials for clearance of data collection and analysis activities by the Office of Management and Budget (OMB);

• Support and participate in network meetings;

• Respond to requests for information from CMHS;

• Agree to provide SAMHSA with data required for the Government Performance and Results Act (GPRA);

• As appropriate, support and disseminate intervention products, training materials, and other publications developed by the NCTSN for use by the field; and

• Produce required SAMHSA reports.

## III. Eligibility Information

*1. Eligible Applicant:* The current National Center for Child Traumatic Stress is the only entity eligible to apply for funding under this announcement. This eligibility criterion supersedes the criteria specified in Section III–1 of the INF–04 PA (MOD). SAMHSA/CMHS plans to award an additional year to the current National Center for Child Traumatic Stress (which received its last year of grant funding at the end of FY 2003) so that the necessary coordination of the current grantees' work can continue, while changes to the overall National Child Traumatic Stress Initiative are planned. In FY 2005, SAMHSA/CMHS plans to announce a new, competitive funding opportunity for a National Center for Child Traumatic Stress.

*2. Cost Sharing or Matching* is not required.

*3. Other:* The applicant must also meet certain application formatting and submission requirements or the application will be screened out and will not be reviewed. These requirements are described in Section IV–2 below as well as in the INF–04 PA (MOD).

## IV. Application and Submission Information

*1. Address to Request Application Package:* Complete application kits may be obtained from: the National Mental Health Information Center at 1–800–789–2647. When requesting an application kit for this program, the applicant must specify the funding opportunity title (NCTSI—National Center) and the funding opportunity number (SM 04–008). All information necessary to apply, including where to submit applications and application deadline instructions, is included in the application kit. The PHS 5161–1 application form is also available electronically via SAMHSA's World Wide Web Home Page: *http://www.samhsa.gov* (click on 'Grant Opportunities') and the INF–04 PA (MOD) is available electronically at *http://www.samhsa.gov/grants/2004/standard/Infrastructure/index.asp.*

When submitting an application, be sure to type "SM 04–008, NCTSI—National Center'' in Item Number 10 on the face page of the application form. Also, SAMHSA applicants are required to provide a DUNS Number on the face page of the application. To obtain a DUNS Number, access the Dun and Bradstreet Web site at *http://www.dunandbradstreet.com* or call 1–866–705–5711.

*2. Content and Form of Application Submission:* Additional information including required documents, required application components, and application formatting requirements is available in the INF–04 PA (MOD) in Section IV–2.

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❑ Use the PHS 5161–1 application.

❑ Applications must be received by the application deadline. Applications received after this date must have a proof of mailing date from the carrier dated at least 1 week prior to the due date. Private metered postmarks are not acceptable as proof of timely mailing. Applications not received by the application deadline or not postmarked at least 1 week prior to the application deadline will not be reviewed.

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These are:

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- Certifications (a form in PHS 5161–1)
- Disclosure of Lobbying Activities (Standard Form LLL, which is in PHS 5161–1)
- Checklist (a form in PHS 5161–1)

☐ Applications should comply with the following requirements:

- Provisions relating to confidentiality, participant protection and the protection of human subjects, as indicated in the specific funding announcement.
- Budgetary limitations as indicated in Sections I, II, and IV–5 of the specific funding announcement.
- Documentation of nonprofit status as required in the PHS 5161–1.

☐ Pages should be typed single-spaced with one column per page.

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☐ Send the original application and two copies to the mailing address in the funding announcement. Please do not use staples, paper clips, and fasteners. Nothing should be attached, stapled, folded, or pasted. Do not use heavy or lightweight paper, or any material that cannot be copied using automatic copying machines. Odd-sized and oversized attachments such as posters will not be copied or sent to reviewers. Do not include videotapes, audiotapes, or CD–ROMs.

*3. Submission Dates and Times:* Applications must be received by June 10, 2004. You will be notified by postal mail that your application has been received. Additional submission information is available in the INF–04 PA (MOD) in Section IV–3.

*4. Intergovernmental Review:* The applicant for this funding opportunity must comply with Executive Order 12372 (E.O.12372). E.O.12372, as implemented through Department of Health and Human Services (DHHS) regulation at 45 CFR Part 100, sets up a system for State and local review of applications for Federal financial assistance. Instructions for complying with E.O. 12372 are provided in the INF–04 PA (MOD) in Section IV–4. A current listing of State Single Points of Contact (SPOCs) is included in the application kit and is available at *http:*

*//www.whitehouse.gov/omb/grants/spoc.html.*

*5. Funding Restrictions:* Information concerning funding restrictions is available in the INF–04 PA (MOD) in Section IV–5.

*6. Other Submission Requirements:* Instructions for submitting applications, including where and how to send applications, are provided in the INF–04 PA (MOD) in Section IV–6.

## V. Application Review Information

*1. Evaluation Criteria:* The application will be reviewed against the Evaluation Criteria and requirements for the Project Narrative specified in the INF–04 PA (MOD). The following information describes exceptions or limitations to the INF–04 PA (MOD) and provides special requirements that pertain only to the NCTSI-National Center cooperative agreement. The applicant for the NCTSI-National Center cooperative agreement is required to discuss the following requirements in its application, in addition to the requirements specified in the INF–04 PA (MOD):

*1.1 In "Section A: Statement of Need"*

(a) The applicant's statement of need should specify the current target population of the National Child Traumatic Stress Initiative. Rather than specify a catchment area, the applicant must describe nationwide needs for children experiencing traumatic stress. In addition, the applicant must specify needs within the "target population" of the network. As a leadership and coordinating entity for a national network of grantees, the "target populations" or "target issues" for the NCCTS are (1) the currently funded CTSCs and IDECs in the NCTSN; (2) the current types and mechanisms of collaborative activities taking place within the network; and (3) currently developed interventions for child/adolescent trauma as well as potential new interventions for different types of child trauma and in different service settings.

(b) The applicant must demonstrate familiarity with the needs throughout the network and describe interests and activities in child trauma at existing centers, organizational structure of the network and ongoing collaborative activities, and types of interventions that need to be developed by the NCTSN. The applicant should describe strengths of the current structure of the National Child Traumatic Stress Network, and should also outline areas for potential improvement and suggestions for potential modifications in the upcoming year.

*1.2 In "Section B: Proposed Approach"*

(a) The applicant must describe how it will provide leadership and support for collaborative activities, including establishing, supporting, and monitoring, collaborative network activities throughout the National Child Traumatic Stress Network.

(b) The applicant must describe how it will conduct national leadership activities, including promoting national attention to child trauma, promoting policy initiatives, and collaborating with national consumer and professional organizations.

(c) The applicant must describe processes to: (1) improve collaborative activity among NCTSN centers; (2) address strategic issues in core network activity areas; and (3) develop, document and promote intervention approaches through a process of standardization, evaluation, and dissemination.

(d) The applicant must describe the activities of the steering committee for the National Child Traumatic Stress network, including membership, roles, functions, and frequency of meetings. If changes from current practice are proposed, these changes must be described.

(e) The applicant must describe strategies for disseminating effective approaches to child trauma through training of professionals, developing training materials and training curricula.

(f) The applicant must describe methods for developing a national media strategy and marketing plan for the National Child Traumatic Stress network that reaches professional and government organizations.

*1.3 In "Section C: Staff, Management, and Relevant Experience"*

The applicant must describe their experience and expertise in developing the National Child Traumatic Stress Network. If changes in management or staffing are proposed for the upcoming year, these changes must be specifically addressed in the application.

*1.4 In "Section D: Evaluation and Data"*

(a) The applicant must describe current activities in the areas of data collection, analysis, evaluation, and reporting of findings to SAMHSA and to other grantees within the National Child Traumatic Stress Network. The applicant must indicate a plan for internal "process evaluation" and correction of coordination issues noted in process evaluation.

(b) The applicant must discuss plans to collaborate with SAMSHA staff in the development and implementation of future cross-site evaluation plans. These plans must include attention to SAMHSA GPRA goals, Infrastructure goals, and program-specific goals.

(c) The applicant must discuss plans to collaborate with SAMSHA staff in providing existing data collection materials and developing new data collection materials for approval by the U.S. Office of Management and Budget (OMB), as necessary.

(d) Standardized instruments that have been included in the core data set for clinical data collection do not need to be included in Appendix 2. However, any process evaluation materials or instruments that will be used to assess network development or operation should be included in Appendix 2.

*1.5 Performance Measurement*

All SAMHSA grantees are required to collect and report certain data, so that SAMHSA can meet its obligations under the Government Performance and Results Act (GPRA). The grantee of the NCTSI-National Center program will be required to report performance in: (1) Increasing the number of children and adolescents reached by improved services; and (2) improving children's outcomes. The applicant must document its ability to collect and report the required data in "Section D: Evaluation and Data" of its application. An instrument will be developed by CMHS staff to report on these indicators.

*2. Review and Selection Process:* Information about the review and selection process is available in the INF–04 PA (MOD) in Section V–2. Because this is a sole source award, equitable distribution of awards in terms of geographic criteria does not apply.

## VI. Award Administration Information

Award administration information, including award notices, administrative and national policy requirements, and reporting requirements are available in the INF–04 PA (MOD) in Section VI. In addition to the reporting requirements stated in the INF–04 PA (MOD), the applicant must provide quarterly progress reports. SAMHSA's standard terms and conditions are available at *http://www.samhsa.gov/grants/2004/useful_info.asp.*

## VII. Agency Contact for Additional Information

For questions about program issues contact: Cecilia Rivera-Casale, Ph.D., Senior Project Officer, Emergency Mental Health and Traumatic Stress Services Branch, Division of Prevention,

Traumatic Stress, and Special Programs, SAMHSA/CMHS, 5600 Fishers Lane, Room 15–99, Rockville, MD 20857; 301–443–4735; E-mail: *ccasale@samhsa.gov*. For questions on grants management issues contact: Ms. Gwendolyn Simpson, SAMHSA/Division of Grants Management, 5600 Fishers Lane, Room 13–103, Rockville, MD 20857; 301–443–4456; E-mail: *gsimpson@samhsa.gov*.

Dated: April 2, 2004.

**Daryl Kade,**

*Director, Office of Policy, Planning and Budget, Substance Abuse and Mental Health Services Administration.*

[FR Doc. 04–7909 Filed 4–7–04; 8:45 am]

**BILLING CODE 4162–20–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

### Funding Opportunity Title: Notice of Funding Availability (NOFA) for Intervention Development and Evaluation Centers of the National Child Traumatic Stress Initiative (Short Title: NCTSI–IDE Centers)

*Announcement Type:* Initial.

*Funding Opportunity Number:* SM 04–009.

*Catalog of Federal Domestic Assistance (CFDA) Number:* 93.243.

*Due Date for Application:* June 10, 2004.

**[Note:** Letters from State Single Point of Contact (SPOC) in response to E.O. 12372 are due August 9, 2004.]

**SUMMARY:** The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Mental Health Services (CMHS), announces the availability of FY 2004 funds for Intervention Development and Evaluation Centers of the National Child Traumatic Stress Initiative (NCTSI–IDE Centers). A synopsis of this funding opportunity, as well as many other Federal Government funding opportunities, are also available at the Internet site: *http://www.grants.gov*.

For complete instructions, potential applicants must obtain a copy of SAMHSA's standard Service-to-Science Grants Announcement [STS–04 PA (MOD)], and the PHS 5161–1 (Rev. 7/00) application form before preparing and submitting an application. The STS–04 PA (MOD) describes the general program design and provides instructions for applying for all SAMHSA Service-to-Science Grants, including the NCTSI–IDE Centers. Additional instructions and specific requirements for this funding opportunity are described below.

### I. Funding Opportunity Description

**Authority:** Section 582 of the Public Health Service Act, as amended and subject to the availability of funds.

The Intervention Development and Evaluation Centers of the National Child Traumatic Stress Initiative (NCTSI–IDE Centers) are SAMHSA Service-to-Science Grants. The purpose of NCTSI–IDE Center grants is to develop, deliver and evaluate improved treatment approaches and service delivery models within the NCTSI for specific types of trauma (*e.g.*, child abuse or refugee trauma) and/or different service settings (*e.g.*, schools or residential treatment centers), and/or diverse populations of traumatized children/adolescents (racial/ethnic, rural.) To complement the development of treatment approaches for acute and chronic trauma in children and adolescents, the IDE Centers also develop intervention manuals, and training procedures for service providers in effective trauma interventions. In their defined area of national expertise, IDE Centers serve as a resource for public and professional education, training, consultation and technical assistance on effective treatments and services.

This one-year funding announcement will allow the initial cohort of IDE Centers to continue activities begun during the current funding period, further refine specialized treatment approaches, tailor practice manuals for new service settings, and update procedures to disseminate intervention products nationally. Grantees may complete ongoing Phase I activities but may not begin new ones under this grant.

*Expectations:*

The major emphasis of the NCTSI–IDE Centers grant will be the development of intervention approaches, evaluation of these intervention approaches in community settings, or the development of processes for disseminating effective practices to a diverse array of providers and communities. These quantitative and qualitative evaluations must meet the Phase 2 requirements described in the STS–04 PA (MOD). At the end of this year of funding, SAMHSA expects the IDE Centers to have completed one evaluation for entrance in SAMHSA's National Registry of Effective Programs (NREP), a SAMHSA effort initiated in 1998 to search for and to certify effective substance abuse prevention and mental health interventions. SAMHSA intends to promote a more systematic collection of evaluation results and dissemination of effective service practices as a cornerstone of the NCTSN in the future.

A critical aspect of the IDE Centers is their role in the National Child Traumatic Stress Network. Therefore, applicants must describe the following when completing their applications:

- How they will develop, implement, evaluate and disseminate their intervention approaches within the existing framework of the National Child Traumatic Stress Network.
- How they participate in the current structure and operation of the NCTSN to develop intervention products within this collaborative framework.
- What consultation services, training, and resource development they provide to (1) other NCTSN centers, (2) local service programs, and (3) other service programs.
- For grantees who provide direct clinical services, their participation in clinical data collection, both in the development of clinical data collection protocols for the NCTSI network and collection of clinical data from service recipients.
- Assessment of effectiveness of training activities.

Applicants may build upon existing evaluation activities begun during the previous three years of funding. Applicants may do more than one evaluation, especially if several evaluations are underway or if several approaches have completed Phase I activities and are poised for evaluation. The desired endpoint for Phase II is the documented achievement of the intervention's effectiveness and readiness for submission in NREP or experimental study.

### II. Award Information

1. *Estimated Funding Available/ Number of Awards:* It is expected that up to $3 million will be available to fund up to 5 awards in FY 2004. The maximum allowable award is $600,000 in total costs (direct and indirect) for one year. Proposed budgets cannot exceed the allowable amount. The actual amount available for the award may vary, depending on unanticipated program requirements and the number and quality of the applications received.

2. *Funding Instrument: Cooperative Agreement.*

*Role of Federal Staff*

- Consult with Intervention Development and Evaluation Center project directors on all phases of the project to ensure accomplishment of the goals of the Initiative;

• Review critical project activities for conformity to the goals of NCTSI;
• Monitor the conduct and progress of NCTSI project activities;
• Provide feedback on project design and components;
• Participate in selected policy and steering groups or related work groups;
• Review quarterly reports and conduct site visits, as needed;
• Provide support services or recommend outside consultants, if needed;
• Author or co-author publications on program findings; and
• Provide technical assistance on ways to help disseminate and implement products of collaborative activities.

*Role of Awardee*

• Comply with the terms of the cooperative agreement award as specified in the requirements of the STS–04 PA (MOD), the Notice of Funding Availability (NOFA), and the Notice of Grant Award (NOGA);
• Participate in collaborative activities with other National Child Traumatic Stress Network (NCTSN) centers and other collaborative network activities;
• Participate in grantee meetings;
• Accept guidance and respond to requests for data from CMHS;
• Participate in policy steering groups and other work groups to help accomplish project goals;
• As appropriate, author or co-author publications on project results for use by the field;
• Participate in post-award, cross-site process and outcome evaluation activities; and
• Implement specified activities, data collection, and quality control; and
• Complete required SAMHSA reports.

## III. Eligibility Information

1. Eligible Applicants are limited to the original cohort of five IDE Centers (Category II grantees) funded in FY 2001 under the National Child Traumatic Stress Initiative. These eligibility criteria supersede the criteria specified in Section III–1 of the STS–04 PA (MOD). SAMHSA/CMHS is currently funding four cohorts of IDE Center grantees with different start and end dates, as well as different project periods.

2. Cost Sharing or Matching is not required.

3. *Other:* Applicants must also meet certain application formatting and submission requirements or the application will be screened out and will not be reviewed. These requirements are described in Section IV–2 below as well as in the STS–04 PA (MOD).

## IV. Application and Submission Information

1. *Address to Request Application Package:* Complete application kits may be obtained from: the National Mental Health Information Center at 1–800–789–2647. When requesting an application kit for this program, applicants must specify the funding opportunity title (NCTSI–IDE Centers) and the funding opportunity number (SM 04–009). All Information necessary to apply, including where to submit applications and application deadline instructions, is included in the application kit. The PHS 5161–1 application form is also available electronically via SAMHSA's World Wide Web Home Page: *http://www.samhsa.gov* (click on "Grant Opportunities'') and the STS–04 PA (MOD) is available electronically at *http://www.samhsa.gov/grants/2004/standard/srv2sci/index.asp*. When submitting an application, be sure to type "SM 04–009, NCTSI–IDE Centers'' in Item Number 10 on the face page of the application form. Also, SAMHSA applicants are required to provide a DUNS Number on the face page of the application. To obtain a DUNS Number, access the Dun and Bradstreet Web site at *http://www.dunandbradstreet.com* or call 1–866–705–5711.

2. *Content and Form of Application Submission:* Additional information including required documents, required application components, and application formatting requirements is available in the STS–04 PA (MOD) in Section IV–2.

### Checklist for Formatting Requirements and Screen out Criteria for SAMHSA Grant Applications

SAMHSA's goal is to review all applications submitted for grant funding. However, this goal must be balanced against SAMHSA's obligation to ensure equitable treatment of applications. For this reason, SAMHSA has established certain formatting requirements for its applications. If you do not adhere to these requirements, your application will be screened out and returned to you without review.

❑ Use the PHS 5161–1 application.
❑ Applications must be received by the application deadline. Applications received after this date must have a proof of mailing date from the carrier dated at least 1 week prior to the due date. Private metered postmarks are not acceptable as proof of timely mailing. Applications not received by the application deadline or not postmarked at least 1 week prior to the application deadline will not be reviewed.
❑ Information provided must be sufficient for review.
❑ Text must be legible.
• Type size in the Project Narrative cannot exceed an average of 15 characters per inch, as measured on the physical page. (Type size in charts, tables, graphs, and footnotes will not be considered in determining compliance.)
• Text in the Project Narrative cannot exceed 6 lines per vertical inch.
❑ Paper must be white paper and 8.5 inches by 11.0 inches in size.
❑ To ensure equity among applications, the amount of space allowed for the Project Narrative cannot be exceeded.
• Applications would meet this requirement by using all margins (left, right, top, bottom) of at least one inch each, and adhering to the page limit for the Project Narrative stated in the specific funding announcement.
• Should an application not conform to these margin or page limits, SAMHSA will use the following method to determine compliance: The total area of the Project Narrative (excluding margins, but including charts, tables, graphs and footnotes) cannot exceed 58.5 square inches multiplied by the page limit. This number represents the full page less margins, multiplied by the total number of allowed pages.
• Space will be measured on the physical page. Space left blank within the Project Narrative (excluding margins) is considered part of the Project Narrative, in determining compliance.
❑ The page limit for Appendices stated in the specific funding announcement cannot be exceeded.

To facilitate review of your application, follow these additional guidelines. Failure to adhere to the following guidelines will not, in itself, result in your application being screened out and returned without review. However, the information provided in your application must be sufficient for review. Following these guidelines will help ensure your application is complete, and will help reviewers to consider your application.

❑ The 10 application components required for SAMHSA applications should be included. These are:
• Face Page (Standard Form 424, which is in PHS 5161–1)
• Abstract
• Table of Contents
• Budget Form (Standard Form 424A, which is in PHS 5161–1)
• Project Narrative and Supporting Documentation

• Appendices
• Assurances (Standard Form 424B, which is in PHS 5161–1)
• Certifications (a form in PHS 5161–1)
• Disclosure of Lobbying Activities (Standard From LLL, which is in PHS 5161–1)
• Checklist (a form in PHS 5161–1)

❑ Applications should comply with the following requirements:
• Provisions relating to confidentiality, participant protection and the protection of human subjects, as indicated in the STS–04 PA (MOD).
• Budgetary limitations as specified in Section I, II, and IV–5 of the FY 2004 STS–04 PA (MOD).
• Documentation of nonprofit status as required in the PHS 5161–1.

❑ Pages should be typed single-spaced with one column per page.

❑ Pages should not have printing on both sides.

❑ Please use black ink, and number pages consecutively from beginning to end so that information can be located easily during review of the application. The cover page should be page 1, the abstract page should be page 2, and the table of contents page should be page 3. Appendices should be labeled and separated from the Project Narrative and budget section, and the pages should be numbered to continue the sequence.

❑ Send the original application and two copies to the mailing address in the funding announcement. Please do not use staples, paper clips, and fasteners. Nothing should be attached, stapled, folded, or pasted. Do not use any material that cannot be copied using automatic copying machines. Odd-sized and oversized attachments such as posters will not be copied or sent to reviewers. Do not include videotapes, audiotapes, or CD–ROMs.

*3. Submission Dates and Times:* Applications must be received by June 10, 2004. You will be notified by postal mail that your application has been received. Additional submission Information is available in the STS–04 PA (MOD) in Section IV–3.

*4. Intergovernmental Review:* Applicants for this funding opportunity must comply with Executive Order 12372 (E.O.12372). E.O.12372, as implemented through Department of Health and Human Services (DHHS) regulation at 45 CFR Part 100, sets up a system for State and local review of applications for Federal financial assistance. Instructions for complying with E.O. 12372 are provided in the STS–04 PA (MOD) in Section IV–4. A current listing of State Single Points of Contact (SPOCs) is included in the application kit and is available at *http://www.whitehouse.gov/omb/grants/spoc.html.*

*5. Funding Restrictions:* Information concerning funding restrictions is available in the STS–04 PA (MOD) in Section IV–5.

*6. Other Submission Requirements:* Instructions for submitting applications, including where and how to send applications, are provided in the STS–04 PA (MOD) in Section IV–6.

## V. Application Review Information

*1. Evaluation Criteria:* Applications will be reviewed against the Evaluation Criteria and requirements for the Project Narrative specified in the STS–04 PA (MOD). The following information describes exceptions or limitations to the STS–04 PA (MOD) and provides special requirements that pertain only to the NCTSI–IDE Centers cooperative agreements. Applicants must discuss the following requirements in their applications, in addition to the requirements specified in the STS–04 PA (MOD). Applicants may apply for Phase I and Phase II combined or Phase II only. Grantees may complete ongoing Phase I activities, but may not begin new ones. Applications for Phase I alone will not be accepted.

*1.1 Allowable Activities:*

(a) In addition to the allowable activities stated in the STS–04 PA (MOD), applicants must collaborate with other grantees within the National Child Traumatic Stress Network in completing their Phase I and Phase II activities.

(b) IDE Centers are permitted to provide and support services in inpatient settings.

*1.2 In "Section A: Statement of Need:"*

(a) Given the efforts that have been implemented during the previous three-year grant cycle, applicants should complete the Statement of Need by defining the need/problem as the remaining work of the network or service gaps related to the IDE Center's trauma focus.

(b) Rather than provide a literature review in their area of child trauma expertise, applicants must describe the following in this section:

(1) Accomplishments in providing leadership within the NCTSN in area(s) of trauma expertise;

(2) Participation of current center staff in network collaborative activity;

(3) Progress on identifying/developing intervention approaches;

(4) Accomplishments in collaborating with other NCTSI–IDE, and with Community Treatment and Service Centers (Category III grantees).

(5) Progress in developing approaches to disseminating practices that have a documented evidence base; and

(6) Progress on dissemination of effective evidence-based practices.

*1.2a In "Section B: Proposed Approach:"*

In Section B, applicants should describe a proposed approach for addressing the problem/s described in Section A. At least one major intervention approach must meet most of the criteria specified for readying the "practice" for evaluation as described in the standard announcement. The discussion of the "practice" for evaluation should indicate which of the criteria have been addressed and the plan for meeting any criteria that have not been addressed. For example, applicants that do not currently have a logic model for their intervention approaches must provide a plan for developing a logic model.

Applicants may provide information and documentation on multiple practices that are at different stages of development, standardization, and dissemination. If applicants intend to enhance work on these, applicants must include documentation for the additional practices considered ready for systematic evaluation in Appendix 2. Applicants must indicate that they will participate in cross-site evaluation efforts. Applicants should refer to Section I–Expectations of this NOFA when completing Section B of their applications.

*1.3 In "Section C: Evaluation Design and Analysis:"*

(a) Applicants should refer to Section I–Expectations of this NOFA when completing Section C of their applications.

(b) For those IDE Centers which have already completed the evaluation of an intervention approach and another evaluation is not feasible within the year, these applicants may select among the following evaluation options:

(1) Choose to test other related interventions;

(2) Prepare other communities to replicate the specific practice with the objective of subsequent evaluation;

(3) Document and evaluate particular elements of the existing evidence-based practice that need further study.

*1.4 In "Section D: Management Plan and Staffing:"*

In addition to describing the adequacy of staffing for administering the management aspects of the grant, applicants must describe the expertise and experience of staff in providing

services, intervention development, and/or training in the specialized areas of child trauma for which the IDE is responsible.

*1.5 Performance Measurement*

All SAMHSA grantees are required to collect and report certain data, so that SAMHSA can meet its obligations under the Government Performance and Results Act (GPRA). Grantees of the NCTSI-IDE Centers will be required to report performance in: (1) increasing the number of children and adolescents reached by improved services; and (2) improving children's outcomes. Applicants must document their ability to collect and report the required data in "Section C: Evaluation Design and Analysis'' of their applications.

*2. Review and Selection Process*

Information about the review and selection process is available in the STS–04 PA (MOD) in Section V–2. Because eligibility is limited to NCTSI–IDE Centers grantees funded in FY 2001, equitable distribution of awards in terms of geographic criteria does not apply.

## VI. Award Administration Information

Award administration information, including award notices, administrative and national policy requirements, and reporting requirements are available in the STS–04 PA (MOD) in Section VI. SAMHSA's standard terms and conditions are available at *http://www.samhsa.gov/grants/2004/useful_info.asp.* In addition to the reporting requirements stated in the STS–04 PA (MOD), applicants must provide quarterly progress reports, as well as an annual evaluation report.

## VII. Agency Contact for Additional Information

For questions about program issues contact: Malcolm Gordon, Ph.D., Division of Prevention, Traumatic Stress, and Special Programs, SAMHSA/CMHS, 5600 Fishers Lane, Room 15–77, Rockville, MD 20857; 301–443–2957; E-mail: *mgordon@samhsa.gov.* For questions on grants management issues contact: Gwendolyn Simpson, SAMHSA/Division of Grants Management, 5600 Fishers Lane, Room 13–105, Rockville, MD 20857; 301–443–3896; E-mail: *gsimpson@samhsa.gov*.

Dated: April 2, 2004.

**Daryl Kade,**

*Director, Office of Policy, Planning and Budget, Substance Abuse and Mental Health Services Administration.*

[FR Doc. 04–7910 Filed 4–7–04; 8:45 am]

BILLING CODE 4162–20–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

### Funding Opportunity Title: Notice of Funding Availability (NOFA) for Community Treatment and Services Centers of the National Child Traumatic Stress Initiative (Short Title: NCTSI—Community Treatment and Services Centers)

*Announcement Type:* Initial.

*Funding Opportunity Number:* SM 04–010.

*Catalog of Federal Domestic Assistance (CFDA) Number:* 93.243.

*Due Date for Application:* June 10, 2004.

**Note:** Letters from State Single Point of Contact (SPOC) in response to E.O. 12372 are due August 9, 2004.

**SUMMARY:** The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Mental Health Services (CMHS), announces the availability of FY 2004 funds for Community Treatment and Services Centers of the National Child Traumatic Stress Initiative (NCTSI). A synopsis of this funding opportunity, as well as many other Federal Government funding opportunities, is also available at the Internet site: *http://www.grants.gov.*

For complete instructions, potential applicants must obtain a copy of SAMHSA's standard Best Practices Planning and Implementation Grant Program Announcement [BPPI–04 PA (MOD)], and the PHS 5161–1 (Rev. 7/00) application form before preparing and submitting an application. The BPPI–04 PA (MOD) describes the general program design and provides instructions for applying for all SAMHSA Best Practices Planning and Implementation Grants, including the Community Treatment and Services Centers of the National Child Traumatic Stress Initiative (NCTSI). Additional instructions and specific requirements for this funding opportunity are described below.

## I. Funding Opportunity Description

**Authority:** Section 582 of the Public Health Service Act, as amended and subject to the availability of funds.

Community Treatment and Services Centers of the National Child Traumatic Stress Initiative (NCTSI—Community Treatment and Services Centers) is one of SAMHSA's Best Practices and Planning Implementation Grants.

The purpose of NCTSI—Community Treatment and Services Centers grants is to improve treatment and services for all children and adolescents in the United States who have experienced traumatic events and to increase access to effective trauma treatment and services. A network of centers, the National Child Traumatic Stress Network (NCTSN), has been established to achieve the goals of the NCTSI. NCTSN consists of three types of centers: a national coordinating center, the National Center for Child Traumatic Stress (NCCTS), Intervention Development and Evaluation Centers (IDECs), and Community Treatment and Services Centers (CTSCs).

NCCTS provides leadership and coordination for the activities of the Network of IDECs and CTSCs. IDECs have primary responsibility for developing effective interventions for specific types of trauma (*e.g.*, child abuse or refugee trauma), different service settings (*e.g.*, schools or residential treatment centers), or different populations of traumatized children and/or adolescents (*e.g.*, preschool children or children living in rural areas). CTSCs are programs that primarily provide treatment or services in community settings or in specialty youth-serving service systems. Centers in NCTSN work collaboratively to identify, develop, and implement effective treatments and services in community and child-serving service systems settings; collect clinical data on child trauma cases and services; develop resources on trauma for professionals, consumers, and the public; and develop trauma-focused public education and professional training. NCTSN grantees not only assist the children directly affected by traumatic events, but also provide support and assistance to their families, caretakers, and advocacy/consumer groups.

*Background:* In recognition of the serious impact that trauma can have on children's mental health, Congress authorized the development of programs focusing on psychological trauma response and the development of knowledge in evidence-based practices for treating trauma-related psychiatric disorders of children and youth. The target populations for this initiative are children who are abused, witness family or community violence, lose a family member, experience serious medical problems, experience war zone or displacement trauma, or endure natural and human caused disasters or terrorism. Traumatic events often involve a life-threat, severe physical injury, threat to psychological control or physical or psychological integrity, loss of a primary caretaker, or loss of one's community or social environment.

Effects of trauma can include emotional problems such as depression, anxiety, and chronic or impulsive outbursts of anger; suicide attempts; behavior problems such as antisocial behavior and substance abuse; cognitive and motivational distortions including hopelessness, chronic shame, or guilt; learning and academic problems resulting from learning, memory, and attention difficulties; and interpersonal problems. Intervention in the aftermath of trauma is perhaps the most significant clinical issue in child and adolescent mental health. Of particular concern for receipt of intervention services are children in child service systems with high rates of trauma exposures such as the child welfare and child protective services systems, the juvenile justice system, hospitals and emergency clinics, child rehabilitation services, and service systems for refugee children.

## II. Award Information

1. *Estimated Funding Available/ Number of Awards:* It is expected that up to $4.8 million will be available to fund up to 12 awards in FY 2004. There will be no Phase I awards for NCTSI—Community Treatment and Services Centers. These Phase II awards will be up to $400,000 in total costs (direct and indirect) for one year, rather than the award duration stated in the BPPI–04 PA (MOD). Proposed budgets cannot exceed the allowable amount. The actual amount available for the award may vary, depending on unanticipated program requirements and the number and quality of the applications received.

2. *Funding Instrument:* Cooperative Agreement

*Role of Federal Staff:*

- Consult with NCCTS staff, IDEC project directors, and CTSC project directors on all phases of the project to ensure accomplishment of the goals of the Initiative;
- Review critical project activities for conformity to the goals of NCTSI;
- Assume overall responsibility for monitoring the conduct and progress of NCTSI programs;
- Make recommendations regarding continued funding;
- Provide feedback on project design and components;
- Participate in selected policy and steering groups or related work groups;
- Review quarterly reports and conduct site visits, if warranted;
- Provide support services or recommend outside consultants, if needed;
- Author or co-author publications on program findings;
- Collect and disseminate site- and NCTSN-developed intervention and training products; and
- Provide technical assistance on ways to help disseminate and implement products of collaborative activities.

*Role of Awardee:*

- Comply with the terms of the cooperative agreement award as specified in the requirements of the BPPI–04 PA (MOD) and the Notice of Grant Award (NOGA);
- Participate in collaborative activities with other NCTSN centers and other collaborative Network activities;
- Participate in grantee meetings;
- Accept guidance and respond to requests for data from CMHS;
- Participate in policy steering groups and other work groups to help accomplish project goals;
- As appropriate, author or co-author publications on project results for use by the field;
- Provide at least one electronic or other-media-type copy of all site- or NCTSN-developed intervention or training products developed through the use of grant funds to the Government Project Officer;
- Participate in post-award, cross-site process and outcome evaluation activities; and
- Implement specified activities, data collection, quality control, and complete required SAMHSA reports.

## III. Eligibility Information

1. Eligible Applicants are limited to CTSCs (Category III grantees) funded in FY 2001 under the NCTSI. These eligibility criteria supersede the criteria specified in Section III–1 of the BPPI–04 PA (MOD). SAMHSA/CMHS is currently funding four cohorts of CTSC grantees with different start and end dates, as well as different project periods. By funding the original cohort of grantees for an additional year, SAMHSA/CMHS will: (1) Enable the original cohort of grantees (whose funding is coming to an end) to continue the positive work they have started; and (2) bring three of the four cohorts of grantees to a common developmental endpoint. This will set the stage for grantees in those three cohorts, along with other providers in the field that have not yet received funding, to compete in FY 2005 for National Child Traumatic Stress Initiative grants.

2. Cost Sharing or Matching is not required.

3. Other: Applicants must also meet certain application formatting and submission requirements or the application will be screened out and will not be reviewed. These requirements are described in section IV–2 below as well as in the BPPI–04 PA (MOD).

## IV. Application and Submission Information

1. *Address to Request Application Package:* Complete application kits may be obtained from: the National Mental Health Information Center at 1–800–789–2647. When requesting an application kit for this program, applicants must specify the funding opportunity title (NCTSI—Community Treatment and Services Centers) and the funding opportunity number (SM 04–010). All information necessary to apply, including where to submit applications and application deadline instructions, is included in the application kit. The PHS 5161–1 application form is also available electronically via SAMHSA's World Wide Web Home Page: *http://www.samhsa.gov/* (click on "Grant Opportunities'') and the BPPI–04 PA (MOD) is available electronically at *http://www.samhsa.gov/grants/2004/standard/BPPI/index.asp.*

When submitting an application, be sure to type "SM 04–010, NCTSI—Community Treatment and Services Centers'' in Item Number 10 on the face page of the application form. Also, SAMHSA applicants are required to provide a DUNS Number on the face page of the application. To obtain a DUNS Number, access the Dun and Bradstreet Web site at *http://www.dunandbradstreet.com* or call 1–866–705–5711.

2. *Content and Form of Application Submission:* Information including required documents, required application components, and application formatting requirements is available in the BPPI–04 PA (MOD) in section IV–2.

### Checklist for Formatting Requirements and Screenout Criteria for SAMHSA Grant Applications

SAMHSA's goal is to review all applications submitted for grant funding. However, this goal must be balanced against SAMHSA's obligation to ensure equitable treatment of applications. For this reason, SAMHSA has established certain formatting requirements for its applications. If you do not adhere to these requirements, your application will be screened out and returned to you without review.

☐ Use the PHS 5161–1 application.

☐ Applications must be received by the application deadline. Applications received after this date must have a proof of mailing date from the carrier

dated at least 1 week prior to the due date. Private metered postmarks are not acceptable as proof of timely mailing. Applications not received by the application deadline or not postmarked at least 1 week prior to the application deadline will not be reviewed.

☐ Information provided must be sufficient for review.

☐ Text must be legible.

• Type size in the Project Narrative cannot exceed an average of 15 characters per inch, as measured on the physical page. (Type size in charts, tables, graphs, and footnotes will not be considered in determining compliance.)

• Text in the Project Narrative cannot exceed 6 lines per vertical inch.

☐ Paper must be white paper and 8.5 inches by 11.0 inches in size.

☐ To ensure equity among applications, the amount of space allowed for the Project Narrative cannot be exceeded.

• Applications would meet this requirement by using all margins (left, right, top, bottom) of at least one inch each, and adhering to the page limit for the Project Narrative stated in the specific funding announcement.

• Should an application not conform to these margin or page limits, SAMHSA will use the following method to determine compliance: The total area of the Project Narrative (excluding margins, but including charts, tables, graphs and footnotes) cannot exceed 58.5 square inches multiplied by the page limit. This number represents the full page less margins, multiplied by the total number of allowed pages.

• Space will be measured on the physical page. Space left blank within the Project Narrative (excluding margins) is considered part of the Project Narrative, in determining compliance.

☐ The page limit for Appendices stated in the specific funding announcement cannot be exceeded.

To facilitate review of your application, follow these additional guidelines. Failure to adhere to the following guidelines will not, in itself, result in your application being screened out and returned without review. However, the information provided in your application must be sufficient for review. Following these guidelines will help ensure your application is complete, and will help reviewers to consider your application.

☐ The 10 application components required for SAMHSA applications should be included. These are:

• Face Page (Standard Form 424, which is in PHS 5161–1)
• Abstract
• Table of Contents
• Budget Form (Standard Form 424A, which is in PHS 5161–1)
• Project Narrative and Supporting Documentation
• Appendices
• Assurances (Standard Form 424B, which is in PHS 5161–1)
• Certifications (a form in PHS 5161–1)
• Disclosure of Lobbying Activities (Standard Form LLL, which is in PHS 5161–1)
• Checklist (a form in PHS 5161–1)

❑ Applications should comply with the following requirements:

• Provisions relating to confidentiality, participant protection and the protection of human subjects, as indicated in the specific funding announcement.

• Budgetary limitations as indicated in sections I, II, and IV–5 of the specific funding announcement.

• Documentation of nonprofit status as required in the PHS 5161–1.

❑ Pages should be typed single-spaced with one column per page.

❑ Pages should not have printing on both sides.

❑ Please use black ink, and number pages consecutively from beginning to end so that information can be located easily during review of the application. The cover page should be page 1, the abstract page should be page 2, and the table of contents page should be page 3. Appendices should be labeled and separated from the Project Narrative and budget section, and the pages should be numbered to continue the sequence.

❑ Send the original application and two copies to the mailing address in the funding announcement. Please do not use staples, paper clips, and fasteners. Nothing should be attached, stapled, folded, or pasted. Do not use heavy or lightweight paper, or any material that cannot be copied using automatic copying machines. Odd-sized and oversized attachments such as posters will not be copied or sent to reviewers. Do not include videotapes, audiotapes, or CD-ROMs.

3. *Submission Dates and Times:* Applications must be received by June 10, 2004. You will be notified by postal mail that your application has been received. Additional submission information is available in the BPPI–04 PA (MOD) in section IV–3.

4. *Intergovernmental Review:* Applicants for this funding opportunity must comply with Executive Order 12372 (E.O. 12372). E.O. 12372, as implemented through Department of Health and Human Services (DHHS) regulation at 45 CFR part 100, sets up a system for State and local review of applications for Federal financial assistance. Instructions for complying with E.O. 12372 are provided in the BPPI–04 PA (MOD) in section IV–4. A current listing of State Single Points of Contact (SPOCs) is included in the application kit and is available at *http://www.whitehouse.gov/omb/grants/spoc.html.*

5. *Funding Restrictions:* Information concerning funding restrictions is available in the BPPI–04 PA (MOD) in section IV–5.

## V. Application Review Information

1. *Evaluation Criteria:* Eligible applicants have been determined to have met comparable requirements to those required in BPPI Phase I grants. Therefore, applicants are expected to apply for a Phase II grant and to follow procedures outlined in the BPPI–04 PA (MOD) for applicants who have not previously applied for a Phase I award. In sections where the language in the BPPI–04 PA (MOD) requires discussion of Phase I BPPI activities, applicants are expected to discuss activities conducted to date within their previous Community Treatment and Services Center grant.

Applications will be reviewed against the Evaluation Criteria and requirements for the Project Narrative specified in the BPPI–04 PA (MOD). The following information describes exceptions or limitations to the BPPI–04 PA (MOD) and provides special requirements that pertain only to the NCTSI—Community Treatment and Services Centers cooperative agreement.

*1.1 Allowable Activities:* Community Treatment and Services Centers are allowed to provide and support inpatient treatment, which is an exception to the BPPI–04 PA (MOD). Additional Network participation activities allowed and expected of NCTSI—Community Treatment and Services Centers grantees include:

(1) Providing outreach to the community in the areas of identifying and providing trauma services to children and families who do not seek services;

(2) Training community providers in child trauma services;

(3) Developing or monitoring trauma services appropriate to the race/ethnicity/culture/age of the community's service population;

(4) Educating the community on child trauma issues; and

(5) Educating and training staff in specialty child service systems such as juvenile justice, emergency medical services, or child protective services.

*1.2 Applicants for the NCTSI—Community Treatment and Services*

*Centers cooperative agreement are required to discuss the following requirements in their applications, in addition to the requirements specified in the BPPI–04 PA (MOD):*

a. In "Section A: Need, Justification of Best Practice, and Readiness'':

(1) Applicants do not need to produce evidence that a community of stakeholders has achieved a "decision to adopt'' the best practices. Instead, applicants may describe relationships with existing community "stakeholders'' and partnerships with key community "stakeholders'' already achieved under current NCSTI Category III Community Treatment and Service grants.

(2) Applicants must include in their financing plan a statement and description of their plan to dedicate at least 20% of the grant funds to the following Network participatory and collaborative activities:

- Linking, networking, collaborating, and coordinating with other NCTSN Centers to improve access to and quality of treatment and services for children and adolescents exposed to traumatic events such as collaborating with other NCTSN centers in multi-site treatment/services studies, jointly developing clinical data and evaluation data collection protocols, etc.;
- Participating in NCTSN committees, workgroups, and taskforces;
- Implementing consensus decisions made by the NCTSI Steering Committee;
- Serving as a resource for the NCTSI and the National Resource Center for Child Traumatic (NRC–CTS) in aspects of community treatment/service delivery; and
- Working with the NCTSN and NRC–CTS to ensure that best practices in training, assessment, and/or intervention approaches from your center can be documented, standardized, evaluated, and disseminated to other service programs nationwide.

b. *In "Section B: Proposed Approach'':* Applicants are required to document their plans for continuing to participate and collaborate in the Network for pilot testing, adaptation, implementation, and evaluation of the best practice. They should indicate with which IDECs and CTSCs in the Network they will collaborate for these purposes.

c. *In "Section D: Evaluation Design and Analysis'':* Applicants must indicate that they will participate in cross-site evaluation efforts.

*1.3 Performance Measurement:* All SAMHSA grantees are required to collect and report certain data, so that SAMHSA can meet its obligations under the Government Performance and Results Act (GPRA). Grantees of the NCTSI " Community Treatment and Services Centers program will be required to report performance in: (1) increasing the number of children and adolescents reached by improved services; and (2) improving children's outcomes. Specific indicators include: (1) Number of persons served; (2) number, type, and capacity of services available; and (3) participants (consumer/family) reporting involvement in behavioral/emotional outcomes. The applicant must document its ability to collect and report the required data in "Section D: Evaluation Design and Analysis'' of its application. An instrument will be developed by CMHS staff to report on these indicators.

2. *Review and Selection Process:* Information about the review and selection process is available in the BPPI–04 PA (MOD) in section V–2. *Award Criteria:* Because eligibility is limited to NCTSI—Community Treatment and Services Centers grantees funded in FY 2001, equitable distribution of awards in terms of geographic criteria does not apply.

## VI. Award Administration Information

Award administration information, including award notices, administrative and national policy requirements, and reporting requirements are available in the BPPI–04 PA (MOD) in section VI. In addition to the reporting requirements stated in the BPPI–04 PA (MOD), the applicant must provide quarterly progress reports and an annual evaluation report that documents progress in achieving project goals. SAMHSA's standard terms and conditions are available at *http://www.samhsa.gov/grants/2004/useful_info.asp.*

## VII. Agency Contact for Additional Information

For questions about program issues contact: Christine Guthrie, MPH, Division of Prevention, Traumatic Stress, and Special Programs, SAMHSA/CMHS, 5600 Fishers Lane, Room 15–99, Rockville, MD 20857; (301) 443–0691; E-mail: *cguthrie@samhsa.gov.* For questions on grants management issues contact: Gwendolyn Simpson, SAMHSA/Division of Grants Management, 5600 Fishers Lane, Room 13–101, Rockville, MD 20857; (301) 443–4456; E-mail: *gsimpson@samhsa.gov.*

Dated: April, 2, 2004.

**Daryl Kade,**

*Director, Office of Policy, Planning and Budget, Substance Abuse and Mental Health Services Administration.*

[FR Doc. 04–7911 Filed 4–7–04; 8:45 am]

BILLING CODE 4162–20–P

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## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR–4903–N–27]**

## Notice of Submission of Proposed Information Collection to OMB: Early Doctoral Student Research Grant Program

**AGENCY:** Office of the Chief Information Officer, HUD.

**ACTION:** Notice.

**SUMMARY:** The proposed information collection requirement described below has been 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.

This is a request for an extension of the current approval to collect information necessary to select grant applicants among doctoral students and monitor the grantees performance. Grants will enable them to complete research papers on HUD-related topics.

**DATES:** *Comments Due Date:* May 10, 2004.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2528–0216). Should be sent to: HUD Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503; Fax number (202) 395–6974; E-mail *Melanie_Kadlic@omb.eop.gov.*

**FOR FURTHER INFORMATION CONTACT:** Wayne Eddins, Reports Management Officer, AYO, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail *Wayne_Eddins@HUD.gov*; telephone (202) 708–2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins or on HUD's web page at *http://www5.hud.gov:63001/po/i/icbts/collectionsearch.cfm.*

**SUPPLEMENTARY INFORMATION:** The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as

required by the Paperwork Reduction Act (44 U.S.C. chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the contact information of an agency official familiar with the proposal and the OMB Desk Officer for the Department.

This Notice also lists the following information:

*Title of Proposal:* Early Doctoral Student Research Grant Program.

*OMB Approval Number:* 2528–0216.

*Form Numbers:* SF–424, HUD–424B, HUD–424CB, HUD–2993, HUD–2994, and HUD–96010.

*Description of the Need for the Information and Its Proposed Use:* This is a request for an extension of the current approval to collect information necessary to select grant applicants among doctoral students and monitor the grantees performance. Grants will enable them to complete research papers on HUD-related topics.

*Respondents:* Individuals or households, Not-for-profit institutions.

*Frequency of Submission:* On occasion, Semi-annually.

| | Number of respondents | Annual responses | × | Hours per response | = | Burden hours |
|---|---|---|---|---|---|---|
| Reporting Burden | 80 | 125 | | 22.16 | | 2,770 |

*Total Estimated Burden Hours:* 2,770.

*Status:* Extension of a currently approved collection.

**Authority:** Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: April 2, 2004.

**Wayne Eddins,**

*Departmental Reports Management Officer, Office of the Chief Information Officer.*

[FR Doc. 04–7915 Filed 4–7–04; 8:45 am]

**BILLING CODE 4210–72–P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[WY–920–1310–01; WYW147452]**

### Notice of Proposed Reinstatement of Terminated Oil and Gas Lease

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice or Proposed Reinstatement of Terminated Oil and Gas Lease.

**SUMMARY:** Under the provisions of 30 U.S.C. 188(d) and (e), and 43 CFR 3108.2–3(a) and (b)(1), the Bureau of Land Management (BLM) received a petition for reinstatement of oil and gas lease WYW147452 for lands in Sweetwater County, Wyoming. The petition was filed on time and was accompanied by all the rentals due since the date the lease terminated under the law.

**FOR FURTHER INFORMATION CONTACT:** Bureau of Land Management, Pamela J. Lewis, Chief, Fluid Minerals Adjudication, at (307) 775–6176.

**SUPPLEMENTARY INFORMATION:** The lessees have agreed to the amended lease terms for rentals and royalties at rates of $10.00 per acre, or fraction thereof, per year and 16–2/3 percent, respectively. The lessees have paid the required $500 administrative fee and $166 to reimburse the Department for the cost of this **Federal Register** notice. The lessee has met all the requirements for reinstatement of the lease as set out in Section 31(d) and (e) of the proposing to reinstate lease WYW147452 effective February 1, 2003, under the original terms Mineral Lands Leasing Act of 1920 (30 U.S.C. 188), and the Bureau of Land Management is and conditions of the lease and the increased rental and royalty rates cited above. BLM has not issued a valid lease affecting the lands.

**Pamela J. Lewis,**

*Chief, Fluid Minerals Adjudication.*

[FR Doc. 04–7943 Filed 4–7–04; 8:45 am]

**BILLING CODE 4310–22–P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[ID–957–1420–BJ]**

### Idaho: Filing of Plats of Survey

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of filing of plats of surveys.

**SUMMARY:** The Bureau of Land Management (BLM) has officially filed the plats of survey of the lands described below in the BLM Idaho State Office, Boise, Idaho, effective 9 a.m., on the dates specified.

**FOR FURTHER INFORMATION CONTACT:** Bureau of Land Management, 1387 South Vinnell Way, Boise, Idaho, 83709–1657.

**SUPPLEMENTARY INFORMATION:** The following surveys were executed at the request of the Bureau of Land Management to meet administrative and management purposes: The plat, in 2 sheets, constitutes the entire survey record of the dependent resurvey of portions of the south, east, and west boundaries, and subdivisional lines, and a metes-and-bounds survey of a portion of the Craters of the Moon National Monument in sections 31, 35, and 36, in T. 5 S., R. 25 E., Boise Meridian, Idaho, was accepted February 4, 2004. The plat, in 2 sheets, constitutes the entire survey record of the dependent resurvey of portions of the east boundary, and subdivisional lines, and a metes-and-bounds survey of a portion of the Craters of the Moon National Monument in sections 2, 3, 5, 6, 8, 9, and 10, in T. 6 S., R. 25 E., Boise Meridian, Idaho, was accepted February 5, 2004.

The plat representing the dependent resurvey of a portion of the north boundary and subdivisional lines, and the subdivision of section 5, in T. 10 S., R. 2 E., Boise Meridian, Idaho was accepted February 23, 2004.

The following surveys were executed at the request of the Bureau of Reclamation to meet administrative and management purposes:

The plat presenting the dependent resurvey of portions of the Fifth Auxiliary Guide Meridian East (east boundary), north boundary, and the subdivisional lines and the subdivision of sections 2, 11, 12, 13, and 14, and a metes-and-bounds survey in section 12, in T. 1 N., R. 20 E., Boise Meridian, Idaho, and the plat representing the dependent resurvey of a portion of the subdivisional lines, and the subdivision

of sections 34 and 35, in T. 2 N., R. 20 E., Boise Meridian, Idaho, were accepted February 23, 2004.

Dated: April 2, 2004.

**Harry K. Smith,**

*Chief Cadastral Surveyor for Idaho.*

[FR Doc. 04–7939 Filed 4–7–04; 8:45 am]

BILLING CODE 4310–GG–P

## DEPARTMENT OF THE INTERIOR

### Bureau of Reclamation

### City of Albuquerque Drinking Water Project, New Mexico

**AGENCY:** Bureau of Reclamation, Interior.

**ACTION:** Notice of Availability for the Final Environmental Impact Statement for the City of Albuquerque Drinking Water Project.

**INT–FES 04–10**

**SUMMARY:** Pursuant to the National Environmental Policy Act (NEPA) of 1969 (as amended), the Bureau of Reclamation (Reclamation), as lead federal agency, and the City of Albuquerque (City), as joint lead agency, have prepared a final environmental impact statement (FEIS) for the City of Albuquerque Drinking Water Project. The project is the main component of the Albuquerque Water Resources Management Strategy, adopted by the City Council, which aims to efficiently use existing water resources and develop a safe and sustainable water supply for City residents to the year 2060. The proposed alternatives provide a means of action through which the City would fully consumptively use the City's San Juan-Chama Project water to provide a sustainable water supply.

**ADDRESSES:** Copies of the FEIS are available from Marsha Carra, Bureau of Reclamation, Albuquerque Area Office, 555 Broadway, NE., Suite 100, Albuquerque, New Mexico 87102; telephone (505) 462–3602; facsimile (505) 462–3797; e-mail: *mcarra@uc.usbr.gov.* The FEIS is also available on Reclamation's Web site at *http://www.usbr.gov/uc/albuq/library/eis/adwp/adwp.html.*

Copies of the document are also available for public review and inspection at the following locations:

City of Albuquerque Water Resources Office, Public Works Department, Water Resources Department, One Civic Plaza, 5th Floor, Albuquerque, New Mexico

Bureau of Reclamation, Upper Colorado Regional Office, 125 South State Street, Room 6107, Salt Lake City, Utah 84138–1147;

Bureau of Reclamation, Albuquerque Area Office, 555 Broadway, NE., Suite 100, Albuquerque, New Mexico 87102;

Energy, Minerals and Natural Resources Department, Attention: Joanna Prukop, Wendell Chino Building, P.O. Box 6429, Santa Fe, New Mexico 87505; and

Environment Department, Attention: Ron Curry, Harold Runnels Building, P.O. Box 26110, Santa Fe, New Mexico 87502.

**Libraries**

Albuquerque Public Library, Reference Desk, Main Library, 501 Copper, NW., Albuquerque, New Mexico 87102;

North Valley Public Library, Reference Desk, 7704 2nd Street, NW., Albuquerque, New Mexico 87107;

South Broadway Public Library, Reference Library, 1025 Broadway, SE., Albuquerque, New Mexico 87108;

Cherry Hills Public Library, Reference Library, 6901 Barstow, NE., Albuquerque, New Mexico 87111;

Socorro Public Library, 401 Park Street, Socorro, New Mexico;

Española Public Library, 921 Paseo del Norte, Española, New Mexico; and

Santa Fe Public Library, 145 Washington Avenue, Santa Fe, New Mexico.

**FOR FURTHER INFORMATION CONTACT:** Marsha Carra, Bureau of Reclamation, Albuquerque Area Office, 555 Broadway, NE., Suite 100, Albuquerque, New Mexico 87102; telephone (505) 462–3602; facsimile (505) 462–3797; e-mail: *mcarra@uc.usbr.gov.*

**SUPPLEMENTARY INFORMATION:** The FEIS considers the effects of the City of Albuquerque using San Juan-Chama Project water to provide a sustainable drinking water supply for its citizens. The four primary project elements are (1) Diverting San Juan-Chama Project water after it is released to the Rio Grande, (2) transporting the raw water to a water treatment plant, (3) treating the raw water to drinking water standards, and (4) distributing the treated, potable water to customers in the City's water service area. At present, the City water is supplied by aquifer pumping. Continued reliance on this source is unsustainable and could have other serious environmental consequences for the City and its water customers. The San Juan-Chama Project water has been contracted for a number of years and will allow the City to fully develop its water resources.

The FEIS evaluates several alternatives, including the no action alternative, and describes the existing environmental consequences of using the San Juan-Chama water source. The FEIS considers the following issues: aesthetics and visual resources, air quality, aquatic life, biodiversity, cultural resources, energy, environmental justice, floodplains, geology, hazardous materials, human health and safety, hydrology (surface and groundwater), Indian trust assets and other tribal resources, land use, noise and vibration, recreation, riparian areas, socioeconomic conditions, soils, threatened and endangered species, traffic and circulation, upland vegetation, water quality, wetlands/non-wetland waters, wildlife, and cumulative effects.

The construction and operation of a low-head diversion dam is the preferred alternative. It permits the greatest flexibility for diverting the San Juan-Chama water from the Rio Grande, meets the project purpose and need, and avoids major impacts to environmental resources. With mitigation measures incorporated, there are no significant environmental or socioeconomic impacts under the preferred alternative.

Reclamation requested government-to-government consultation with 27 federally recognized Pueblos and Tribes and contacted the Bureau of Indian Affairs to help identify and determine any effects to Indian trust assets. Implementation of the preferred alternative will not cause adverse effects to Indian trust assets.

The draft environmental impact statement (DEIS) was issued in June 2002. Responses to comments received from organizations and individuals on the DEIS have been addressed in the FEIS. No decision will be made on the proposed federal action until 30 days after release of the FEIS. After the 30-day waiting period, Reclamation will complete a Record of Decision. The Record of Decision will state the action that will be implemented and discuss all factors leading to that decision.

Dated: March 30, 2004.

**Connie L. Rupp,**

*Assistant Regional Director, Bureau of Reclamation.*

[FR Doc. 04–7981 Filed 4–7–04; 8:45 am]

BILLING CODE 4310–MN–P

## DEPARTMENT OF THE INTERIOR

### Bureau of Reclamation

### Freeport Regional Water Project, Sacramento, California

**AGENCY:** Bureau of Reclamation, Interior.

**ACTION:** Notice of availability of the Final Environmental Impact Statement (EIS) and Environmental Impact Report (EIR)

**SUMMARY:** Pursuant to the National Environmental Policy Act (NEPA) and the California Environmental Quality Act (CEQA), the Bureau of Reclamation (Reclamation) and the Freeport Regional Water Authority (FRWA) have prepared a Final Environmental Impact Statement (EIS) and a Final Environmental Impact Report (EIR) for the Freeport Regional Water Project. The proposed project would construct and operate a water supply project to meet regional water supply needs.

A Notice of Availability of the joint Draft EIS/EIR was published in the **Federal Register** on Friday, August 8, 2003 (68 FR 47363). The written comment period on the Draft EIS/EIR ended Friday, December 15, 2003. The Final EIS and Final EIR contain responses to all comments received and reflect comments and any additional information received during the review period.

**DATES:** Reclamation will not make a decision on the proposed action until at least 30 days after release of the Final EIS. After the 30-day waiting period, Reclamation will complete a Record of Decision (ROD). The ROD will state the action that will be implemented and will discuss all factors leading to the decision.

**ADDRESSES:** A compact disk or a copy of the Final EIS and Final EIR may be requested from Mr. Kurt Kroner, Freeport Regional Water Authority, 1510 J Street, Suite 140, Sacramento, CA 95814, at 916–326–5489, or by e-mail at *k.kroner@frwa.com*. The final documents are available online at *http://www.freeportproject.org*.

See the **SUPPLEMENTARY INFORMATION** section for locations where copies of the Final EIS and Final EIR are available.

**FOR FURTHER INFORMATION CONTACT:** Mr. Rob Schroeder, Bureau of Reclamation, at 916–989–7274; or Mr. Kurt Kroner, FRWA, at 916–326–5489, or e-mail at *k.kroner@frwa.com*.

**SUPPLEMENTARY INFORMATION:** The project would (1) support acquisition of additional Sacramento County Water Agency (SCWA) surface water entitlements to promote efficient conjunctive use of groundwater in its Zone 40 area, consistent with the Sacramento Area Water Forum Agreement and County of Sacramento General Plan policies; (2) provide facilities through which SCWA can deliver existing and anticipated surface water entitlements to Zone 40 area; (3) provide facilities through which East Bay Municipal Utility District (EBMUD) can take delivery of a supplemental supply of water that would substantially meet its need for water and reduce existing and future customer deficiencies during droughts; and (4) improve EBMUD system reliability and operational flexibility during droughts, catastrophic events, and scheduled major maintenance at Pardee Dam/Reservoir.

The Draft EIS/EIR addressed facilities-related impacts including the effects of project construction and operation on hydrology, water quality, fish resources, recreation, vegetation and wildlife, visual resources, cultural resources, land use, geology, soils, seismicity, groundwater, traffic and circulation, air quality, noise, and public health and safety. Diversion-related impacts include the effects of increased diversions from the Sacramento River and associated changes in Reclamation's operation of Central Valley Project facilities. Project diversions therefore may directly or indirectly affect the Sacramento River, its tributaries, and Delta resources including water supply, fish and aquatic habitat, riparian vegetation and habitat, water quality, recreation, visual and cultural resources, and power supply. The Draft EIS/EIR also evaluated potential growth-inducing impacts for the SCWA and EBMUD water service areas. An evaluation of cumulative hydrologic and water service area impacts associated with reasonably foreseeable actions was also included.

Public hearings were held on the following dates and locations: Thursday, September 4, 2003, in Sacramento, CA; Tuesday, September 9, 2003, in Herald, CA; Wednesday, September 10, 2003, in Oakland, CA; Thursday, September 11, 2003, in Sacramento, CA; and Monday, September 29, 2003, in Sacramento, CA.

Copies of the final documents are available for public inspection and review at the following locations:

- East Bay Municipal Utility District, 375 11th Street, Oakland, CA 94607.
- Sacramento County Water Agency, 827 Seventh Street, Room 301, Sacramento, CA 95814.
- Sacramento County Clerk-Recorder's Office, 600 Eighth Street, Sacramento, CA 95814.
- Sacramento Public Library, 828 I Street, Sacramento, CA 95814.
- Bureau of Reclamation, 7794 Folsom Dam Road, Folsom, CA 95630.

Bureau of Reclamation, Denver Office Library, Building 67, Room 167, Denver Federal Center, 6th and Kipling, Denver, CO 80225; telephone: 303–445–2072.

- Bureau of Reclamation, Office of Public Affairs, 2800 Cottage Way, Sacramento, CA 95825–1898; telephone: 916–978–5100.
- Natural Resources Library, U.S. Department of the Interior, 1849 C Street N.W., Main Interior Building, Washington, D.C. 20240–0001.
- Elk Grove Community Library, 8962 Elk Grove Boulevard, Elk Grove, CA 95624.
- Belle Cooledge Community Library, 5600 Southland Park Drive, Sacramento, CA 95822.
- Valley Hi—North Laguna, 6351 Mack Road, Sacramento, CA 95823.
- Southgate Community Library, 6132 66th Avenue, Sacramento, CA 95823.
- Galt Neighborhood Library, 1000 Caroline Avenue, Sacramento, CA 95632.
- Pannell Community Center, 2450 Meadowview Road, Sacramento, CA 95832.
- Clarksburg Branch Library, 52915 Netherlands Road, P.O. Box 229, Clarksburg, CA 95612.
- Lodi Public Library, 201 W. Locust Street, Lodi, CA 95240.

It is Reclamation's practice to publicly disclose respondents' comments, including names and addresses. Respondents may request that their address be withheld from disclosure; this will be honored to the extent allowable by law. There may also be circumstances in which a respondent's identity may be withheld from disclosure; again, this will be honored to the extent 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. All submissions from organizations or businesses will be publicly disclosed in their entirety.

Dated: February 19, 2004.

**John F. Davis,**

*Deputy Regional Director, Mid-Pacific Region.*

[FR Doc. 04–7948 Filed 4–7–04; 8:45 am]

BILLING CODE 4310–MN–P

## INTERNATIONAL TRADE COMMISSION

### Government in the Sunshine Act Meeting Notice

**AGENCY HOLDING THE MEETING:** United States International Trade Commission.

**TIME AND DATE:** April 12, 2004, at 1 p.m.

**PLACE:** Room 101, 500 E Street, SW., Washington, DC 20436. Telephone: (202) 205–2000.

**STATUS:** Open to the public.

**MATTERS TO BE CONSIDERED:**

1. Agenda for future meetings: none.
2. Minutes.
3. Ratification List.
4. Inv. Nos. 731–TA–1071–1072 (Preliminary) (Magnesium from China and Russia)—briefing and vote. (The Commission is currently scheduled to transmit its determination to the Secretary of Commerce on or before April 12, 2004; Commissioners' opinions are currently scheduled to be transmitted to the Secretary of Commerce on or before April 19, 2004.)
5. Outstanding action jackets: none.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.
Issued: April 2, 2004.

**Marilyn R. Abbott,**

*Secretary to the Commission.*

[FR Doc. 04–8061 Filed 4–6–04; 10:54 am]

BILLING CODE 7020–02–P

## DEPARTMENT OF JUSTICE

### Office of Justice Programs

### Agency Information Collection Activities: Proposed Collection; Comments Requested

**ACTION:** 30-Day notice of information collection under review: Report of Public Safety Officers permanent and total disability.

The Department of Justice (DOJ), Office of Justice Programs (OJP) 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 68, Number 205, page 60715 on October 23, 2003, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until May 10, 2004. 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 agencies 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) *The title of the form/collection:* Report of Public Safety Officer's Permanent and Total Disability.

(3) *The agency form number, if any, and the applicable component of the department sponsoring the collection:* Form Number: OJP ADMIN FORM 3650/7. Bureau of Justice Assistance, Office of Justice Programs, Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or Households. Other: Federal, State, Local, or Tribal Government. The Report of Public Safety Officer's Permanent and Total Disability form is required to carry out the functions of the Public Safety Officers' Benefits Program. The information collected is pursuant to the Public Safety Officers' Benefits Act of 1976. Benefits are provided to claimant public safety officers found to have been permanently and totally disabled as the direct result of a catastrophic line of duty injury sustained on or after November 29, 1990. The form includes information necessary to determine that the circumstances that lead to the disability meet the requirements prescribed in 42 U.S.C. 3796.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply: It is estimated that each of the 45 respondents will complete the application in approximately 2 hours.

(6) An estimate of the total public burden (in hours) associated with the collection: The estimated total public burden associated with this application is 90 hours.

If additional information is required contact: Brenda E. Dyer, Deputy Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, Suite 1600, 601 D Street NW., Washington, DC 20530.

Dated: April 2, 2004.

**Brenda E. Dyer,**

*Department Deputy Clearance Officer, PRA, Department of Justice.*

[FR Doc. 04–7945 Filed 4–7–04; 8:45 am]

BILLING CODE 4410–18–P

## DEPARTMENT OF JUSTICE

### Office of Justice Programs

### Agency Information Collection Activities: Proposed Collection; Comments Requested

**ACTION:** 30-Day notice of information collection under review: Claim for death benefits.

The Department of Justice (DOJ), Office of Justice Programs (OJP) 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 68, Number 205, page 60713 on October 23, 2003, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until May 10, 2004. 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 agencies 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) *The title of the form/collection:* Claim for Death Benefits.

(3) *The agency form number, if any, and the applicable component of the department sponsoring the collection:* Form Number: None. Bureau of Justice Assistance, Office of Justice Programs, Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: individuals or households. Other: None. The Public Safety Officers' Benefits (PSOB) Program provides a one-time benefit of $250,000 (adjusted for cost-of-living) to the eligible survivors of local, state, and federal public safety officers whose deaths result from traumatic injuries sustained in the line of duty. The agency requires the information requested on this form to identify survivors and determine their eligibility for the PSOB benefit in accordance with the statutory requirements found in 42 U.S.C. 3796. Respondents will include surviving spouses, children, and/or parents of deceased public safety officers.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply: It is estimated that each of the 320 respondents will complete the application in approximately 90 minutes.

(6) An estimate of the total public burden (in hours) associated with the collection: The estimated annual total public burden associated with this application is 480 hours.

If additional information is required contact: Brenda E. Dyer, Deputy Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, Suite 1600, 601 D Street NW., Washington, DC 20530.

Dated: April 2, 2004.

**Brenda E. Dyer,**

*Department Deputy Clearance Officer, PRA, Department of Justice.*

[FR Doc. 04–7946 Filed 4–7–04; 8:45 am]

**BILLING CODE 4410–18–P**

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## DEPARTMENT OF JUSTICE

### Office of Justice Programs

### Agency Information Collection Activities: Proposed Collection; Comments Requested

**ACTION:** 30-Day notice of information collection under review: Subgrant Award Report (STOP Violence Against Women Formula Grant Program) and Subgrant Award Report Instructions.

The Department of Justice (DOJ), Office of Justice Programs (OJP) 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 68, Number 198, page 59198 on October 14, 2003, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until May 10, 2004. 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 agencies 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) *The title of the form/collection:* Subgrant Award Report (STOP Violence Against Women Formula Grant Program) and Subgrant Award Report Instructions.

(3) *The agency form number, if any, and the applicable component of the department sponsoring the collection:* Form Number: none. Office on Violence Against Women, Office of Justice Programs, Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: the affected public includes the 56 STOP state and administrators (from 50 States, the District of Columbia and five territories and commonwealths (Guam, Puerto Rico, American Samoa, Virgin Islands, Northern Marina Islands)) and their subgrantees. The STOP Violence Against Women Formula Grant was authorized through the Violence Against Women Act of 1994 (VAWA) and reauthorized and amended by the Violence Against Women Act of 2000 (VAWA 2000). Its purpose is to promote a coordinated, multi-disciplinary approach to improving the criminal justice system's response to violence against women. The STOP Formula Grant Program envisions a partnership

among law enforcement, prosecution, courts, and victim advocacy organizations to enhance victim safety and hold offenders accountable for their crimes of violence against women. The Department of Justice's Office on Violence Against Women administers the STOP Formula Grant Program funds which must be distributed by STOP state administrators according to a statutory formula (as amended by VAWA 2000).

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply: It is estimated that it will take the 56 respondents (STOP administrators) approximately one hour to complete an annual progress report. It is estimated that it will take approximately one hour for roughly 2500 subgrantees to complete the relevant portion of the annual progress report. The Annual Progress Report for the STOP Formula Grant Program is divided into sections that pertain to the different types of activities that grantees may engage in and the different types of grantees that receive funds, *i.e.* law enforcement agencies, prosecutors' offices, courts, victim services agencies, etc.

(6) An estimate of the total public burden (in hours) associated with the collection: The estimated total annual public burden associated with this application is 2,556 hours.

If additional information is required contact: Brenda E. Dyer, Deputy Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, Suite 1600, 601 D Street NW., Washington, DC 20530.

Dated: April 2, 2004.

**Brenda E. Dyer,**

*Department Deputy Clearance Officer, PRA, Department of Justice.*

[FR Doc. 04–7947 Filed 4–7–04; 8:45 am]

**BILLING CODE 4410–18–P**

## DEPARTMENT OF LABOR

### Employment and Training Administration

### Workforce Investment Act—Work Incentive Program To Enhance Service Delivery for Jobseekers With Disabilities Through the National One-Stop Delivery System, Fourth Round Solicitation for Grant Applications

*Announcement Type:* New. Notice of solicitation for grant applications.

*Funding Opportunity Number:* SGA/DFA–04–107.

*Catalog of Federal Domestic Assistance (CFDA) Number:* 17.266.

*Key Dates:* Deadline for Application Receipt—May 11, 2004.

*Executive Summary:* The U.S. Department of Labor (USDOL), Employment and Training Administration (ETA), announces the availability of approximately $14 million to be granted to qualifying applicants for the period of June 2004 to June 2006. The Work Incentive Grant Program provides grant funds to entities administering Workforce Investment Act Title I programs to augment the One-Stop delivery system to facilitate programmatic access and enhanced, streamlined service delivery for jobseekers with disabilities, including psychiatric and other hidden disabilities.

**Authority:** Key provisions relating to the One-Stop delivery system and this Solicitation for Grant Applications are at sections 121, 134(c), and 189(c) of the Workforce Investment Act [29 U.S.C. 2841, 2864(c), 2939(c)]; the Wagner-Peyser Act [29 U.S.C. 49f(d) and (e)]; and Department of Labor Appropriations Act, 2003 [Pub. L. 108–7]. Key regulations governing Workforce Investment Act programs are at 20 CFR parts 652 and 660–671 [65 FR 49294 (August 11, 2000)].

### I. Funding Opportunity Description

1. *Overview of the One Stop Career Center System:* Section 121 of the Workforce Investment Act (WIA) authorizes programs to serve the employment and training needs of Americans through the One-Stop Career Center system. This system was established through the 1998 passage of WIA as the key element in comprehensive reform of existing Federal job training programs, with amendments impacting service delivery under the adult, dislocated and youth programs, as well as the Wagner-Peyser Act, Adult Education and Literacy Act, and the Rehabilitation Act. Additional Federal programs are identified as required partners in the One-Stop Career Center system with the goal of giving all Americans access to comprehensive services, information and resources that can help them achieve their career goals. The intention of the One-Stop Career Center system is to establish a network of programs and providers in co-located and integrated settings that are accessible for individuals and businesses in each of the approximately 600 workforce investment areas established throughout the nation. WIA established state and local Workforce Investment Boards focused on strategic planning, policy development, and oversight of the workforce investment system, and accorded significant authority to the nation's Governors and local chief elected officials to implement innovative and comprehensive delivery systems. The vision, goals and objectives for workforce development under the WIA decentralized system are described in the state strategic plan required under section 112 of the legislation. This state strategic workforce investment plan—and the operational experience gained by all the partners to date in implementing the WIA-instituted reforms—help identify the important "unmet needs'' of employers and opportunities to expand access to One-Stop Career Centers for employers and all population segments within the local labor market.

*2. ETA's Division of Disability and Workforce Programs (DDWP):* DDWP develops and implements disability policy and program initiatives related to the workforce system, including cross-agency collaborations to address structural barriers to employment. Since the implementation of the WIA, ETA has directed funds and resources to improve workforce services for persons with disabilities, including those with psychiatric and other hidden disabilities. DDWP's major initiatives to embrace the population of jobseekers with disabilities are:

- *Increasing* the value and use of the One-Stop Career Center system through the Work Incentive Grants, by providing comprehensive informational and assistance services on multiple programs for which jobseekers with disabilities are eligible. Eighty-eight grants have been awarded in three rounds since October 2000 to state and/or local workforce investment boards, and to public and nonprofit organizations working closely with these entities. The fourth round for this initiative is the subject of this SGA. The One-Stop Toolkit Web site at *http://www.onestoptoolkit.org* includes numerous training materials, strategies and products developed by grantees to assist their workforce investment systems in serving the disability community. Reviewing these materials will help you avoid proposing activities that duplicate products already available on the Toolkit.
- *Enhancing* comprehensive services and work incentive information for Social Security Administration (SSA) beneficiaries and other jobseekers with disabilities through an ETA/SSA jointly funded Disability Program Navigator Initiative in 14 states in which SSA is establishing employment support initiatives. Information on this initiative, and on SSA's Ticket to Work and Work Incentive Improvement Act

(Training and Employment Notice No. 6–02), can be found at *http://wdsc.doleta.gov/disability.*

• *Improving* training and career opportunities and outcomes for jobseekers with disabilities through grants focused on innovative skill training and systems change. Twelve multi-site Disability Employment Grants totaling $5.5 million were awarded in 2002 to showcase innovative training options within the One-Stop Career Center system for people with significant disabilities. DDWP also administers several Disability Information Technology (IT) Grants, awarded in June 2001 to improve employment opportunities for people with disabilities through intensive IT skills training and close working partnerships with the IT employer community.

Please note that the Department of Labor's Office of Disability Employment Policy (ODEP) has also awarded a number of grants to the workforce system related to customized employment and youth services for persons with disabilities. Information on these grants can be obtained at *http://dol/odep.gov.*

*3. Problem Statement:* People who have disabilities want and need to work. Employers need a qualified work force. Communities work best when their citizens are productive. Yet a distressingly low percentage of working age people with disabilities is employed. The Social Security Administration provides benefits to nearly 13 million people with disabilities at a cost of more than $100 billion annually; 48% of those under 60 have a mental disability. The rate of job entry or reentry into the workforce of SSA disability beneficiaries, including those with psychiatric disabilities, has historically been less than ½ of 1%. President Bush announced the New Freedom Initiative in February 2001 to address this serious unemployment situation and to advance community integration of individuals with disabilities. Reasons for the low employment levels in this population include fragmented funding sources, differing criteria and priorities for these resources, misconceptions among jobseekers with disabilities about integrative support systems as well as about losing benefits if they become employed, fear of employing jobseekers with disabilities, a history of inflexible referral protocols, and inconsistent staff training across systems. Our Work Incentive Grant program confronts these issues.

*4. Objectives for Round IV of Work Incentive Grants:* The Work Incentive Grant program is consistent with the objectives of the President's New Freedom Initiative, signed on February 1, 2001, to increase employment opportunities and promote the full participation of people with disabilities in all areas of society. These Fourth Round Work Incentive Grants will emphasize:

• Improving the One-Stop system for jobseekers with disabilities through implementing strategies for physical, communication and programmatic access to One-Stop services for persons with disabilities, including psychiatric disabilities, and facilitating coordination and collaboration of multiple agencies and providers that impact job seekers with disabilities;

• Enhancing comprehensive services through implementation of Disability Program Navigator strategies; and

• Increasing the number of people with disabilities served under WIA and employment outcomes for jobseekers with disabilities, including psychiatric and other hidden disabilities, accessing WIA Title I and Wagner-Peyser programs.

## II. Award Information

*1. Type of assistance instrument:* Two year grant.

*2. Amount of funds to be awarded:* Through this fourth Work Incentive Grant Program SGA, ETA will award approximately $14 million in funds made available under the DOL Fiscal Year 2003 appropriation.

*3. Anticipated number of awards:* Approximately 30 grants will be awarded under this SGA.

*4. Expected amounts of individual awards:* We anticipate awarding grants of up to $600,000 to WIA Title I and Wagner-Peyser administering entities, including State or local Workforce Investment Boards. Grant awards will be limited to $600,000 for state-wide grants, $400,000 for proposals covering more than one workforce investment area, and $200,000 for a single workforce investment area.

*5. Anticipated start date and period of performance for awards:* Work Incentive Grants will be funded for the period of June 2004 through June 30, 2006. Funds must be expended by this date or will revert to the U.S. Treasury. ETA cannot provide a no-cost extension beyond June 30, 2006 since these funds are only available up to and including that date.

## III. Eligibility Information

*1. Eligible Applicants:* Five types of applicants are eligible to apply for these grants:

• The state organizational entity that administers Workforce Investment Act Title I and Wagner-Peyser programs in partnership with its state level Workforce Investment Board;

• The state level Workforce Investment Board in partnership with its state organizational entity that administers WIA Title I and Wagner-Peyser programs;

• A local Workforce Investment Board in partnership with its One-Stop Career Center operators;

• Consortia of local Workforce Investment Boards in partnerships with their One-Stop Career Center operators; and

• Indian and Native American tribal entities, or consortia of tribes.

It is important to note the following eligibility factors:

• The Grant Officer will take into account whether applicants have received a prior grant, or current grant funded in Round III, with the intent of providing preference to workforce investment areas that have not previously received a Work Incentive Grant. In general, additional grant funds will not be awarded to workforce investment areas under Round III WIGs since these grants are funded through June 2005.

• Fourteen (14) states have entered into cooperative agreements with ETA to implement the Disability Program Navigator initiative. Additional funds will be available to those states under the Interagency Agreement between ETA and SSA. In general, additional grant funds under this fourth WIG solicitation will not be awarded to state and/or local areas that are in the fourteen states. The fourteen (14) Navigator states are: Arizona, California, Colorado, Delaware, Florida, Illinois, Iowa, Maryland, Massachusetts, New York, Oklahoma, South Carolina, Vermont, and Wisconsin.

• The grantee will be expected to perform both administrative and operational responsibilities for the grant; subcontracting out of these functions will not be allowed.

• The Department will give preference to states and local workforce area(s) that have not previously received a Work Incentive Grant. Please note that a complete list of prior and current Work Incentive Grants and Disability Program Navigator cooperative agreements is provided at ETA's disability Online Web site: *http://wdsc.doleta.gov/disability/.*

• ETA encourages state and local workforce area(s) that have previously received a Work Incentive Grant to focus their proposal during this fourth round WIG on implementing Disability Program Navigator positions. We expect that significant progress has already

been made under the prior WIG and that implementation of Navigators would be the most productive application of resources available under the fourth round WIG.

• Applications involving one or more local workforce investment areas must include letters of commitment from each local board covered under the proposal, or one letter signed by all participating local boards (commitment letter(s) are not counted against the page limits). Please note that letters from local boards are not required for state level proposals.

• Proposals for tribal entities should coordinate services and enhance a One-Stop system approach for jobseekers with disabilities in specific Indian communities or covering multiple tribal entities that may cut across multiple states and/or workforce investment areas. In such cases, letters of commitment from local boards are not required. Grants to Indian and Native American tribal grantees are treated differently because of sovereignty and self-governance principles established under the Indian Self-Determination and Education Assistance Act allowing for the government-to-government relationship between the federal and tribal governments.

*2. Cost Sharing and Matching Funds:* Identification of funds related to cost sharing, matching funding, or in-kind participation is not required from applicants for this grant opportunity and, therefore, specific dollar amounts associated with public or private contributions will not be considered in the review and decision of award by the Grant Officer. At the same time, ETA encourages applicants to leverage funding resources in the delivery of One-Stop Career Center services to job seekers with disabilities, as well as coordinate other activities across state and local disability or workforce initiatives, when applicable, as these are primary goals of the Work Incentive Grant program.

*3. Other Eligibility Criteria:* ETA encourages applicants to develop partnerships with disability-related public and private organizations in the development and implementation plan. Such organizations may include: State Councils for Independent Living and local Centers for Independent Living; state mental health agencies, state mental retardation and Developmental Disability Councils; Temporary Assistance for Needy Families (TANF) agencies; and other private, non-profit organizations such as disability advocacy and providers and community-based and faith-based organizations that provide services for people with disabilities.

Except as specifically provided, DOL/ETA's acceptance of a proposal and an award of Federal funds to sponsor any program(s) does not provide a waiver of any grant requirement and/or procedures. For example, the OMB circulars stipulate that an entity's entire procurement procedures and transactions, including subcontracts, must provide for free and open competition. If a proposal identifies a specific entity to provide the services, the DOL/ETA's award does not provide the justification or basis to sole-source the procurement, *i.e.*, avoid competition, *unless the activity is regarded as the primary work of an official partner to the application.* The official partner must therefore identify the work it intends to do within the grant application and attach a letter of agreement to this effect.

## IV. Application and Submission Information

*1. Address to Request Application Package:* This SGA contains all of the information and forms needed to apply for grant funding.

*2. Content and Form of Application Submission:* A cover letter, the original proposal, plus three copies of the proposal must be submitted. In the original proposal, the SF 424 must be signed in blue ink. Applications must include two separate parts—Part I provides financial and budget information; Part II provides the statement of work.

*Part I*

*Part I* of the application must contain the Standard Form (SF) 424, "Application for Federal Assistance'' and a fully completed Budget Information Form (*see* Appendix ). The SF 424 and the Budget Information forms are also available at *http://wdsc.doleta.gov/sga/forms.asp.* The SF 424 must clearly identify the applicant (*i.e.*, the fiscal agent) and be signed with original signatures by the representative authorized by the governing body of the applicant to enter into the grant agreement. Applicants shall indicate on the SF 424 the organization's IRS Status, if applicable. Under the Lobbying Disclosure Act of 1995, section 18 (29 U.S.C. 1611), an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 which engages in lobbying activities shall not be eligible for the receipt of Federal funds constituting an award, grant, or loan.

*Dun and Bradstreet Number.* Beginning October 12, 2003, all applicants for Federal grant and funding opportunities are required to have a Dun and Bradstreet (DUNS) number. *See* OMB Notice of Final Policy Issuance, 68 FR 38402 (June 27, 2003). Applicants must supply their DUNS number in item #5 of the new SF–424 issued by OMB (Rev. 9–2003). *See* Attachment A. The DUNS number is a nine-digit identification number that uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access this Web site: *www.dunandbradstreet.com* or call 1–866–705–5711.

*Financial Narrative.* The Budget Information Form must incorporate financial narrative information that describes all costs associated with implementing the activities to be covered with grant funds. Applicants should anticipate, for their travel budget, costs for three key staff to attend an annual policy and training meeting in Washington, DC, and one or two regional meetings.

*Part II*

*Part II—Technical Proposal* contains an Executive Summary and the Statement of Work that provides narrative information on your plans for carrying out the objectives of the Work Incentive Grant. With the exception of the two-page single-spaced executive summary, the Part II Statement of Work narrative must not exceed 30 pages, double-spaced on single-sided, numbered pages with a 12-point font required throughout. Please note that letters of commitment from local boards, and official partnership agreements, do not count against the page limitations; however, general letters of support for the application *will* count against the page limit.

The Executive Summary, or Abstract, summarizes the proposal and the primary objectives and scope of activities to be covered, including how activities address the Statement of Work criteria. Demonstrate that these activities are new and unique to the geographic area entailed. In addition, include the following information in the Executive Summary:

• The number of workforce investment areas in the state and the number of comprehensive One-Stop Career Centers in the state, and the workforce area(s) to be covered in the grant proposal.

• The extent to which physical, programmatic and communication access has been achieved in the One-Stop Career Center(s) for persons with disabilities and how the proposal will address deficiencies, if applicable.

• The core, intensive and training service levels for persons with disabilities compared to all participants in WIA Title I adult, dislocated worker, and youth programs, and labor exchange services under Wagner-Peyser, and activity levels planned under the proposal.

• The percentage of people with disabilities in the state and/or local area, including the percentage of people who are beneficiaries of Social Security Disability Insurance (SSDI) and/or Social Security Income Program (SSI).

• The most recent unemployment rate(s) in the workforce investment area(s) covering the project, including short and long-range employment projections.

• A description of primary industries in the workforce investment area(s), including new or emerging industries that are projected to expand and occupational skills in most demand.

• Partners, if any, who will be collaborating on proposal activities.

The Statement of Work narrative represents your plan to meet the system-building objectives of this SGA to increase, enhance, and improve services for jobseekers with disabilities, including psychiatric disabilities, with verifiable training and employment outcomes, in the nation's workforce investment system.

(i) Statement of Need;

(ii) Workplan to Increase Comprehensive Services and Enhance One-Stop Career Center Services: Choose (1) or (2).

(1) Comprehensive One-Stop Career Center Strategies

(2) Staff Capacity—Disability Program Navigator

(iii) Annotated Project Timeline

(iv) Improve Participation and Employment Outcomes for Persons with Disabilities

(v) Plan to Sustain Activities Beyond WIG IV Funding

The Work Incentive Grant program represents an important element of an overall strategy to improve employment and workforce participation of people with disabilities, including psychiatric disabilities, through access to the One-Stop Career Center system. Your proposal should seek to:

• *Workplan 1:* Increase comprehensive service delivery through increased outreach and coordination with organizations that serve jobseekers with disabilities, especially in States and local workforce areas that have not previously received a Work Incentive Grant and may not have adequate services in place.

• *Or Workplan 2:* Enhance One-Stop Career Center service delivery through expanded implementation of Disability Program Navigator positions, especially in states and local areas that have previously received a Work Incentive Grant. (As indicated above, 14 states funded through Disability Program Navigator initiative will continue to receive funding support through their cooperative agreement rather than this fourth round WIG solicitation.)

• *All applications:* Improve the number of people with disabilities registered and participating in WIA Title I or Wagner-Peyser programs as well as improving their employment outcomes and career advancement and plan for sustainability.

Part II consists of the following parts; which are described in detail in section V(1) Criteria.

PART II: STATEMENT OF WORK

| Categories | Maximum pages, double spaced | Maximum points |
|---|---|---|
| (A) Statement of Need | 5 pages | 15 points. |
| (B) Workplan 1 or 2 | 10 pages | 40 points. |
| (C) Timeline | 5 pages | 15 points. |
| (D) Improve Participation and Employment Outcomes | 5 pages | 15 points. |
| (E) Plans to Sustain WIG Activities | 5 pages | 15 points. |

*3. Submission Dates and Addresses:*

*Dates:* The closing date for receipt of applications is May 11th, 2004. Applications must be received by 4 p.m. (eastern standard time) at the address below: Applications sent by e-mail, telegram, or telefacsimile (fax) will not be accepted. Applicants are advised that the Department's receipt of mail has encountered delays because of mail screening procedures at local post offices.

*Addresses:* Applications must be mailed to: U.S. Department of Labor, Employment and Training Administration, Division of Federal Assistance, Attention: Eric Luetkenhaus, Reference: *SGA/DFA 04–107,* 200 Constitution Avenue, NW., Room N–4438, Washington, DC 20210.

*Hand Delivered Proposals:* If proposals are hand delivered, they must be received at the designated address by 4 p.m., eastern time on May 11th, 2004. All overnight mail will be considered to be hand delivered and must be received at the designated place by the specified closing date and time. Telegraphed, e-mail and/or fax proposals will not be honored. Failure to adhere to the above instructions will be a basis for determination of non-responsiveness.

*4. Intergovernmental Review:* This funding opportunity is not subject to Executive Order (EO) 12372, "Intergovernmental Review of Federal Programs.''

*5. Funding Restrictions:* All proposed costs should be necessary and reasonable according to the Federal guidelines set forth in the "Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments'' codified at 29 CFR part 97, and "Grants and Agreements with Institutes of Higher Education, Hospitals, and Other Non-Profit Organizations'' codified at 29 CFR part 95, and must comply with the applicable OMB cost principles circulars, as identified in 29 CFR 95.27 and 29 CFR 97.22(b). There is no administrative cost limitation under the WIG funding authority and the nature of the WIG program assumes that the majority of applicable costs will be administrative in nature. The cost of procurement or implementation of software or hardware to assure assistive and accessible technologies in the One-Stop setting may account for up to 40% of the budget if warranted by compelling need.

*6. Other Submission Requirements: Late Proposals.* A proposal received at the designated office after the exact time specified for receipt will not be considered unless it is received before the award is made and it:

• Was sent by U.S. Postal Service registered or certified mail not later than the fifth day (5th) calendar day before the closing date specified for receipt of applications (*e.g.*, an offer submitted in response to a solicitation requiring receipt of application by the 20th of the month must be mailed by the 15th); or

• Was sent by U.S. Postal Service Express Mail Next Day Service, Post Office to Addressee, not later than 5 p.m. at the place of mailing two working days prior to the deadline date specified for receipt of proposals in this SGA. The term "working days'' excludes weekends and U.S. Federal holidays.

The only acceptable evidence to establish the date of mailing of an application received after the deadline date for the receipt of proposals sent by the U.S. Postal Service registered or certified mail is the U.S. post mark on the envelope or wrapper affixed by the U.S. Postal Service and on the original receipt from the U.S. Postal Service. The term "post mark'' means a printed, stamped, or otherwise placed impression (exclusive of a postage meter machine impression) that is identifiable without further action as having been supplied or affixed on the date of mailing by employees of the U.S. Postal Service.

*Withdrawal of Applications.* Applications may be withdrawn by written notice or telegram (including mailgram) received at any time before an award is made. Application may be withdrawn in person by the applicant or by an authorized representative thereof, if the representative's identify is made known and the representative signs a receipt for the proposal.

**V. Application Review Information**

*1. Criteria:* Applications will be reviewed based upon the following criteria:

*A. Statement of Need (Not To Exceed 5 Double-Spaced Pages; Maximum of 15 Points)*

Your Statement of Need will be evaluated on (1) the overall status of disability-related issues in the workforce investment areas covered by your proposal; (2) the One-Stop Career Center system's strengths and deficiencies that you and the One-Stop Career Center system will address; and (3) your past performance in supporting service delivery to people with disabilities. *Please note:* To learn about the ETA and ODEP grants in your state and local area, *see http://wdsc.doleta.gov/disability/* and click on *Grants and Contracts* on the menu to the left. At this site you can view a map indicating the location of related grants awarded in your area. To learn about the work of previously awarded Work Incentive Grants, go to *http://www.onestoptoolkit.org.*

• Describe the level of expertise of the One-Stop system in the local area(s) addressed in the grant and the project plans for addressing inadequacies.

• Describe the overall status and actions taken to-date by the One-Stop delivery system to address services to people with disabilities, including levels of participation and outcomes in core, intensive and training services.

• For the state or local workforce area(s) related to your proposal, identify WIA Title I adult, dislocated worker, and youth program and Wagner-Peyser data covering the past two Program Years (PY) for the:

(1) number and percent of people with disabilities participating or exiting the programs compared with that of all individuals served; and

(2) number and percent of people with disabilities that entered employment compared with employment outcomes of all individuals exiting these programs.

• Identify whether a Work Incentive Grant award was received in the October 2000 or May 2002 award announcements along with accomplishments and reasons for application to this solicitation.

• Identify whether Disability Program Navigator(s) have been implemented in the state or local workforce investment area(s) under previous Work Incentive or other grants.

• Identify whether an Office of Disability Employment Policy grant has been received in the workforce investment area(s) and how activities will be coordinated with this project proposal.

• Identify the status of physical accessibility of state and/or local One-Stop Career Center facilities and plans for addressing deficiencies.

• Identify the status of programmatic accessibility and plans for addressing deficiencies.

• Identify the status of communication accessibility—including availability of assistive technology—in your One-Stop Career Centers and plans for addressing deficiencies.

• Describe significant deficiencies in the state or local workforce investment system that represent barriers to employment for people with disabilities and what will be accomplished under this grant to address them.

• Identify ETA, ODEP or other grants and resources in the state or local workforce area(s) which impact the delivery of such services as well as the unmet needs of job seekers with disabilities and can be used to enhance your project.

• Identify additional state and/or local funds and resources, if any, that will be used to support the overall objectives of the grant and will assist in addressing the identified issues of the grant project.

*B. Workplan To Increase Comprehensive Services and Enhance One-Stop Career Center Services (Not To Exceed 10 Double-Spaced Pages; Maximum of 40 Points)*

The purpose of the Workplan criteria is to identify the approach proposed by the grantee to establish a welcoming and seamless One-Stop Career Center service delivery system for persons with disabilities, that addresses identified needs described under Section B (Statement of Need), and achieves Work Incentive Grant objectives. In general, achieving a seamless system requires extensive linkages and on-site knowledge of applicable resources that address multiple disability issues and barriers to employment that are commonly experienced by persons with disabilities. Disability issues are often very complex and the disability community is very diverse. These factors present significant challenges to the workforce system in providing effective services to individuals with disabilities. At the same time, the comprehensive nature of the One-Stop Career Center system establishes a workforce infrastructure that is uniquely positioned to provide the kind of seamless service delivery that the disability community has long been seeking. Some workforce investment areas have made great strides in achieving universal access for their customers with disabilities while others are at a more preliminary stage with minimal services or assistive technology available.

Based upon the progress to-date achieved by the applicant and their One-Stop Career Center system, we request that you identify the primary approach of your proposal in terms of addressing Workplan (1) or (2) described below. Although you may select both options when such an approach will best address shortcomings in your current system, your Workplan description must provide your rational for selecting either (1) or (2) or both. As noted above, we are encouraging prior recipients of Work Incentive Grants to focus solely on Workplan (2): establishing Disability Program Navigator positions.

*(1) Workplan to Address Systemic One-Stop Career Center.* This section addresses universal access and model One-Stop services for job seekers with disabilities, including psychiatric disabilities, in a way that is distinct from implementing Disability Program Navigator positions.

• Describe the activities you will implement to maintain and expand the service structure for individuals with

disabilities who are accessing the workforce investment system. Include capacity building of the Employment Service component of the One-Stop system.

• Identify plans to address accessibility needs of your One-Stop Career Centers and plans to procure and implement accessible technologies, including video interpreting services for clients who are deaf, and how these activities will meet current system deficiencies.

• Describe plans to improve access to One-Stop Career Center services for customers with disabilities involving: (1) Inclusion in core, intensive and training services; (2) referral processes for Vocational Rehabilitation services or other agency programs; (3) joint funding of training and supportive services with Vocational Rehabilitation or other available resources; and (4) plans for establishing common intake or other administrative procedures that reduce duplication.

• Identify plans to implement assessment tools or procedures to help identify individuals with learning disabilities in the One-Stop delivery system and plans for implementing additional tools, if applicable.

• Describe plans for outreach, marketing, training, or on-going coordination and collaboration to the disability community and organizations that represent or work with people with disabilities. These entities, programs or systems may include but are not limited to: State and local Independent Living Center (CIL) systems, mental health departments, mental retardation/developmental disability agencies, State Councils on Developmental Disabilities, State Vocational Rehabilitation, and other local provider or advocate organizations, Regional Disability Business and Technical Assistance Centers (DBTAC's) and State Governors Committees on Employment of People with Disabilities, Learning Disabilities and Training Dissemination hub centers established under grants from the U.S. Department of Education's Office of Vocational and Adult Education, faith-based organizations and other community-based organizations, Benefits Planning, Assistance and Outreach specialists funded by SSA, Medicaid and Medicare system, including infrastructure grants and Medicaid buy-in provisions, Employment Networks (EN) established under the Ticket to Work and Work Incentive Improvement Act (TWWIIA).

• Identify whether you are an EN under the Ticket to Work program and whether you plan to become an EN as part of your grant activities.

• Describe specific state or local area provisions regarding Medicaid and/or Medicare coverage, the current transportation infrastructure, and how individuals with disabilities will access training, employment, housing, food stamps and other supportive services;

• Describe other plans, as applicable, under your proposal that will address or facilitate other improvements to your state or local One-Stop Career Center system.

*(2) Workplan to Implement Disability Program Navigator Positions. These criteria build upon the joint ETA/SSA Disability Program Navigator (DPN) initiative underway and provide for additional states or local areas to establish similar positions through the WIG program.*

The ETA/SSA position description (PD) for the Navigator is attached (Attachment D) to this SGA for guidance on establishing Disability Program Navigator positions in the One-Stop Career Center system. The PD is neither prescriptive nor all-inclusive; rather, it provides examples of the roles and functions of such a position depending upon the needs of the One-Stop and the skills and talents of the individual Navigator. We encourage you to consider hiring people with disabilities for the Navigator position(s) since, in general, they are intimately familiar with barriers to employment that others with disabilities face.

Navigators established under this grant will be expected to participate in training and technical assistance activities provided under ETA's Disability Program Navigator initiative that is currently functioning in 14 states. We will also expect that Navigator activities will be coordinated throughout a state, to the extent there is more than one Navigator, funded under this or other WIG or Disability Program Navigator grants (this may not be known at time of proposal and we will facilitate coordination when applicable subsequent to grant award).

Plans to implement Disability Program Navigator positions must identify:

• Administrative support;

• The hiring process;

• Management and supervision responsibility;

• Workforce investment area(s) that will include Navigators;

• One-Stop Career Center(s) to which Navigators will be assigned; and

• Anticipated role the Disability Program Navigator(s) will fill in the workforce investment area(s) over the course of the grant (as it relates to the attached Navigator PD).

State level proposals focused on implementing Disability Program Navigator positions should identify a state project lead to work closely with ETA and the University of Iowa's Law, Health Policy and Disability Center and their Rehabilitation Research and Training Center (RRTC) that provides training and technical assistance to this national initiative. Proposals involving single or multiple workforce areas will also be expected to coordinate their implementation with ETA and the RRTC, and work with a state Navigator project lead if s/he has been established under this or other ETA grant awards.

*C. Annotated Project Timeline: (Not To Exceed 5 Pages; Maximum of 15 Points)*

You must complete and annotate a Project Timeline related to your activities proposed in the applicable Workplan section above. A model "timeline'' is attached (Attachment C). Please provide additional timeline information as applicable. Provide:

• Goals, objectives, responsibilities, implementation strategies and time frames, expected outcomes, and evaluation indicators for assuring your successful completion of critical activities.

• Project organizational chart that identifies key management staff and their responsibilities, with a matrix of organizational responsibilities of key partner organizations, if applicable.

*D. Improve Participation and Employment Outcomes for Persons With Disabilities (Not To exceed Five Double-Spaced Pages; Maximum of 15 Points)*

These criteria seek to identify: (1) How you will increase services, skill training, employment outcomes, job retention and career advancement for persons with disabilities utilizing WIA Title I and Wagner-Peyser services and programs to achieve the Government Performance and Results Act (GPRA) goals for the Work Incentive Grant program; (2) how you will coordinate services and training with other programs or resources for which these individuals may be eligible and that may impact successful employment outcomes; and (3) how you will work to sustain programs and achievements beyond the period of performance.

**Please note:** Employment with special wage provisions authorized under section 14(c) of the Fair Labor Standards Act (29 U.S.C. 214) is not considered a positive employment outcome for the purpose of Work Incentive Grants.

Proposed GPRA goals for PY 2004 and PY 2005 for Work Incentive Grants are:

• Eight percent (8%) of participants served in adult, dislocated worker, and

youth programs will be persons with disabilities in workforce investment areas that receive Work Incentive Grants. (6.5% of total participants were persons with disabilities in PY 2001)

• Seventy percent (70%) of participants with disabilities that exit the WIA adult, dislocated worker and adult youth programs in workforce areas receiving grants will enter employment (65% of WIA exiters with disabilities entered employment during April 1, 2001–March 31, 2002)

• A measure of efficiency will be calculated. Total costs of the grant will be divided by the total participants in the workforce investment areas funded under the grant.

Please remember that Work Incentive Grant funds are not to be used for direct training of participants; therefore, intensive and training funds must be made available through WIA program and/or other mandated (or non-mandated) partner resources in order to meet participant employment goals and objectives. If you do blend resources across funding streams, it is accepted practice under WIA to report participant services and outcomes for each program involved.

Provide the following levels of planned services under state Wagner-Peyser (*e.g.,* Job Service, Employment Service, Labor Exchange), state or local WIA Title I adult, dislocated worker and youth programs, and planned levels of services and outcomes under the proposed grant for participants in these programs (planned goals do not have to be at the level of national GPRA goals; however, state and local workforce area(s) should be working towards these goals):

| State or local WIA | Wagner-Peyser/Labor exchange | | | Wagner-Peyser/Labor exchange | | |
|---|---|---|---|---|---|---|
| | Served (registered) | | | Entered employment | | |
| | Total No. served | No. with disabilities | Percent with disabilities | Total No. entered employment | No. with disabilities | Percent with disabilities |
| | | | | | | |
| | | | | | | |
| | | | | | | |

| State or local WIA | Adult, dislocated worker, and youth | | | Adult, dislocated worker, and youth | | |
|---|---|---|---|---|---|---|
| | Served (registered) | | | Entered employment | | |
| | Total No. served | No. with disabilities | Percent with disabilities | Total No. entered employment | No. with disabilities | Percent with disabilities |
| | | | | | | |
| | | | | | | |
| | | | | | | |

Your narrative must include the following information for this criterion.

• Describe your strategy for increasing the number and percent of people with disabilities served, trained and placed into unsubsidized employment through WIA Title I and Wagner-Peyser programs. Your state or local workforce area(s) may already be serving and achieving employment levels for persons with disabilities that are at or above the GPRA goals identified. If that is the case, please identify actions to be taken to sustain these levels of performance.

• Identify how joint funding of training or employment services may be leveraged across available programs to which job seekers with disabilities may be eligible, including Vocational Rehabilitation services.

• Identify how your planned activities to train and place individuals with disabilities will meet employer skill shortage needs, including how available federal and state tax incentives will be utilized or marketed to improve employment outcomes.

• Identify the extent to which planned training for customers with disabilities will be provided through the state or local community college system.

• Within demand industries and occupations in the labor market to be served, describe a plan for identifying growth occupations with positive earnings trajectories and their education and training requirements and how job seekers with disabilities will be included.

• Describe how public supports needed by people with disabilities may be affected by their employment or training and state or local conditions, and then describe your proposed actions to sustain benefits and services following successful job placement. For example, does the state or local area have provisions to continue supported or Section 8A housing (The Housing Act of 1992, Title IV), where applicable, for individuals who enter unsubsidized employment?

• Provide the following information concerning developing or providing skill training and employment opportunities for individuals with disabilities within the local workforce investment area:

—Plans for using on-the-job training opportunities;

—Approaches for mentoring adults and youth through faith-based and community-based organizations, employers, and Independent Living Centers, among others;

—Strategies to foster entrepreneurial and self-employment options;

—Strategies to increase employment outcomes through individualized or customized job development;

—Plans for Individual Development Accounts and other asset building programs for control of training funds, Vocational Rehabilitation funds, Individual Training Accounts, and other funds to which these individuals may have access (*e.g.,* Medicaid personal assistance services);
—Strategies to incorporate apprenticeship into planned career opportunities;
—Strategies to deploy Plans for Achieving Self-Support (PASS), tickets under the SSA Ticket to Work program, or other SSA work incentives when providing services for beneficiaries of SSDI and SSI programs;
—Strategies to sustain projects and achievements beyond the period of performance; and
—Approaches for developing employer relationships such as linkages with Business Leadership Networks (BLNs) in achieving employment outcomes for people with disabilities.

*E. Plans To Sustain the Activities Beyond WIG IV Funding (Not To Exceed 5 Double-Spaced Pages; Maximum of 15 Points)*

Identify state or local workforce plans to sustain activities or accomplishments to be achieved under your proposal. What approaches do you envision to achieve permanent, systemic change? What approach is planned to assure increased coordination of services of mandated and non-mandated partner programs that impact successful employment of job seekers with disabilities following the end of the grant? If Navigators are planned under your proposal, how will these positions continue to be supported at the end of the grant? We would like to make sure that state and local workforce areas are looking beyond the end of this grant as part of institutionalizing the goals and objectives of the Work Incentive Grant program to increase, enhance and improve services and outcomes for people with disabilities accessing the workforce program.

*2. Review and Selection Process:*

• Technical review panels will evaluate each application against the rating criteria listed in this SGA. Priority will be given to applicants from states in which a work incentive grant has yet to be awarded.

• The Department may elect to award grants either with or without discussions with the offeror. In situations without discussions, an award will be based on the offeror's signature on the SF 424, which constitutes a binding offer.

• The panel recommendations are advisory and not binding on the Grant Officer. The ETA grant officer will fully consider the panel recommendations but take into account geographic dispersion, program balance, diversity, the availability of funds, and other factors to ensure the most advantageous award of these funds to accomplish the system-building purposes outlined in this SGA. Please note that Disability Program Navigator initiative states may be expanded through cooperative agreements established in June 2003 rather than through awards under this Work Incentive Grant solicitation.

## VI. Award Administration Information

*1. Award Notices:* All award notifications will be posted on the ETA Homepage at *http://www.doleta.gov.* Grant awards will be made no later than June 30, 2004.

*2. Administrative and National Policy Requirements:* Grantees must comply with the following provisions:

• 29 CFR parts 30, 31, 32, 33 and 36—Equal Employment Opportunity in Apprenticeship and Training; Nondiscrimination in Federally Assisted Programs of the Department of Labor-Effectuation of the Title VI of the Civil Rights Act of 1964; Nondiscrimination on the Basis of Handicap in Programs or Activities Conducted by the Department of Labor; and Nondiscrimination on the Basis of Sex in Education Programs Receiving or Benefiting from Federal Financial Assistance;

• 29 CFR part 37—Implementation of the Nondiscrimination and Equal Opportunity Provisions of the Workforce Investment Act of 1988 (WIA);

• 29 CFR part 93—Lobbying;

• 29 CFR part 95—Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations, and with Commercial Organizations;

• 29 CFR PART 96—Audit Requirements for Grants, Contracts and Other Agreements;

• 29 CFR part 97—Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments;

• 29 CFR part 98—Governmentwide Debarment and Suspension (Non-Procurement) and Governmentwide Requirements for Drug-Free Workplace;

• 29 CFR part 99—Audit of States, Local Governments, and Non-Profit Organizations.

In accordance with section 18 of the Lobbying Disclosure Act of 1995, Public Law 104–65 (2 U.S.C. 1611) non-profit entities incorporated under Internal Revenue Service Code section 501(c)(4) that engage in lobbying activities are not eligible to receive Federal funds and grants. Further, this program is subject to the provisions of the "Jobs for Veterans Act,'' Public Law 107–288, which provides priority of service to veterans and spouses of certain veterans for the receipt of employment, training, and placement services in any job training program directly funded, in whole or in part, by the Department of Labor. Please note that, to obtain priority of service, a veteran must meet the program's eligibility requirements. ETA Training and Employment Guidance Letter (TEGL) No. 5–03 (September 16, 2003) provides general guidance on the scope of the veterans priority statute and its effect on current employment and training programs. DOL anticipates updating this guidance at the time of WIA reauthorization and issuing individual guidance on each affected employment and training program.

*3. Reporting, Monitoring and Technical Assistance:* We require two types of progress reports during each quarter, or three month period, during the period of performance: quarterly narrative progress and financial reports. Disability Program Navigator positions may require an additional progress report. Quarterly reports are due within 30 days following the end of each quarter (ending on September 30, December 31, March 31, and June 30) from the date of grant award. It is likely that grant funds will be awarded by early June 2004 and the first quarterly reports will be due 30 days following September 30, 2004. Between reporting dates, the grantee shall also immediately inform the assigned ETA Federal Project Officer of significant developments and/or problems affecting the grantee's ability to accomplish the Workplan. At the end of the grant, the grantee must also prepare and submit a final report summarizing all accomplishments under the grant. The format of all reports and submission instructions will be provided following grant award.

ETA is responsible for ensuring effective implementation of each competitive grant project through active technical assistance and on-site project monitoring. This monitoring will focus on timely project implementation in accordance with the Workplan and Timeline, the appropriate expenditure of grant funds, integration and coordination with other service providers in the local area, and the effectiveness of project management in achieving project goals. Finally, on-site

monitoring will examine the fruitfulness of efforts to build sustainability.

We will provide extensive technical assistance over the duration of the Round IV Work Incentive Grant through ETA's contract with the University of Iowa's Law, Health Policy and Disability Center and their Research Rehabilitation and Training Center on Workforce Investment and Employment Policy for Persons with Disabilities. Technical assistance and training will include extensive information sharing across grantees as well as numerous topical phone conferences. The selected grantees will also share responsibility for identifying, showcasing and replicating successful instances of involvement in the One-Stop system by partners and organizations assisting jobseekers with disabilities.

## VII. Agency Contacts

Questions should be faxed to Eric Luetkenhaus, Grant Officer, Division of Federal Assistance at (202) 693–2705 (This is not a toll free number). All inquiries should include the SGA/DFA 04–107 and a contact name, fax and phone number. For more information contact Mr. Luetkenhaus at 202–693–3109 (This is not a toll free number). This solicitation will be also published on the Internet, on ETA's disability online home page at *http://wdsc.doleta.gov/disability/,* and the ETA home page at *http://www.doleta.gov.* Award notifications will also be published on the ETA home page.

Signed in Washington, DC, this 2nd of April, 2004.

**Eric D. Luetkenhaus,**

*Grant Officer, Employment and Training Administration.*

**Attachments**

1. (SF) 424: Application Form
2. Budget Information Form
3. OMB No. 1890–0014: Survey on Ensuring Equal Opportunity for Applicants
4. Project Timeline Format
5. Disability Program Navigator Position Description—7 pages

BILLING CODE 4510–30–P

# APPLICATION FOR FEDERAL ASSISTANCE

OMB Approval No. 0348-0043

| | | | |
|---|---|---|---|
| | | 2. DATE SUBMITTED | Applicant Identifier |
| 1. TYPE OF SUBMISSION: Application ☐ Construction ☐ Non-Construction | Preapplication ☐ Construction ☐ Non-Construction | 3. DATE RECEIVED BY STATE | State Application Identifier |
| | | 4. DATE RECEIVED BY FEDERAL AGENCY | Federal Identifier |

DUNS NUMBER:

| | |
|---|---|
| Legal Name: | Organizational Unit: |
| Address (give city, county, State and zip code): | Name, telephone number and fax number of the person to be contacted on matters involving this application (give area code): |

5. EMPLOYER IDENTIFICATION NUMBER (EIN):

6. TYPE OF APPLICANT: (enter appropriate letter in box)
A. State
B. County
C. Municipa
D. Township
E. Interstate
F. Intermunicipal
G. Special District
H Independent School Dist.
I State Controlled Institution of Higher Learning
J . Private University
K Indian Tribe
L. Individual
M. Profit Organization
N. Other (Specify): _____

7. TYPE OF APPLICATION:
☐ New ☐ Continuation ☐ Revision

If Revision, enter appropriate letter(s) in box(es):
A. Increase Award B. Decrease Award C. Increase Duration
D. Decrease Duration Other (specify):
_____

8. NAME OF FEDERAL AGENCY:

9. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:

TITLE:

10. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

11. AREAS AFFECTED BY PROJECT (cities, counties, States, etc.):

| 12. PROPOSED PROJECT: | | 13. CONGRESSIONAL DISTRICTS OF: | |
|---|---|---|---|
| Start Date | Ending Date | a. Applicant | b. Project |

| 14. ESTIMATED FUNDING: | |
|---|---|
| a. Federal | $ .00 |
| b. Applicant | $ .00 |
| c. State | $ .00 |
| d. Local | $ .00 |
| e. Other | $ .00 |
| f. Program Income | $ .00 |
| g. TOTAL | $ .00 |

15. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES. THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON

DATE _____

b. NO. ☐ PROGRAM IS NOT COVERED BY E.O. 12372

☐ OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

16. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?

☐ Yes If "Yes," attach an explanation. ☐ No

17. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION ARE TRUE AND CORRECT. THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCES IF THE ASSISTANCE IS AWARDED.

| | | |
|---|---|---|
| a. Typed Name of Authorized Representative | b. Title | c. Telephone number |
| d. Signature of Authorized Representative | | e. Date Signed |

Previous Editions Not Usable

Standard Form 424 (REV 4-88)
Prescribed by OMB Circular A-102

**Authorized for Local Reproduction**

## INSTRUCTIONS FOR THE SF-424

Public reporting burden for this collection of information is estimated to average 45 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0043), Washington, DC 20503.

**PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE OFFICE OF MANAGEMENT AND BUDGET. SEND IT TO THE ADDRESS PROVIDED BY THE SPONSORING AGENCY.**

This is a standard form used by applicants as a required face sheet for pre-applications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

| Item: | Entry: | Item: | Entry: |
|---|---|---|---|
| 1. | Select Type of Submission. | 11. | Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project. |
| 2. | Date application submitted to Federal agency (or State if applicable) and applicant's control number (if applicable). | 12. | List only the largest political entities affected (e.g., State, counties, cities). |
| 3. | State use only (if applicable). | 13 | Enter the proposed start date and end date of the project. |
| 4. | Enter Date Received by Federal Agency<br>Federal identifier number: If this application is a continuation or revision to an existing award, enter the present Federal Identifier number. If for a new project, leave blank. | 14. | List the applicant's Congressional District and any District(s) affected by the program or project |
| 5. | Enter legal name of applicant, name of primary organizational unit (including division, if applicable), which will undertake the assistance activity, enter the organization's DUNS number (received from Dun and Bradstreet), enter the complete address of the applicant (including country), and name, telephone number, e-mail and fax of the person to contact on matters related to this application. | 15 | Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate only the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15. |
| 6. | Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service. | 16. | Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process. |
| 7. | Select the appropriate letter in the space provided.<br>A. State<br>B. County<br>C. Municipal<br>D. Township<br>E. Interstate<br>F. Intermunicipal<br>G. Special District<br>H. Independent School District<br>I. State Controlled Institution of Higher Learning<br>J. Private University<br>K. Indian Tribe<br>L. Individual<br>M. Profit Organization<br>N. Other (Specify)<br>O. Not for Profit Organization | 17. | This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes. |
| 8. | Select the type from the following list:<br>• "New" means a new assistance award.<br>• "Continuation" means an extension for an additional funding/budget period for a project with a projected completion date.<br>• "Revision" means any change in the Federal Government's financial obligation or contingent liability from an existing obligation. If a revision enter the appropriate letter:<br>A. Increase Award B. Decrease Award<br>C. Increase Duration D. Decrease Duration | 18 | To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.) |
| 9. | Name of Federal agency from which assistance is being requested with this application. | | |
| 10. | Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested. | | |

# PART II - BUDGET INFORMATION

## SECTION A - Budget Summary by Categories

| | (A) | (B) | (C) |
|---|---|---|---|
| 1. Personnel | | | |
| 2. Fringe Benefits (Rate %) | | | |
| 3. Travel | | | |
| 4. Equipment | | | |
| 5. Supplies | | | |
| 6. Contractual | | | |
| 7. Other | | | |
| 8. Total, Direct Cost (Lines 1 through 7) | | | |
| 9. Indirect Cost (Rate %) | | | |
| 10. Training Cost/Stipends | | | |
| 11. TOTAL Funds Requested (Lines 8 through 10) | | | |

## SECTION B - Cost Sharing/ Match Summary (if appropriate)

| | (A) | (B) | (C) |
|---|---|---|---|
| 1. Cash Contribution | | | |
| 2. In-Kind Contribution | | | |
| 3. TOTAL Cost Sharing / Match (Rate %) | | | |

NOTE: Use Column A to record funds requested for the initial period of performance (i.e. 12 months, 18 months, etc.); Column B to record changes to Column A (i.e. requests for additional funds or line item changes; and Column C to record the totals (A plus B).

# INSTRUCTIONS FOR PART II - BUDGET INFORMATION

## SECTION A - Budget Summary by Categories

1. Personnel: Show salaries to be paid for project personnel which you are required to provide with W2 forms.

2. Fringe Benefits: Indicate the rate and amount of fringe benefits.

3. Travel: Indicate the amount requested for staff travel. Include funds to cover at least one trip to Washington, DC for project director or designee.

4. Equipment: Indicate the cost of non-expendable personal property that has a useful life of more than one year with a per unit cost of $5,000 or more. Also include a detailed description of equipment to be purchased including price information.

5. Supplies: Include the cost of consumable supplies and materials to be used during the project period.

6. Contractual: Show the amount to be used for (1) procurement contracts (except those which belong on other lines such as supplies and equipment); and (2) sub-contracts/grants.

7. Other: Indicate all direct costs not clearly covered by lines 1 through 6 above, including consultants.

8. Total, Direct Costs: Add lines 1 through 7.

9. Indirect Costs: Indicate the rate and amount of indirect costs. Please include a copy of your negotiated Indirect Cost Agreement.

10. Training /Stipend Cost: (If allowable)

11. Total Federal funds Requested: Show total of lines 8 through 10.

## SECTION B - Cost Sharing/Matching Summary

Indicate the actual rate and amount of cost sharing/matching when there is a cost sharing/matching requirement. Also include percentage of total project cost and indicate source of cost sharing/matching funds, i.e. other Federal source or other Non-Federal source.

NOTE: PLEASE INCLUDE A DETAILED COST ANALYSIS OF EACH LINE ITEM.

# SURVEY ON ENSURING EQUAL OPPORTUNITY FOR APPLICANTS

OMB No. 1890-0014 Exp. 1/31/2006

**Purpose:** The Federal government is committed to ensuring that all qualified applicants, small or large, non-religious or faith-based, have an equal opportunity to compete for Federal funding. In order for us to better understand the population of applicants for Federal funds, we are asking nonprofit private organizations (not including private universities) to fill out this survey.

Upon receipt, the survey will be separated from the application. Information provided on the survey will not be considered in any way in making funding decisions and will not be included in the Federal grants database. While your help in this data collection process is greatly appreciated, completion of this survey is voluntary.

**Instructions for Submitting the Survey:** If you are applying using a hard copy application, please place the completed survey in an envelope labeled "Applicant Survey." Seal the envelope and include it along with your application package. If you are applying electronically, please submit this survey along with your application.

**Applicant's (Organization) Name:** _____

**Applicant's DUNS Number:** _____

**Grant Name:** _____ **CFDA Number:** _____

1. Does the applicant have 501(c)(3) status?

   ☐ Yes ☐ No

2. How many full-time equivalent employees does the applicant have? *(Check only one box).*

   ☐ 3 or Fewer ☐ 15-50
   ☐ 4-5 ☐ 51-100
   ☐ 6-14 ☐ over 100

3. What is the size of the applicant's annual budget? *(Check only one box.)*

   ☐ Less Than $150,000
   ☐ $150,000 - $299,999
   ☐ $300,000 - $499,999
   ☐ $500,000 - $999,999
   ☐ $1,000,000 - $4,999,999
   ☐ $5,000,000 or more

4. Is the applicant a faith-based/religious organization?

   ☐ Yes ☐ No

5. Is the applicant a non-religious community-based organization?

   ☐ Yes ☐ No

6. Is the applicant an intermediary that will manage the grant on behalf of other organizations?

   ☐ Yes ☐ No

7. Has the applicant ever received a government grant or contract (Federal, State, or local )?

   ☐ Yes ☐ No

8. Is the applicant a local affiliate of a national organization?

   ☐ Yes ☐ No

## Survey Instructions on Ensuring Equal Opportunity for Applicants

**Provide the applicant's (organization) name and DUNS number and the grant name and CFDA number.**

1. 501(c)(3) status is a legal designation provided on application to the Internal Revenue Service by eligible organizations. Some grant programs may require nonprofit applicants to have 501(c)(3) status. Other grant programs do not.

2. For example, two part-time employees who each work half-time equal one full-time equivalent employee. If the applicant is a local affiliate of a national organization, the responses to survey questions 2 and 3 should reflect the staff and budget size of the local affiliate.

3. Annual budget means the amount of money your organization spends each year on all of its activities.

4. Self-identify.

5. An organization is considered a community-based organization if its headquarters/service location shares the same zip code as the clients you serve.

6. An "intermediary" is an organization that enables a group of small organizations to receive and manage government funds by administering the grant on their behalf.

7. Self-explanatory.

8. Self-explanatory.

**Paperwork Burden Statement**

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless such collection displays a valid OMB control number. The valid OMB control number for this information collection is 1890-0014. The time required to complete this information collection is estimated to average five (5) minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. **If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to:** U.S. Department of Education, Washington, D.C. 2202-4651.

**If you have comments or concerns regarding the status of your individual submission of this form, write directly to:** Joyce I. Mays, Application Control Center, U.S. Department of Education, 7th and D Streets, SW, ROB-3, Room 3671, Washington, D.C. 20202-4725

OMB No. 1890-0014 Exp. 1/31/2006

# Goal Implementation Timeline Format

(Applicants are not limited in their number of goals or objectives)

| Goal #1: | | | | | |
|---|---|---|---|---|---|
| Objective #1 by Goal | Responsible person or team | Implementation | | Expected Outcomes | Indicators |
| | | Strategy | Time Frame | | |
| | | | | | |
| Objective #2 by Goal | Responsible person or team | Implementation | | Expected Outcomes | Indicators |
| | | Strategy | Time Frame | | |
| | | | | | |

| Goal #2: | | | | | |
|---|---|---|---|---|---|
| Objective #1 by Goal | Responsible person or team | Implementation Strategy | Time Frame | Expected Outcomes | Indicators |
| | | | | | |
| Objective #2 by Goal | Responsible person or team | Implementation Strategy | Time Frame | Expected Outcomes | Indicators |
| | | | | | |

**Etc.**

# Position Description for the DISABILITY PROGRAM NAVIGATOR

## *BACKGROUND*

The Disability Program Navigator (Navigator) is the focus of a demonstration project jointly sponsored by the Department of Labor, Employment and Training Administration (DOL/ETA) and the Social Security Administration, Office of Program Development and Research (SSA/OPDR). The DOL and SSA are jointly funding and training individuals selected as Navigators and will pilot and evaluate the Navigator positions. DOL/ETA encourages applicants for WIG IV grants to consider including Navigator positions in their applications, using this position description below for guidance.

The Navigator will address the needs of people with disabilities seeking training and employment opportunities through the One-Stop Career Center system established under the Workforce Investment Act (WIA) of 1998. The Navigator will provide expertise and serve as a resource person to the workforce investment system and persons with disabilities, including Social Security Disability Insurance (DI) and Supplemental Security Income (SSI) disability and blindness beneficiaries. Navigators will have expertise regarding the One-Stop partner programs, services and information and Social Security Administration (SSA) work incentives and other employment support programs, including the Ticket to Work programs and SSA demonstration projects focused on improving employment opportunities for persons with disabilities.

The Navigator will expand consumer choice in addressing the needs of people with disabilities seeking training and employment opportunities through the One-Stop Career

Center system established under WIA. The Navigator position is intended to increase employment and self-sufficiency for persons with disabilities by linking them to employers and by facilitating access to supports and services that will enable the transition to employment.

NOTE: The following duties and responsibilities of the Navigator are advisory and applicants may adjust and expand them to meet the needs of the local workforce investment area.

DUTIES

Serves as an expert on workforce development issues and policies impacting persons with disabilities who are seeking employment, skill development, job retention assistance, or career advancement through the One-Stop Career Center system (including the use of Individual Training Accounts, which are typically underutilized for people with disabilities). Serves as a resource to the workforce investment community within their service area to ensure the availability of comprehensive knowledge on federal, state, local and private programs that impact the ability of persons with disabilities to enter and remain in the workforce. Facilitates universal access to the One-Stop system for persons with disabilities.

On a "consumer choice" model, the Navigator will, as necessary, work directly with One Stop Career Center customers with disabilities, including SSI and DI beneficiaries, to provide the customer with options and assistance in accessing and navigating the complex provisions under various governmental and non-governmental programs that impact their ability to gain, return to, or retain employment. In dealing with youth, the Navigator will be available and prepared to assist these customers in accessing the

individualized supports (including IDEA mandated special education and related services) needed to successfully transition to adulthood.

RECOMMENDED CORE FUNCTIONS OF THE NAVIGATOR POSITION

- Assists people with disabilities to access the wide variety of programs available to support their successful entry or re-entry into the workforce, connecting such individuals to those programs and the benefits, services and/or supports that they provide and following up to assure that each individual is receiving the level of benefits, services and/or supports needed.
- Serves as a resource to the workforce investment staff within the service area to ensure the availability of comprehensive knowledge on federal, state, local and private programs that impact the ability of persons with disabilities to enter and remain in the workforce;
- Trains One-Stop Career Center staff and other staff on activities, services and resources available in the One-Stop system, SSA employment support programs and demonstration projects and other programs;
- Serves as a One-Stop Career Center resource on Social Security work incentives and other employment support programs, including the Ticket to Work Program and the provision of services through Benefits Planning, Assistance and Outreach organizations (BPAOs), the Protection and Advocacy systems (P&As), SSA's employment-related demonstration projects, and State Vocational Rehabilitation (VR) Agencies;
- Develops linkages and collaborates on an ongoing basis with employers and employer organizations, such as the Chamber of Commerce and the Business

Leadership Network, to promote the hiring of people with disabilities and to facilitate their job placement;

- Trains or makes training available to One-Stop Career Center staff on disability etiquette; facility, communication and program accessibility requirements; Americans with Disability Act (ADA); Section 504 (Part 32) of the Rehabilitation Act (29 CFR part 32) and WIA section 188 (29 CFR part 37) definitions and requirements; assessment tools and their applicability; SSA employment support programs; employer federal and state tax incentives, and other relevant information that may be applicable;
- Facilitates the transition of in or out of school youth with disabilities to secure employment and economic self-sufficiency, including outreach to schools and the design and coordination of customized assistance;
- Conducts outreach to, and coordination with, community service providers working with people with disabilities, local Independent Living Centers and public and private mental health and developmental disability organizations. Fosters linkages between these organizations and programs operating through One-Stop Career Centers, including Social Security employment support programs;
- Serves as a One-Stop Career Center resource on pertinent workforce development issues and policies for jobseekers with disabilities who seek employment, skill development, job retention assistance, or career advancement through the One- Stop Career Center system (including the use of Individual Training Accounts);

- Provides an ongoing assessment of One-Stop Career Center facilities, services, programs and equipment to ensure these are accessible to people with disabilities, including ensuring that informational materials on the Social Security Ticket to Work Program, Plan to Achieve Self Support (PASS) and other programs are available in alternate formats;
- Works with designated Equal Employment Opportunity officer(s), the local Workforce Investment Board and the One-Stop operator to ensure that One-Stop Career Center facilities, services, programs and equipment are accessible to people with disabilities, including ensuring the availability of publications and materials in alternate formats;

Provides information on assistive technologies and/or referral to organizations that can serve as a resource (e.g., State Services for the Blind offices, regional Disability and Business Technical Assistance Centers, Job Accommodation Networks, etc.);

- Provides information on complaint procedures established under the nondiscrimination provisions of WIA section 188 as well as those provided in SSA's Ticket to Work Program (i.e., P&As); and
- Facilitates the collection of participant data that may be required to effectively evaluate the Navigator initiative.

RELEVANT KNOWLEDGE

The Navigator will be trained on a broad range of Federal, State, local and private work incentives and other employment support programs and services, including One-Stop partner programs and Social Security work incentives and related employment support programs, including the Ticket to Work Program. The Navigator will be expected to

acquire knowledge in the following areas of sufficient depth and detail to effectively impart program and service information to One-Stop customers and staff and to successfully facilitate referrals and improve job opportunities for persons with disabilities.

- Title XVI of the Social Security Act, including the Plan to Achieve Self Support provision and other work incentives as well as Title II of the Social Security Act, with particular attention to work incentives.
- Title XVIII and Title XIX of the Social Security Act, with particular attention to state "buy-in" options with regard to Medicaid.
- The Ticket to Work and Work Incentives Improvement Act of 1999.
- The Workforce Investment Act, with particular attention to adult, dislocated worker, and youth programs.
- The goals, policies and operations of the state and local workforce investment systems and the partner agencies and their programs.
- The Individuals with Disabilities Education Act (IDEA) and State Title V (Maternal and Child Health) Agency programs.
- Vocational rehabilitation agency services provided through the State Vocational Rehabilitation (VR) agency.
- Functional assessment tools available through VR, adult literacy programs, and other partner programs in the One-Stop Career Center system.
- Local transportation resources and the availability of alternative transportation modes.
- Housing availability, programs and limitations.

- Temporary Assistance for Needy Families (TANF) and welfare-to-work requirements affecting TANF recipients.
- The legal requirements related to accessibility of programs and services for people with disabilities.
- The array of available assistive technologies and resources, including an awareness of local, state, regional and national resources related to assistive technology.
- Basic office computer skills (word processing, presentation, and database programs).
- The ability to communicate orally and in writing.

[FR Doc. 04–7906 Filed 4–7–04; 8:45 am]
BILLING CODE 4510–30–C

## NATIONAL COMMISSION ON TERRORIST ATTACKS UPON THE UNITED STATES

### Public Testimony

**ACTION:** Notice of public testimony.

**SUMMARY:** The National Commission on Terrorist Attacks Upon the United States will take public testimony from Dr. Condoleezza Rice, Assistant to the President for National Security Affairs, at 9–11:30 a.m., on April 8, 2004, in Room 216 of the Hart Senate Office Building. The proceedings will be open to the public and members of the media. Seating will be provided on a first-come, first-served basis. Members of the media must register by the close of business on April 6, 2004, by visiting the Commission's Web site, *http://www.9-11commission.gov.* Members of the media, particularly photographers and radio and television broadcasters, also must contact the appropriate Senate Press Gallery for accreditation as soon as possible.

**DATES:** April 8, 2004, 9 a.m. to 11:30 a.m.

**LOCATION:** Hart Senate Office Building, Room 216, Washington, DC 20510.

**FOR FURTHER INFORMATION CONTACT:** Al Felzenberg or Jonathan Stull at (202) 401–1627, (202) 494–3538 (cellular), or *jstull@9-11commission.gov.*

**SUPPLEMENTARY INFORMATION:** Please refer to Pub. L. 107–306 (November 27, 2002), title VI (Legislation creating the Commission), and the Commission's Web site: *http://www.9-11commission.gov.*

Dated: April 5, 2004.

**Philip Zelikow,**

*Executive Director.*

[FR Doc. 04–8020 Filed 4–7–04; 8:45 am]

**BILLING CODE 8800–01–M**

## NUCLEAR REGULATORY COMMISSION

**[Docket Nos. 50–245, 50–336, and 50–423; License Nos. DPR–21, DPR–65 and NPF–49]**

### In the Matter of Dominion Nuclear Connecticut, Inc., Millstone Power Station, Unit Nos. 1, 2, and 3; Order Approving Indirect Transfer of Control of Licenses

Dominion Nuclear Connecticut, Inc. (DNC or the licensee) is licensed by the U.S. Nuclear Regulatory Commission (NRC or Commission) to possess and maintain, but not operate, Millstone Power Station, Unit No. 1, and possess, maintain, and operate (in conjunction with certain unaffiliated owners of Millstone, Unit No. 3) Millstone Power Station, Unit Nos. 2 and 3 (Millstone Units or the facilities) under Facility Operating License Nos. DPR–21, DPR–65, and NPF–49, issued by the Commission on October 7, 1970, September 26, 1975, and January 31, 1986, respectively. The Millstone Units are located at the licensee's site in New London County, Connecticut.

By application dated October 8, 2003, as supplemented November 7, 2003, DNC requested that the Commission consent, to the extent that proposed corporate restructuring results in an indirect transfer, to the indirect transfer of control of these facility operating licenses for the Millstone Units. The indirect transfer would result from the planned corporate restructuring involving certain intermediate subsidiaries of DNC's parent company, Dominion Resources, Inc. (DRI). DNC is a wholly-owned, indirect subsidiary of DRI.

DRI directly owns Virginia Electric & Power Company (VEPCO), Dominion Energy, Inc. (DEI), and Consolidated Natural Gas Company (CNG). DEI owns 100% of Dominion Nuclear, Inc. (DNI), and CNG owns 100% of Dominion Retail, Inc. (Retail). DNI is the parent company of Dominion Nuclear Holdings, Inc. (DNH), Dominion Nuclear Marketing I, Inc. (DNMI), Dominion Nuclear Marketing II, Inc. (DNMII), and Dominion Nuclear Marketing III, LLC (DNMIII). DNH and Retail also have part ownership of DNMIII. DNMI, DNMII, and DNMIII are the direct parent companies of DNC, the holder of the licenses of the Millstone Units. This corporate structure can be graphically seen as Exhibit B, "Current Corporate Ownership of Dominion Nuclear Connecticut,'' in the October 8, 2003, Application.

The proposed corporate restructuring will have DRI continue to own VEPCO, DEI and CNG. Dominion Energy Marketing, Inc. (DEM) will be formed by merging DNMI and DNMII, and will be the direct subsidiary of DEI and a parent company of DNC. DNI will be eliminated and, therefore, will no longer be a subsidiary of DEI, and DNH will become a direct subsidiary of DEI. CNG will continue to be the direct parent company of Retail, and Retail will continue to be a direct parent company of DNMIII. Thus, only DEM and DNMIII will be the direct parent companies of DNC. This proposed corporate restructuring can be graphically seen as Exhibit C, "Corporate Ownership of Dominion Nuclear Connecticut, After Proposed Realignment,'' in the October 8, 2003, Application.

DNC would continue to own (in the case of Millstone, Unit No. 3, along with certain unaffiliated co-owners) the Millstone Units following approval of the proposed indirect transfer of the license, and would continue to be exclusively responsible for the operation (except for Millstone Power Station, Unit No. 1), maintenance and eventual decommissioning of the facilities. No physical changes to the facilities or operational changes were proposed in the application.

Approval of the indirect transfer of the operating licenses was requested by DNC pursuant to title 10 of the Code of Federal Regulations (10 CFR), section 50.80. Notice of the request for approval and an opportunity for a hearing was published in the **Federal Register** on November 12, 2003 (68 FR 64132). No hearing requests or written comments were received.

Pursuant to 10 CFR 50.80, no license, or any right thereunder, shall be transferred, directly or indirectly, through transfer of control of the license, unless the Commission gives its consent in writing. After reviewing the information in the application from DNC and other information before the Commission, the NRC staff has determined that the corporate restructuring involving certain intermediate subsidiaries of DRI will not affect the qualifications of DNC as the holder of the licenses and that the indirect transfer of control of the licenses, to the extent effected by the foregoing transaction, is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission, subject to the conditions set forth below. The foregoing findings are supported by a Safety Evaluation (SE) dated April 2, 2004.

Accordingly, pursuant to sections 161b, 161i, 161o, and 184 of the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2201(b), 2201(i), 2201(o), and 2234, and 10 CFR 50.80, it is hereby ordered that the application regarding the indirect transfer of the control of Facility Operating License Nos. DPR–21, DPR–65 and NPF–49 referenced above is approved, subject to the following condition: should the planned restructuring by DRI not be completed by December 31, 2004, this Order shall become null and void, provided that upon written application and for good cause shown, such date may be extended.

This Order is effective upon issuance.

For further details with respect to this action, *see* the application dated October 8, 2003, as supplemented on November 7, 2003, and the SE dated April 2, 2004, which are available for public inspection at the Commission's Public Document Room, located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland, and accessible from the Agencywide Documents Access and Management Systems (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/NRC/ADAMS/index.html*.

Dated in Rockville, Maryland, this 2nd day of April, 2004.

For the Nuclear Regulatory Commission.

**Herbert N. Berkow,**

*Acting Director, Division of Licensing Project Management, Office of Nuclear Reactor.*

[FR Doc. E4–780 Filed 4–7–04; 8:45 am]

**BILLING CODE 7590–01–P**

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## NUCLEAR REGULATORY COMMISSION

**[Docket No. 50–317]**

## Calvert Cliffs Nuclear Power Plant; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of an amendment to Facility Operating License No. DPR–53, issued to Calvert Cliffs Nuclear Power Plant, Inc. (the licensee), for operation of the Calvert Cliffs Nuclear Power Plant, Unit No. 1 (CCNPP1), located in Calvert County, MD. Therefore, as required by 10 CFR 51.21, the NRC is issuing this environmental assessment and finding of no significant impact.

### Environmental Assessment

*Identification of the Proposed Action*

The proposed action would increase the maximum enrichment limit of fuel assemblies stored in the CCNPP1 spent fuel pool from 4.52 weight percent $U^{235}$ to 5.00 weight percent $U^{235}$. This would be accomplished by the licensee taking credit for soluble boron in maintaining acceptable margins of subcriticality. The proposed action only relates to Unit 1 because the storage racks in the Unit 2 spent fuel pool are of a different design, and require different controls. The Unit 2 spent fuel pool will remain at the current enrichment level of 4.52 weight percent $U^{235}$. The proposed action will result in modification of Technical Specification (TS) Section 4.3.1, "Criticality,'' addition of a new Section 3.7.16, "Spent Fuel Pool Boron Concentration,'' and addition of a license condition to require the development of a long-term coupon surveillance program for the Carborundum samples.

The proposed action is in accordance with the licensee's application dated May 1, 2003, as supplemented September 25, 2003, November 3, 2003, and February 25, 2004.

*The Need for the Proposed Action*

The proposed action would allow the number of fresh fuel assemblies per cycle to be decreased, through allowing the maximum enrichment for fresh fuel to be increased to 5.00 weight percent $U^{235}$ and allowing credit for soluble boron in the spent fuel pool. Through decreasing the number of fresh fuel assemblies per cycle, Independent Spent Fuel Storage Installation storage requirements will decrease, permanent Department of Energy storage requirements will decrease, and fuel cycle costs will decrease. Currently, TS Section 4.3.1, "Criticality'', limits the maximum enrichment for fuel assemblies to 4.52 weight percent $U^{235}$, and does not allow the licensee to take credit for soluble boron in the spent fuel pool. Thus, the proposed changes to the TSs were requested.

*Environmental Impacts of the Proposed Action*

The NRC has completed its safety evaluation of the proposed action and concludes that the storage and use of fuel enriched with $U^{235}$ up to 5.00 weight percent at CCNPP1, is acceptable. The staff's safety evaluation addresses safety considerations at the higher enrichment level, and the staff has concluded that the proposed action will not adversely effect plant safety.

The proposed action will not significantly increase the probability or consequences of accidents. Even though there will be a higher enrichment of $U^{235}$ in the fuel rods, accident consequences will not increase. According to the TSs, the spent fuel pool will contain enough soluble boron to ensure both subcriticality in the event of a dropped rod or accidental misloading, and significant negative reactivity in the event of a loss of normal spent fuel pool cooling.

No changes are being made in the types of effluents that may be released off site. Water and soluble boron will continue to be the materials used to ensure subcriticality in the spent fuel pool. There is no significant increase in the amount of any effluent released off site. Due to the higher enrichment of fuel, the boron concentration in the spent fuel pool will increase from the current value of 300 ppm to 350 ppm to safely store the higher enrichment fuel in the spent fuel pool. The addition of 50 ppm boron is approximately a 15-percent increase in boron concentration, but this is not a significant increase in the amount of radioactive waste. Boron will continue to be collected on the spent fuel pool filters as the water in the spent fuel pool is purified. The filters are replaced periodically and treated as low-level waste. There is no significant increase in occupational or public radiation exposure. Doses to workers will not increase from their current level due to the increased soluble boron concentration absorbing neutrons from the higher enrichment fuel rods in the spent fuel pool. Therefore, there are no significant radiological environmental impacts associated with the proposed action.

With regard to potential non-radiological impacts, the proposed action does not have a potential to affect any historic sites. It does not affect non-radiological plant effluents and has no other environmental impact. Therefore, there are no significant non-radiological environmental impacts associated with the proposed action.

Accordingly, the NRC concludes that there are no significant environmental impacts associated with the proposed action.

*Environmental Impacts of the Alternatives to the Proposed Action*

As an alternative to the proposed action, the staff considered denial of the proposed action (*i.e.*, the "no-action'' alternative). Denial of the application would result in no change in current environmental impacts. The environmental impacts of the proposed action and the alternative action are similar.

*Alternative Use of Resources*

The action does not involve the use of any different resources than those previously considered in the Final Environmental Impact Statement for CCNPP1 dated April 1973, and the Final Supplemental Environmental Impact Statement (NUREG–1437, Supplement 1) dated October 1999.

*Agencies and Persons Consulted*

On August 21, 2003, the staff consulted with the Maryland State official, Richard McLean of the Department of the Environment, regarding the environmental impact of the proposed action. The State official had no comments.

**Finding of No Significant Impact**

On the basis of the environmental assessment, the NRC concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the NRC has determined not to prepare an environmental impact statement for the proposed action.

For further details with respect to the proposed action, see the licensee's letters dated May 1, 2003, September 23, 2003, November 3, 2003, and February 25, 2004. Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room (PDR), located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the Agencywide Documents Access and Management System (ADAMS) Public Electronic Reading Room on the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html*. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC PDR Reference staff at 1–800–397–4209, or 301–415–4737, or send an e-mail to *pdr@nrc.gov*.

Dated at Rockville, Maryland, this 2nd day of April, 2004.

For the Nuclear Regulatory Commission.

**Guy S. Vissing,**

*Senior Project Manager, Section I, Project Directorate I, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.*

[FR Doc. E4–781 Filed 4–7–04; 8:45 am]

BILLING CODE 7590–01–P

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## NUCLEAR REGULATORY COMMISSION

**[Docket Nos. 50–369 and 50–370]**

## Duke Energy Corporation, McGuire Nuclear Station, Units 1 and 2; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of an exemption from title 10 of the Code of Federal Regulations (10 CFR) part 73, Appendix B, section I.B.b(1), "Vision," for Renewed Facility Operating License Nos. NPF–9 and NPF–17, issued to Duke Energy Corporation (the licensee), for operation of the McGuire Nuclear Station, Units 1, and 2, (McGuire) located in Mecklenburg County, North Carolina. Therefore, as required by 10 CFR 51.21, the NRC is issuing this environmental assessment and finding of no significant impact.

**Environmental Assessment**

*Identification of the Proposed Action*

The proposed action would grant an exemption from the requirements of 10 CFR part 73, Appendix B, section I.B.b(1), "Vision.'' The proposed action is in accordance with the licensee's application dated June 12, 2003, that is being withheld from public disclosure pursuant to 10 CFR 2.390(a)(6). It is being withheld from public disclosure because it contains information about an employee's personnel and medical records, a disclosure of which would constitute a clearly unwarranted invasion of privacy.

The NRC staff's Safety Evaluation will be issued along with the exemption; it will be withheld from public disclosure because it also contains information about an employee's personnel and medical records.

*The Need for the Proposed Action*

The proposed action is needed so that the licensee can institute some specified action for a particular individual. Providing additional information pertaining to the need for the proposed action would require discussing information about the employee's personnel and medical records. The NRC staff has determined that granting the exemption will not jeopardize the health and safety of the public or endanger security operations, and approval of the proposed exemption not be inimical to the common defense and security or to the health and safety of the public. The basis for this determination will be provided in a Safety Evaluation that will be an enclosure to the exemption. This Safety Evaluation will be withheld from public disclosure because it contains information about an employee's personnel and medical records.

**Environmental Impacts of the Proposed Action**

The NRC has completed its evaluation of the proposed action and concludes that there are no environmental impacts.

The proposed action will not significantly increase the probability or consequences of accidents, no changes are being made in the types of effluents that may be released off-site, and there is no significant increase in occupational or public radiation exposure. Therefore, there are no significant radiological environmental impacts associated with the proposed action.

With regard to potential nonradiological impacts, the proposed action does not have a potential to affect any historic sites. It does not affect nonradiological plant effluents and has no other environmental impact. Therefore, there are no significant nonradiological environmental impacts associated with the proposed action.

Accordingly, the NRC concludes that there are no significant environmental impacts associated with the proposed action.

*Environmental Impacts of the Alternatives to the Proposed Action*

As an alternative to the proposed action, the staff considered denial of the proposed action (*i.e.*, the "no-action'' alternative). Denial of the application would result in no change in current environmental impacts. The environmental impacts of the proposed action and the alternative action are similar.

*Alternative Use of Resources*

The action does not involve the use of any different resource than those previously considered in NUREG–0063, "Final Environmental Statement Related to the Operation of William B. McGuire Nuclear Station, Units 1 and 2,'' April 1976, and the Addendum to NUREG–0063 issued in January 1981; and in NUREG–1437, "Generic Environmental Impact Statement for License Renewal of Nuclear Plants, Supplement 8, Regarding McGuire Nuclear Station, Units 1 and 2, Final Report,'' dated December 2002.

*Agencies and Persons Consulted*

On March 29, 2004, the NRC staff consulted with the South Carolina State official, Mr. Virgil Autry of the Department of Health and Environmental Controls, regarding the environmental impact of the proposed action. The State official had no comments.

**Finding of No Significant Impact**

On the basis of the environmental assessment, the NRC concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the NRC has determined not to prepare an environmental impact statement for the proposed action.

Dated in Rockville, Maryland, this 2nd day of April, 2004.

For the Nuclear Regulatory Commission.

**Edwin M. Hackett,**

*Project Director, Project Directorate II, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.*

[FR Doc. E4–782 Filed 4–7–04; 8:45 am]

BILLING CODE 7590–01–P

## POSTAL SERVICE

### United States Postal Service Board of Governors

### Sunshine Act Meeting

**DATE AND TIMES:** Tuesday, April 15, 2004; 10:30 a.m. and 2:30 p.m.

**PLACE:** Washington, DC, at U.S. Postal Service Headquarters, 475 L'Enfant Plaza, SW., in the Benjamin Franklin Room.

**STATUS:** April 15—10:30 a.m. (Closed); 2:30 p.m. (Open).

**MATTERS TO BE CONSIDERED:**

Thursday, April 15—10:30 a.m. (Closed)

1. Negotiated Service Agreement.
2. Financial Update.
3. Strategic Planning.
4. Personnel Matters and Compensation Issues.

Thursday, April 15—2:30 p.m. (Open)

1. Minutes of the Previous Meeting, March 2, 2004.
2. Remarks of the Postmaster General and CEO.
3. Committee Reports.

Thursday, April 15—2:30 p.m. (Open) [continued]

4. Financing the Postal System, Revenue and Cost Analysis, 2003.
5. Update on usps.com.
6. Tentative Agenda for the May 11–12, 2004, meeting in Dallas, Texas.

**FOR FURTHER INFORMATION CONTACT:** William T. Johnstone, Secretary of the Board, U.S. Postal Service, 475 L'Enfant Plaza, SW., Washington, DC 20260–1000. Telephone (202) 268–4800.

**William T. Johnstone,**

*Secretary.*

[FR Doc. 04–8037 Filed 4–5–04; 4:16 pm]

BILLING CODE 7710–12–M

## 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 April 12, 2004:

An Open Meeting will be held on Tuesday, April 13, 2004 at 10 a.m.

A Closed Meeting will be held on Thursday, April 15, 2004 at 2 p.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the Closed Meeting. 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), (4), (5), (7), (8), (9), and (10) and 17 CFR 200.402(a)(3), (4), (5), (7), (8), 9(ii), and (10), permit consideration of the scheduled matters at the Closed Meeting.

Commissioner Campos, as duty officer, voted to consider the items listed for the closed meeting in closed session.

The subject matter of the Open Meeting scheduled for Tuesday, April 13, 2004 will be:

1. The Commission will consider whether to adopt a rule to exempt qualified foreign banks from the insider lending prohibition of Securities Exchange Act of 1934 Section 13(k), as added by Section 402 of the Sarbanes-Oxley Act. The rule would exempt foreign banks that meet specified criteria similar to those that qualify domestic banks for the exemption under Section 13(k). The Commission will also consider whether to adopt an amendment to Form 20–F that would require a foreign bank issuer to provide the same disclosure regarding certain loans to insiders as that required for domestic banks under Regulation S–K.

For further information contact Elliot Staffin, Special Counsel, Office of International Corporate Finance, Division of Corporation Finance, at (202) 942–2990.

2. The Commission will consider whether to propose amendments to Form S–8 and Form 8–K as well as proposing to define the term "shell company.'' The proposed amendments would: (1) Define the term "shell company'' to mean a registrant with no or nominal operations, and with no or nominal assets or assets consisting solely of cash and cash equivalents; (2) prohibit the use of Form S–8 by shell companies; and (3) revise Form 8–K to require a shell company to include current Form 10 or Form 10–SB information, including audited financial statements, in the filing on Form 8–K that it files to report an event that causes it to cease being a shell company.

For further information, please contact Gerald J. Laporte, Chief, or Kevin M. O'Neill, Special Counsel, Office of Small Business Policy, Division of Corporation Finance, at (202) 942–2908.

3. The Commission will consider whether to adopt amendments to Forms N–1A, N–3, N–4, and N–6 under the Securities Act of 1933 and the Investment Company Act of 1940. The amendments will (1) require open-end management investment companies and variable insurance products to disclose in their prospectuses information about the risks of, and policies and procedures with respect to, the frequent purchase and redemption of investment company shares; (2) clarify that open-end management investment companies and insurance company managed separate accounts that offer variable annuities are required to explain both the circumstances under which they will use fair value pricing and the effects of using fair value pricing; and (3) require open end management investment companies and insurance company managed separate accounts that offer variable annuities to disclose their policies and procedures with respect to disclosure of portfolio holdings information.

For further information, please contact Kieran G. Brown or David Schwartz at (202) 942 0721.

The subject matter of the Closed Meeting scheduled for Thursday, April 15, 2004 will be:

Formal orders of investigation;

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings of an enforcement nature;

Regulatory matter regarding a financial institution; and a litigation matter.

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) 942–7070.

Dated: April 6, 2004.

**Jonathan G. Katz,**

*Secretary.*

[FR Doc. 04–8076 Filed 4–6–04; 12:11 pm]

BILLING CODE 8010–01–P

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–49520; File No. PCAOB–2003–09]**

### Public Company Accounting Oversight Board; Notice of Filing of Proposed Rule and Form Governing Withdrawal From Registration

April 2, 2004.

Pursuant to section 107(b) of the Sarbanes-Oxley Act of 2002 ("Act''), notice is hereby given that on October 15, 2003, the Public Company Accounting Oversight Board ("Board'' or "PCAOB'') filed with the Securities and Exchange Commission ("Commission'') the proposed rule and form preparation

instructions described in items I and II below, which items have been prepared by the Board. The Commission is publishing this notice to solicit comments on the proposed rule and form preparation instructions from interested persons.

**I. Board's Statement of the Terms of Substance of the Proposed Rule**

The PCAOB proposes to adopt a rule for public accounting firms registered with the Board to implement section 102 of the Act. The proposal consists of a rule (PCAOB Rule 2107) and instructions to prepare a form (PCAOB Form 1–WD). The text of the proposed rule and form preparation instructions are available for inspection at the Office of the Secretary, the PCAOB, the Commission's Public Reference Room and on the PCAOB's Internet Web site at *http://www.pcaobus.org/pcaob_rulemaking.htm.*

**II. Board's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule**

*(A) Purpose*

Section 102 of the Act makes it unlawful for any person that is not a public accounting firm registered with the Board to prepare or issue, or to participate in the preparation or issuance of, any audit report with respect to any issuer. The Board has previously adopted, and the Commission has approved, rules governing the process by which a public accounting firm becomes registered with the Board. The proposed rule would govern the process by which a firm, once registered, may withdraw such registration.

*(B) Statutory Basis*

The statutory basis for the proposed rule is Title I of the Act.

**III. Date of Effectiveness of the Proposed Rule and Timing for Commission Action**

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding, or (ii) as to which the Board consents, the Commission will:

(A) By order approve such proposed rule and form preparation instructions; or

(B) Institute proceedings to determine whether the proposed rule and form preparation instructions should be disapproved.

**IV. Solicitation of Comments**

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rules are consistent with the Act. Comments may be submitted electronically or by paper. Electronic comments may be submitted by: (1) Electronic form on the SEC Web site (*http://www.sec.gov*) or (2) e-mail to *rule-comments@sec.gov.* Mail paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. All submissions should refer to File No. PCAOB–2003–09; 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*). Comments are also available for public inspection and copying in the Commission's Public Reference Room, 450 Fifth Street, NW., Washington, DC 20549. We do not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All comments should be submitted on or before April 29, 2004.

By the Commission.

**J. Lynn Taylor,**

*Assistant Secretary.*

[FR Doc. 04–7932 Filed 4–7–04; 8:45 am]

**BILLING CODE 8010–01–P**

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## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–49518; File No. SR–CBOE–2003–23]**

## Self-Regulatory Organizations; Order Granting Approval of Proposed Rule Change and Amendment Nos. 1 and 2 Thereto by the Chicago Board Options Exchange, Inc., Relating to its Autoquote Triggered Ebook Execution System

April 1 , 2004.

On June 2, 2003, the Chicago Board Options Exchange, Inc. ("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 relating to its AutoQuote Triggered Ebook Execution system ("Trigger"). On September 10, 2003,[3] and on December 29, 2003,[4] the Exchange amended the proposed rule change. The proposed rule change, as amended, was published for comment in the **Federal Register** on February 26, 2004.[5] The Commission received no comments on the proposal. This order approves the proposed rule change.

Trigger allows orders resting in the book to automatically execute in the limited situation where the bid or offer for a series of options generated by the Exchange's AutoQuote system (or any Exchange approved proprietary quote generation system used in lieu of the Exchange's Autoquote system) crosses or locks the Exchange's best bid or offer for that series as established by a booked order. The Exchange proposes to amend CBOE Rule 6.8(d)(v) to provide that Trigger will continue to provide automatic executions of orders resting in the book[6] up to the maximum number of contracts permitted to be entered into RAES for that series ("Trigger Volume"), but that the trading crowd would have the ability, but not the obligation, to execute manually the remaining contracts in the order that exceed the Trigger Volume. Any unexecuted contracts in the booked order in excess of the Trigger Volume would remain in the book, and the bid or offer generated by Autoquote would be one tick inferior to the price of the booked order, so that the disseminated quote would not cross or lock the Autoquote bid or offer.

The Commission has reviewed carefully the Exchange's proposed rule change and finds that the proposal is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[7] In the Commission's view, the proposed rule change would continue to ensure that customers receive automatic executions of their booked orders up to the Trigger Volume in the event that Autoquote (Exchange or proprietary) locks or crosses the booked order's limit price.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* letter from Steve Youhn, Senior Attorney, CBOE, to Nancy Sanow, Assistant Director, Division of Market Regulation ("Division"), Commission, dated September 9, 2003.

[4] *See* letter from Steve Youhn, Senior Attorney, CBOE, to Nancy Sanow, Assistant Director, Division, Commission, dated December 22, 2003.

[5] *See* Securities Exchange Act Release No. 49287 (February 19, 2004), 69 FR 8995.

[6] Such orders would be executed against market makers participating in the Exchange's Retail Automated Execution System ("RAES"). CBOE Rule 6.8(d).

[7] 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).

CBOE Rule 6.8(d)(v), however, no longer would assure that an order on the book would be executed in full whenever Autoquote for that series locks or crosses the quotation established by the booked order. The unexecuted portion of the order would remain on the book and the bid or offer generated by Autoquote would be one tick inferior to the price of the booked order such that the Exchange's disseminated quote would not lock or cross with the Autoquote bid or offer.

The Commission finds that the proposed rule change is consistent with section 6(b) of the Act,[8] in general, and furthers the objectives of section 6(b)(5) of the Act.[9] The Commission notes that the proposed rule change does not alter CBOE members' duty to comply with the Commission's rule relating to the firmness of quotations.[10] The trading crowd, as the responsible broker or dealer, would continue to be required to honor its disseminated quote.

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[11] that the proposed rule change (SR–CBOE–2003–23) is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 04–7971 Filed 4–7–04; 8:45 am]

**BILLING CODE 8010–01–P**

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5). Section 6(b)(5) of the Act requires that the rules of a national securities exchange 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 regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system, and in general, to protect investors and the public interest; and are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers."

[10] 17 CFR 240.11Ac1–1.

[11] 15 U.S.C. 78s(b)(2).

[12] 17 CFR 200.30–3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–49512; File No. SR–NASD–2004–054]**

## Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the National Association of Securities Dealers, Inc. To Make Permanent the Current Pilot Program for the Imposition of a Fee for Written Interpretations of Nasdaq Listing Rules

March 31, 2004.

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 March 25, 2004, 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, II, and III below, which Items have been prepared by Nasdaq. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

### I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

Nasdaq proposes to make permanent NASD Rule 4550, which provides for the imposition of fees for written interpretations of Nasdaq listing rules. The text of the proposed rule change is below, which is identical to the text proposed in the pilot.[3]

* * * * *

**4500. Issuer Listing Fees**

**4550. Written Interpretations of Nasdaq Listing Rules**

(a) An issuer listed on The Nasdaq SmallCap Market or The Nasdaq National Market may request from Nasdaq a written interpretation of the Rules contained in the 4000 through 4500 Series. In connection with such a request, the issuer must submit to The Nasdaq Stock Market, Inc. a non-refundable fee of $2,000. A response to such a request generally will be provided within four weeks from the date Nasdaq receives all information necessary to respond to the request.

(b) Notwithstanding paragraph (a), an issuer may request a written interpretation of the Rules contained in the 4000 through 4500 Series by a specific date that is less than four weeks, but at least one week, after the date Nasdaq receives all information necessary to respond to the request. In connection with such a request for an expedited response, the issuer must submit to The Nasdaq Stock Market, Inc. a non-refundable fee of $10,000.

(c) An applicant to The Nasdaq Stock Market that has submitted the applicable entry fee under Rule 4510 or Rule 4520 will not also be required to submit a fee in connection with a request for a written interpretation involving the applicant's initial inclusion on Nasdaq. In addition, an issuer is not required to submit a fee in connection with a request for an exception from the Nasdaq shareholder approval rules pursuant to Rule 4350(i)(2).

(d) The Board of Directors of The Nasdaq Stock Market, Inc. or its designee may, in its discretion, defer or waive all or any part of the written interpretation fee prescribed herein.

* * * * *

### 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 and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. 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

NASD Rule 4550, which was approved by the Commission on September 4, 2003,[4] established a six-month pilot program under which Nasdaq charges fees for written interpretations regarding the application of the listing rules set forth in the NASD Rule 4200, 4300 and 4400 Series. The pilot went into effect October 1, 2003, and is scheduled to expire on April 1, 2004. Based on a review of the pilot to date, Nasdaq proposes adopting this fee on a permanent basis.

Under NASD Rule 4550, an issuer considering a specific action or

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities and Exchange Act Release No. 48450 (September 4, 2003), 68 FR 53770 (September 12, 2003).

[4] Securities and Exchange Act Release No. 48450, 68 FR 53770 (September 12, 2003).

transaction can request an interpretation from Nasdaq's Listing Qualifications staff, and in return, staff will prepare a responsive letter to the issuer as to how the rules apply to the proposed action or transaction. The Office of General Counsel reviews interpretations prior to issuance. This service is provided for a non-refundable fee of $2,000, and the process generally takes four weeks. Alternatively, an issuer may elect to pay a non-refundable fee of $10,000 to receive an expedited response, which will be provided by a specific date that is less than four weeks but at least one week after the date staff receives all information necessary to respond to the request. No fee is charged in connection with requests involving a company's initial listing application on Nasdaq or in cases where the fee would present economic hardship, such as requests for a financial viability exception to Nasdaq's shareholder approval rules.[5]

Prior to issuing a final written interpretation, Nasdaq will advise the company of the result of staff's analysis and the proposed interpretation. If the interpretation is going to be adverse, the company is given the opportunity to amend or withdraw their request for a written interpretation.

In the rule filing establishing the pilot program, Nasdaq stated that it would evaluate the impact of the pilot program and report its findings to the Commission. Nasdaq did so by letters dated March 4, 2004,[6] and March 17, 2004.[7]

Significantly, no comments were received during the comment period for the rule filing establishing the pilot program. As noted in the above-referenced reports, since the program has been in effect, staff has received no complaints from issuers in connection with the fees. In fact, while the rule provides Nasdaq with discretion to waive the fee, no requests for a fee waiver have been made to date. Several issuers and their representatives have expressed unsolicited approval for the expedited process, as it provides a means for issuers to be certain of their compliance with Nasdaq's corporate governance rules, in particular the shareholder approval and voting rights rules, in cases where a transaction must be closed imminently.

An additional public benefit to the program is that staff prepares anonymous summaries of correspondence, as well as frequently asked questions based on requests received from issuers, including those withdrawn before a written response is issued. These summaries and questions are posted on the Nasdaq Legal and Compliance Web site so that the general public, practitioners, and other issuers can better understand how Nasdaq applies its rules and policies. In this way, the overall need to request such interpretations is minimized, thus reducing burdens on issuers and staff alike.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of section 15A of the Act,[8] in general and with section 15A(b)(5) of the Act,[9] in particular, in that the proposal provides for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility or system which the NASD operates or controls. Specifically, the proposed fees will be imposed equally on all listed issuers that request written interpretations of Nasdaq's listing rules and will relieve issuers not availing themselves of this process from subsidizing its cost.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

Written comments were neither solicited nor received. We also note that, during the comment period for the rule filing establishing the pilot program (SR–NASD–2003–105), no comments were received.

## III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective upon filing pursuant to section 19(b)(3)(A)(ii) of the Act[10] and subparagraph (f)(6) of Rule 19b–4[11] thereunder in that it effects a change that does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest; provided that the self-regulatory organization has given the Commission written notice of 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. At any time within 60 days of the filing of the proposed rule change, 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.

Nasdaq has requested that the Commission waive the 5-day pre-filing notice requirement and the 30-day operative delay and permit the proposed rule change to become operative on April 1, 2004. The Commission believes that waiving the 5-day pre-filing notice requirement and the 30-day operative delay is consistent with the protection of investors and the public interest. The Commission notes that the proposal is making the current pilot program permanent, and not making any other modifications to it. In addition, the Commission notes that it did not receive any comment letters in response to the original pilot and has not received any comments during the pilot period. Because the pilot is scheduled to expire on April 1, 2004, acceleration of the operative date will allow the imposition of the fees for written interpretations of Nasdaq's listing rules to continue on an uninterrupted basis.[12]

## IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Comments may also be submitted electronically at the following e-mail address: *rule-comments@sec.gov.* All comment letters should refer to File No.

[5] Telephone call between Mary M. Dunbar, Vice President and Deputy General Counsel, Nasdaq, and Leah Mesfin, Attorney, Division of Market Regulation, Commission on March 31, 2004.

[6] *See* letter from Mary Dunbar, Vice President and Deputy General Counsel, Nasdaq, to Katherine England, Assistant Director, Division of Market Regulation, Commission, dated March 4, 2004.

[7] *See* letter from Mary Dunbar, Vice President and Deputy General Counsel, Nasdaq, to Katherine England, Assistant Director, Division of Market Regulation, Commission, dated March 17, 2004.

[8] 15 U.S.C. 78*o*–3.

[9] 15 U.S.C. 78*o*–3(b)(5).

[10] 15 U.S.C. 78s(b)(3)(A)(ii).

[11] 17 CFR 240.19b–4(f)(6).

[12] 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).

SR–NASD–2004–054. 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, comments should be sent in hardcopy or by e-mail but not by both methods. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of Nasdaq. All submissions should refer to file number SR–NASD–2004–054 and should be submitted by April 29, 2004.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

**J. Lynn Taylor,**

*Assistant Secretary.*

[FR Doc. 04–7931 Filed 4–7–04; 8:45 am]

**BILLING CODE 8010–01–P**

[13] 17 CFR 200.30–3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–49522; File No. SR–NASD–2003–182]**

## Self-Regulatory Organizations; Order Granting Approval of Proposed Rule Change by the National Association of Securities Dealers, Inc. Relating to Proposed Amendments to "TRACE-Eligible Security'' and an Exemption to Trade Reporting

April 1, 2004.

On December 5, 2003, the National Association of Securities Dealers, Inc. ("NASD'') filed with the Securities and Exchange Commission ("SEC'' or "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: (1) Amend Rule 6210(a) to clarify certain terms used in the definition, "TRACE-eligible security'; (2) amend NASD Rule 6230(e)(2) to expand the trade reporting exemption to qualifying transactions in any TRACE-eligible security that is listed and quoted on the Nasdaq Stock Market, Inc. ("Nasdaq''); and (3) make conforming amendments to the defined term, "reportable TRACE transaction,'' in Rule 6210(c). Rules 6210 and 6230 are part of the Trade Reporting and Compliance Engine ("TRACE'') rules. Notice of the proposed rule change was published for comment in the **Federal Register** on December 22, 2003.[3] The Commission received two comment letters regarding the proposal.[4]

On February 13, 2004, NASD filed a response to the two comment letters.[5] On March 10, 2004, NASD provided a supplemental response to the comments regarding NASD's proposal.[6] On March 24, 2004, TBMA submitted a letter in response to NASD's Response Letter and NASD's Supplemental Response Letter.[7] On March 29, 2004, NASD filed an additional supplemental statement to its earlier two letters.[8] This order approves the proposed rule change.

After careful consideration, the Commission finds that the proposed rule change is consistent with the Act and the rules and regulations promulgated thereunder applicable to a registered securities association and, in particular, with the provisions of section 15A(b)(6) of the Act,[9] which requires, among other things, that NASD's rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. [10] The Commission believes that the proposed rule change will provide NASD, as the self-regulatory organization designated to regulate the over-the-counter markets, with appropriate capabilities to regulate and provide surveillance of the debt securities markets to prevent fraudulent and manipulative acts and practices, for the protection of investors and in the public interest.

The comment letter filed by Mr. Scheurer expressed concern that expanding exemptions from TRACE for certain securities subject to Nasdaq bond price reporting would weaken investor protection. The proposed amendment to Rule 6230(e)(2) will exempt a member from reporting to TRACE a transaction in *any* TRACE-eligible security that is listed and quoted on Nasdaq, rather than only convertible debt securities, provided that the other two requirements for the exemption are also present (*i.e.*, the transaction is reported to Nasdaq and the transaction information is disseminated publicly).

NASD's Response Letter stated that currently there are very few debt securities that are listed on Nasdaq, and only some of the transactions occurring in those securities would meet all of the conditions for the exemption and thus not be reported to TRACE. NASD also stated that while there are certain differences between TRACE and Nasdaq reporting via the Automated Confirmation Transaction Service ("ACT'') in the reporting and dissemination of debt securities transactions, NASD does not believe that requiring members to report a transaction to both TRACE and ACT results in a measurable enhancement to investor protection or market integrity. NASD stated, for example, that it does not believe that it is beneficial to require a transaction that will be reported to ACT in 90 seconds also be reported to TRACE within 45 minutes.

NASD also stated that Rule 6230 requires that both sides of a transaction report the transaction to TRACE (if both are NASD members) and the Rule 4650 Series requires that only one member report such a transaction to ACT. After considering Mr. Scheurer's Letter and NASD's Response Letter, the Commission believes that the proposed exemption is not inconsistent with the Act because the proposed exemption will apply to a transaction in a TRACE-eligible security only if the transaction in the Nasdaq-listed and Nasdaq-quoted security is already subject to regulatory reporting and public dissemination.

TBMA's Letter focused exclusively on NASD's proposal to clarify the term "TRACE-eligible security'' to include the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 48926 (December 15, 2003), 68 FR 71207.

[4] *See* e-mail letter from Paul Scheurer to *rule-comments@sec.gov* dated January 12, 2004 ("Mr. Scheurer's Letter'') and letter from Michele C. David, Vice President and Assistant General Counsel, The Bond Market Association ("TBMA''), to Jonathan G. Katz, Secretary, SEC, dated January 16, 2004 ("TBMA's Letter'').

[5] *See* letter from Marc Menchel, Executive Vice President and General Counsel, Regulatory Policy and Oversight, NASD, to Katherine A. England, Assistant Director, Division of Market Regulation, SEC, dated February 13, 2004 ("NASD's Response Letter'').

[6] *See* letter from Marc Menchel, Executive Vice President and General Counsel, Regulatory Policy and Oversight, NASD, to Katherine A. England, Assistant Director, Division of Market Regulation, SEC, dated March 10, 2004 ("NASD's Supplemental Response'').

[7] *See* letter from Michele C. David, Vice President and Assistant General Counsel, The Bond Market Association ("TBMA''), to Jonathan G. Katz, Secretary, SEC, dated March 24, 2004 ("TBMA's Supplemental Letter'').

[8] *See* letter from Marc Menchel, Executive Vice President and General Counsel, Regulatory Policy and Oversight, NASD, to Katherine A. England, Assistant Director, Division of Market Regulation, SEC, dated March 26, 2004 ("NASD's Supplemental Statement'').

[9] 15 U.S.C. 78o–3(b)(6).

[10] In approving this proposed rule change, the Commission has considered the proposal's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

debt securities of all United States and/or foreign private "issuers,'' rather than "corporations.'' TBMA's Letter states that the proposal has the effect of extending TRACE reporting beyond NASD's mandate for the corporate bond market and potentially brings within TRACE securities that were never intended to be included. Further, TBMA stated that rather than clarifying the definition of "TRACE-eligible security,'' the proposal introduces new uncertainty into the definition by possibly bringing within the definition certain types of structured products and asset-backed securities that to date have not been included in the TRACE transaction reporting regime. In addition, TBMA stated that the integration of new financial instruments into TRACE will require significant effort and expenditures by member firms.

NASD's Response Letter stated that it was always NASD's intention that the universe of TRACE-reportable securities would include securities issued not only by corporations, but also by entities such as limited partnerships and trusts. NASD states that at the earliest stages of development of the TRACE regulatory and reporting structure, it was understood by market participants and regulators alike that securities that were Fixed Income Pricing Service ("FIPS'')-eligible would become TRACE-eligible securities. NASD states that securities that were reportable to FIPS included capital trust, equipment trust, trust, and limited partnership securities. NASD states that is has identified more than 100 securities that were not issued by a corporation, were routinely reported to FIPS and that, if still traded at the initiation of TRACE, were incorporated in TRACE and subject to TRACE requirements. NASD's Supplemental Response states that presently there is widespread reporting of debt securities issued by entities that are not corporations.

NASD's Response Letter also addressed the concern expressed in TBMA's Letter that the proposed clarification of the definition of "TRACE-eligible security'' would require members to report to TRACE a variety of "structured'' or "asset-backed'' securities that are not currently being reported to the system. NASD responded that under Rule 6210(a), "asset-backed securities'' are specifically excluded from the universe of TRACE-eligible securities and that NASD is not seeking to amend that exclusion with this proposal.

TBMA's Supplemental Letter states that NASD's Response Letter and Supplemental Response Letter do not address their previously stated concerns that the proposal causes confusion and uncertainty and potentially expands the universe of TRACE-reportable securities to include securities which do not expose bondholders to the credit risk of the issuer and were never intended to be included in a corporate bond reporting system.

NASD stated in its Supplemental Statement that NASD proposes to delete the word "corporations'' and replace it with "issuers'' solely to clarify that the securities of issuers using forms of business organizations other than the corporate form are included in the definition of TRACE-eligible securities. NASD further stated that its interpretation of TRACE eligibility will not change after the adoption of the proposed rule change. Accordingly, the Commission believes the proposal should not cause confusion or require significant effort and expenditures by member firms because NASD is not seeking to change its existing interpretation of TRACE eligibility.

The Commission believes that NASD's clarification of the TRACE rules in this proposed rule change will enable it to implement TRACE more effectively, thus enhancing investor protection by facilitating the availability of TRACE. For the reasons discussed above, the Commission finds that the proposal is consistent with the Act and the rules and regulations thereunder.

*It is therefore ordered,* pursuant to section 19(b)(2) of the Act,[11] that the proposed rule change (SR–NASD–2003–182), be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 04–7970 Filed 4–7–04; 8:45 am]

**BILLING CODE 8010–01–P**

[11] *Id.*

[12] 17 CFR 200.30–3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–49521; File No. SR–NYSE–2004–18]**

## Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the New York Stock Exchange, Inc. Relating to Arbitration

April 2, 2004.

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 March 24, 2004, the New York Stock Exchange, Inc. ("NYSE'' or "Exchange'') filed with the Securities and Exchange Commission ("SEC'' or "Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by NYSE.[3] NYSE filed the proposed rule change 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 from interested persons.

### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of an extension, until September 30, 2004, of NYSE Rule 600(g), relating to arbitration.

### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The NYSE has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

The proposed rule change is intended to extend until September 30, 2004, NYSE Rule 600(g), a pilot program that was most recently extended for a six-month period ending March 31, 2004.[6]

NYSE Rule 600(g) states:

This paragraph applies to the Ethics Standards for Neutral Arbitrators in

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Commission staff made non-substantive changes to the description of the proposed rule change with the permission of the NYSE. Telephone conversations between Daniel Beyda, Vice President—Arbitration and Hearing Board, NYSE, and Andrew Shipe, Special Counsel, Division of Market Regulation, Commission, April 1, 2004.

[4] 15 U.S.C. 78s(b)(3)(A).

[5] 17 CFR 240.19b–4(f)(6).

[6] Release No. 34–48552 (September 26, 2003), 68 FR 57496 (October 3, 2003) (SR–NYSE–2003–28).

Contractual Arbitrations promulgated by the Judicial Council of California (the "California Standards''), which, were they to have effect in connection with arbitrations conducted pursuant to this Code, would conflict with this Code. In light of this conflict, the affected customer(s) or an associated person of a member or member organization who asserts a claim against the member or member organization with which she or he is associated may:

- Request the Director to appoint arbitrators and schedule a hearing outside California, or
- Waive the California Standards and request the Director to appoint arbitrators and schedule a hearing in California. A written waiver by a customer or associated person who asserts a claim against the member or member organization with which he or she is associated on a form provided by the Director of Arbitration under this Code shall also constitute and operate as a waiver for all other parties to the arbitration who are members, allied members, member organizations, and/or associated persons of a member or member organization.

According to the NYSE, Rule 600(g) was adopted by the Exchange in response to the purported imposition of California state law on arbitrations conducted under the auspices of the Exchange and pursuant to a set of nationally-applied rules approved by the Commission.[7] The Exchange states that on July 1, 2002, as a result of the purported application of the Ethics Standards for Neutral Arbitrators in Contractual Arbitrations (the "California Standards'') to Exchange arbitrations and arbitrators, the Exchange suspended the appointment of arbitrators for cases pending in California. The Exchange and NASD Dispute Resolution, Inc. sought a declaratory judgment that the California Standards are pre-empted by federal law. On November 12, 2002, Judge Samuel Conti dismissed the action on Eleventh Amendment grounds.[8] A Notice of Appeal from Judge Conti's decision has been filed with the United States Court of Appeals for the Ninth Circuit.[9] The Exchange has determined that, in the absence of a final judicial determination or legislative resolution of the pre-emption issue, there is a continuing need for the waiver option provided by Rule 600(g).

2. Statutory Basis

The Exchange states that the proposed changes are consistent with Section 6(b)(5) of the Act[10] in that they promote just and equitable principles of trade by ensuring that members and member organizations and the public have a fair and impartial forum for the resolution of their disputes.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others*

The Exchange has neither solicited nor received written comments on the proposed rule change.

## III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The NYSE has stated that because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days (or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest), it has become effective pursuant to Section 19(b)(3)(A) of the Act[11] and Rule 19b–4(f)(6) thereunder.[12] At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate the rule change if it appears to the Commission that the action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

Pursuant to Rule 19b–4(f)(6)(iii) under the Act,[13] the proposal may not become operative for 30 days after the date of its filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, and the SRO must file notice of its intent to file the proposed rule change at least five business days beforehand. The Exchange has requested that the Commission waive the five-day pre-filing requirement and the 30-day operative delay so that the proposed rule change will become immediately effective upon filing.

The Commission believes that waiving the five-day pre-filing provision and the 30-day operative delay is consistent with the protection of investors and the public interest.[14] Waiving the pre-filing requirement and accelerating the operative date will merely extend a pilot program that is designed to inform aggrieved parties about their options regarding mechanisms that are available for resolving disputes with broker-dealers. During the period of this extension, the Commission and NYSE will continue to monitor the status of the previously discussed litigation. For these reasons, the Commission designates the proposed rule change as effective and operative immediately.

## IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the

[7] Release No. 34–46816 (November 12, 2002); 67 FR 69793 (November 19, 2002) (SR–NYSE–2002–56).

[8] *NASD Dispute Resolution, Inc. and New York Stock Exchange, Inc.* v. *Judicial Council of California,* No. C 02 3485 (N.D. Cal.).

[9] In another district court decision, *Mayo* v. *Dean Witter Reynolds, Inc., Morgan Stanley Dean Witter & Co. dba Morgan Stanley Dean Witter, and Does 1–50,* No. C–01–20336 JF, 2003 WL 1922963 (N.D. Cal. Apr. 22, 2003), Judge Jeremy Fogel held that application of the California Standards to the Exchange and other self-regulatory organizations ("SROs'') is preempted by the Act, the comprehensive system of federal regulation of the securities industry established pursuant to the Act, and the Federal Arbitration Act ("FAA''). The *Mayo* decision was not appealed. Since the decision in *Mayo,* the question of the applicability of the California Standards to SROs has been presented in another case in federal court in California, *Credit Suisse First Boston Corp.* v. *Grunwald,* No. C 02–2051 SBA (N.D. Cal. Mar. 31, 2003). The Grunwald court concluded that the California Standards cannot apply to SRO-appointed arbitrators because such arbitrators do not fall within the statutory definition of "neutral arbitrators.'' The appeal in *Grunwald* has been fully briefed and argued, and the Ninth Circuit is considering it on an expedited basis. The Commission and the Judicial Council submitted *amicus* briefs in the Ninth Circuit, and NASD Dispute Resolution and the Exchange were permitted to submit an *amicus* brief. The appeal from Judge Conti's decision in *NASD Dispute Resolution, Inc. and New York Stock Exchange, Inc.* v. *Judicial Council of California* is currently stayed pending a decision in *Grunwald.* NASD Dispute Resolution and the Exchange also submitted an *amicus* brief in *Jevne* v. *Superior Court,* 6 Cal. Rptr. 3d 542, 113 Cal. App. 4th 486 (2d Dist. 2003), in which the California Court of Appeal held that the Judicial Council acted within its authority in drafting the California Standards, that the California Standards are not pre-empted by the FAA, but that they are pre-empted by the Act. On March 17, 2004, the California Supreme Court granted review in *Jevne,* and NASD Dispute Resolution and the Exchange have moved to intervene on appeal or, in the alternative, for leave to file an *amicus* brief with the California Supreme Court.

[10] 15 U.S.C. 78f(b)(5).

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(6).

[13] 17 CFR 240.19b–4(f)(6)(iii).

[14] 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).

Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Comments should be submitted electronically at the following e-mail address: *rule-comments@sec.gov.* All comment letters should refer to File No. SR–NYSE–2004–18. 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, comments should be sent in hard copy or by e-mail but not by both methods. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal 1 office of the NYSE. All submissions should refer to File No. SR–NYSE–2004–18 and be submitted by April 29, 2004.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[15]

**J. Lynn Taylor,**

*Assistant Secretary.*

[FR Doc. 04–7969 Filed 4–7–04; 8:45 am]

**BILLING CODE 8010–01–P**

[15] 17 CFR 200.30–3(a)(12).

## SMALL BUSINESS ADMINISTRATION

### Small Business Innovation Research Rural Outreach Program To Provide Outreach and Technical Assistance to Small Technology-Based Businesses

**AGENCY:** Small Business Administration.

**ACTION:** Program Announcement No. SBIRROP–04–R–0003.

**SUMMARY:** The U.S. Small Business Administration (SBA) plans to issue Program Announcement No. SBIRROP–04–R–0003 to invite applicants from the 25 eligible states including the District of Columbia and the Commonwealth of Puerto Rico to conduct outreach and provide technical assistance to small technology-based small business owners. This program is authorized by the Small Business Act, § 9(s)(2), 15 U.S.C. 638(s)(2). There is a one proposal per state limitation on this competition. Only one proposal from each state may be submitted to SBA for consideration, and this application must have an original signed Letter of Endorsement from the State Governor or Mayor for the District of Columbia. Prospective recipients of SBA funding under this Program Announcement include both new applicants and prior year SBIR–ROP Program service providers. Eligible applicants include, but are not limited to, state and local Economic Development Agencies, colleges and universities and Small Businesses Development Centers. Funds will be provided to conduct programs for a 12–month budget and performance period. Applications/proposals must be postmarked by 4 p.m., Eastern Daylight Time, May 12, 2004. If using a delivery service other than the U.S. Postal Service, the application must be delivered and accepted by the Office of Procurement and Grants Management by the deadline specified above. SBA will select successful applicants using a competitive process. The SBIR–ROP Program is authorized through Fiscal Year 2005 and will be competed annually, subject to availability of funds. There is a non-Federal match requirement for this program. The program announcement will be available at *http://www.sba.gov/sbir*.

**DATES:** The application period will be from March 31, 2004 until May 12, 2004.

**FOR FURTHER INFORMATION CONTACT:** Cherina Hughes, (202) 205–7344, regarding the Program Announcement and Patricia Branch, (202) 205–7081, about budget matters.

**Edsel M. Brown, Jr.,**

*Assistant Administrator, SBA Office of Technology.*

[FR Doc. 04–7972 Filed 4–7–04; 8:45 am]

**BILLING CODE 8025–01–P**

## SOCIAL SECURITY ADMINISTRATION

### Privacy Act of 1974 as Amended; Computer Matching Program (SSA/Centers for Medicare and Medicaid Services (CMS))—Match Number 1300

**AGENCY:** Social Security Administration (SSA).

**ACTION:** Notice of a new computer matching program.

**SUMMARY:** In accordance with the provisions of the Privacy Act, as amended, this notice announces a new computer matching program that SSA will conduct with CMS.

**DATES:** SSA will file a report of the subject matching program with the Committee on Governmental Affairs of the Senate, the Committee on Government Reform of the House of Representatives and the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). The matching program will be effective as indicated below.

**ADDRESSES:** Interested parties may comment on this notice by either telefax to (410) 965–8582 or writing to the Associate Commissioner for Income Security Programs, 245 Altmeyer Building, 6401 Security Boulevard, Baltimore, MD 21235–6401. All comments received will be available for public inspection at this address.

**FOR FURTHER INFORMATION CONTACT:** The Associate Commissioner for Income Security Programs as shown above.

**SUPPLEMENTARY INFORMATION:**

#### A. General

The Computer Matching and Privacy Protection Act of 1988 (Public Law (Pub. L.) 100–503), amended the Privacy Act (5 U.S.C. 552a) by establishing the conditions under which computer matching involving the Federal Government could be performed and adding certain protections for individuals applying for and receiving Federal benefits. Section 7201 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508) further amended the Privacy Act regarding protections for such individuals.

The Privacy Act, as amended, regulates the use of computer matching by Federal agencies when records in a system of records are matched with other Federal, State, or local government records. It requires Federal agencies involved in computer matching programs to:

(1) Negotiate written agreements with the other agency or agencies participating in the matching programs;

(2) Obtain the approval of the matching agreement by the Data Integrity Boards (DIB) of the participating Federal agencies;

(3) Publish notice of the computer matching program in the **Federal Register**;

(4) Furnish detailed reports about matching programs to Congress and OMB;

(5) Notify applicants and beneficiaries that their records are subject to matching; and

(6) Verify match findings before reducing, suspending, terminating or denying an individual's benefits or payments.

#### B. SSA Computer Matches Subject to the Privacy Act

We have taken action to ensure that all of SSA's computer matching

programs comply with the requirements of the Privacy Act, as amended.

Dated: April 2, 2004.

**Martin H. Gerry,**

*Deputy Commissioner for Disability and Income Security Programs.*

**Notice of Computer Matching Program, Social Security Administration (SSA) With the Centers for Medicare and Medicaid Services (CMS)**

*A. Participating Agencies*

SSA and CMS.

*B. Purpose of the Matching Program*

The purpose of this matching program is to establish the conditions, safeguards, and procedures under which SSA will disclose income data on all Medicare eligible individuals from SSA's Master Beneficiary Record (MBR) and its Supplemental Security Income Record and Special Veterans Benefits (SSR) to CMS. These disclosures will provide CMS with information to use in verifying an individual's self-certification of eligibility for Transitional Assistance under the Medicare Prescription Drug Discount Card Program provided under the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

*C. Authority for Conducting the Matching Program*

The legal authority for this computer matching program is contained in the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. 108–173, section 101, 117 Stat. 2066 (2003) and section 1106 (42 U.S.C. 1306) of the Social Security Act.

*D. Categories of Records and Individuals Covered by the Matching Program*

SSA will provide information electronically to CMS from the following systems of records: Master Beneficiary Record (MBR), SSA/OEEAS, 60–0090, last published at 66 FR 11080 (February 21, 2001), and the SSA Supplemental Security Income Record and Special Veterans Benefits (SSR), SSA/OEEAS, 60–0103, last published at 66 FR 11085 (February 21, 2001). SSA will disclose information to CMS from the MBR system of record pursuant to routine use number 24. SSA will disclose information to CMS from the SSR system of record pursuant to routine use number 19.

CMS will match this benefit/income information with the CMS system of records, Medicare Beneficiary Database, System No. 09–70–0536 published in the **Federal Register** at 67 FR 63392 (December 6, 2001). Matched data will be released pursuant to routine use number 2 as set forth in the system notice.

*E. Inclusive Dates of the Matching Program*

The matching program will become effective upon signing of the agreement by all parties to the agreement and approval of the agreement by the Data Integrity Boards of the respective agencies, but no sooner than 40 days after notice of the matching program is sent to Congress and the Office of Management and Budget, or 30 days after publication of this notice in the **Federal Register**, whichever date is later. The matching program will continue for 18 months from the effective date and may be extended for an additional 12 months thereafter, if certain conditions are met.

[FR Doc. 04–7951 Filed 4–7–04; 8:45 am]

BILLING CODE 4191–02–P

## SOCIAL SECURITY ADMINISTRATION

### Privacy Act of 1974 as Amended; Computer Matching Program (SSA/Office of Personnel Management (OPM)/Centers for Medicare & Medicaid Services (CMS))—Match Number 1301

**AGENCY:** Social Security Administration (SSA).

**ACTION:** Notice of a new computer matching program.

**SUMMARY:** In accordance with the provisions of the Privacy Act, as amended, this notice announces a new computer matching program that SSA will conduct with OPM and CMS.

**DATES:** SSA will file a report of the subject matching program with the Committee on Governmental Affairs of the Senate; the Committee on Government Reform of the House of Representatives and the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). The matching program will be effective as indicated below.

**ADDRESSES:** Interested parties may comment on this notice by either telefax to (410) 965–8582 or writing to the Associate Commissioner for Income Security Programs, 245 Altmeyer Building, 6401 Security Boulevard, Baltimore, MD 21235–6401. All comments received will be available for public inspection at this address.

**FOR FURTHER INFORMATION CONTACT:** The Associate Commissioner for Income Security Programs as shown above.

**SUPPLEMENTARY INFORMATION:**

**A. General**

The Computer Matching and Privacy Protection Act of 1988 (Public Law (Pub. L.) 100–503), amended the Privacy Act (5 U.S.C. 552a) by describing the conditions under which computer matching involving the Federal Government could be performed and adding certain protections for individuals applying for and receiving Federal benefits. Section 7201 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508) further amended the Privacy Act regarding protections for such individuals.

The Privacy Act, as amended, regulates the use of computer matching by Federal agencies when records in a system of records are matched with other Federal, State, or local government records. It requires Federal agencies involved in computer matching programs to:

(1) Negotiate written agreements with the other agency or agencies participating in the matching programs;

(2) Obtain the approval of the matching agreement by the Data Integrity Boards (DIB) of the participating Federal agencies;

(3) Publish notice of the computer matching program in the **Federal Register**;

(4) Furnish detailed reports about matching programs to Congress and OMB;

(5) Notify applicants and beneficiaries that their records are subject to matching; and

(6) Verify match findings before reducing, suspending, terminating or denying an individual's benefits or payments.

**B. SSA Computer Matches Subject to the Privacy Act**

We have taken action to ensure that all of SSA's computer matching programs comply with the requirements of the Privacy Act, as amended.

Dated: April 2, 2004.

**Martin H. Gerry,**

*Deputy Commissioner for Disability and Income Security Programs.*

**Notice of Computer Matching Program, Social Security Administration (SSA) With the Office of Personnel Management (OPM) and the Centers for Medicare & Medicaid Services (CMS)**

*A. Participating Agencies*

SSA, OPM and CMS.

*B. Purpose of the Matching Program*

The purpose of this matching program is to establish conditions under which OPM agrees to the disclosure of civil service benefit and payment data to

CMS via SSA. These disclosures will provide CMS with information to use in verifying an individual's self-certification of eligibility for Transitional Assistance under the Medicare Prescription Drug Discount Card Program provided under the Medicare Prescription Drug, Improvement and Modernization Act of 2003. SSA receives the pertinent data from OPM for existing computer matches, and is in a position to provide this data to CMS upon approval of the appropriate computer matching agreements.

*C. Authority for Conducting the Matching Program:*

Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. 108–173, section 101, 117 Stat. 2066 (2003) and section 1106 (42 U.S.C. 1306) of the Social Security Act.

*D. Categories of Records and Individuals Covered by the Matching Program*

**1. Specified Data Elements Used in the Match**

a. OPM will electronically furnish CMS (transmitted via SSA) with the following civil service benefit and payment data: name, Social Security Number, civil service claim number, and amount of current gross civil service benefits.

b. To increase the efficiency and effectiveness of the program, SSA will receive the data from OPM and transmit it to CMS.

c. CMS will match this file against their database of prescription benefit participants and/or applicants.

**2. Systems of Records**

OPM will provide CMS (transmitted via SSA) with a file containing civil service benefit and payment data from the OPM System of Records published as OPM/Central–1 (Civil Service and Insurance Records), on October 8, 1999 (64 FR 54930), as amended on May 3, 2000 (65 FR 25775). Pursuant to 5 U.S.C. 552a(b)(3), OPM has established routine uses to disclose the subject information.

CMS will match the OPM information with the electronic data from the following system of records: Medicare Beneficiary Data Base, System Number 09–70–0536, published at 67 FR 63392 (December 6, 2001).

*E. Inclusive Dates of the Matching Program*

The matching program will become effective upon signing of the agreement by all parties to the agreement and approval of the agreement by the Data Integrity Boards of the respective agencies, but no sooner than 40 days after notice of the matching program is sent to Congress and the Office of Management and Budget, or 30 days after publication of this notice in the **Federal Register**, whichever date is later. The matching program will continue for 18 months from the effective date and may be extended for an additional 12 months thereafter, if certain conditions are met.

[FR Doc. 04–7952 Filed 4–7–04; 8:45 am]

BILLING CODE 4191–02–P

## SOCIAL SECURITY ADMINISTRATION

### Privacy Act of 1974 as Amended; Computer Matching Program (SSA/Railroad Retirement Board (RRB)/Centers for Medicare and Medicaid Services (CMS))—Match Number 1302

**AGENCY:** Social Security Administration (SSA).

**ACTION:** Notice of a new computer matching program.

**SUMMARY:** In accordance with the provisions of the Privacy Act, as amended, this notice announces a new computer matching program that SSA will conduct with RRB and CMS.

**DATES:** SSA will file a report of the subject matching program with the Committee on Governmental Affairs of the Senate, the Committee on Government Reform of the House of Representatives and the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). The matching program will be effective as indicated below.

**ADDRESSES:** Interested parties may comment on this notice by either telefax to (410) 965–8582 or writing to the Associate Commissioner for Income Security Programs, 245 Altmeyer Building, 6401 Security Boulevard, Baltimore, MD 21235–6401. All comments received will be available for public inspection at this address.

**FOR FURTHER INFORMATION CONTACT:** The Associate Commissioner for Income Security Programs as shown above.

**SUPPLEMENTARY INFORMATION:**

**A. General**

The Computer Matching and Privacy Protection Act of 1988 (Pub. L. (Pub. L.) 100–503), amended the Privacy Act (5 U.S.C. 552a) by describing the manner in which computer matching involving Federal agencies could be performed and adding certain protections for individuals applying for and receiving Federal benefits. Section 7201 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508) further amended the Privacy Act regarding protections for such individuals.

The Privacy Act, as amended, regulates the use of computer matching by Federal agencies when records in a system of records are matched with other Federal, State, or local government records. It requires Federal agencies involved in computer matching programs to:

(1) Negotiate written agreements with the other agency or agencies participating in the matching programs;

(2) Obtain the approval of the matching agreement by the Data Integrity Boards (DIB) of the participating Federal agencies;

(3) Publish notice of the computer matching program in the **Federal Register**;

(4) Furnish detailed reports about matching programs to Congress and OMB;

(5) Notify applicants and beneficiaries that their records are subject to matching; and

(6) Verify match findings before reducing, suspending, terminating or denying an individual's benefits or payments.

**B. SSA Computer Matches Subject to the Privacy Act**

We have taken action to ensure that all of SSA's computer matching programs comply with the requirements of the Privacy Act, as amended.

Dated: April 2, 2004.

**Martin H. Gerry,**

*Deputy Commissioner for Disability and Income Security Programs.*

**Notice of Computer Matching Program, Social Security Administration (SSA) With the Railroad Retirement Board (RRB) and the Centers for Medicare and Medicaid Services (CMS)**

*A. Participating Agencies*

SSA, RRB and CMS.

*B. Purpose of the Matching Program*

The purpose of this agreement is to establish the conditions under which RRB agrees to disclose RRB annuity payment data to CMS through a computer matching program. This disclosure will provide CMS with information necessary to verify an individual's self-certification of eligibility for Transitional Assistance under the Medicare Prescription Drug Discount Card Program provided under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. SSA receives the pertinent data from RRB for existing computer matches, and is in a position to provide

this data to CMS upon approval of the appropriate computer matching agreements.

*C. Authority for Conducting the Matching Program*

Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. 108–173, section 101, 117 Stat. 2066 (2003) and section 1106 (42 U.S.C. 1306) of the Social Security Act.

*D. Categories of Records and Individuals Covered by the Matching Program*

RRB will provide CMS with an electronic data file (transmitted via SSA) containing annuity payment data from RRB's system of records, RRB–22 Railroad Retirement, Survivor, and Pensioner Benefits System, entitled Checkwriting Integrated Computer Operation (CHICO) Benefit Payment Master. The records furnished to CMS will be limited to "Medicare eligible'' annuities. These are annuitants who are entitled to Medicare Part A or are within 3 months of attainment of age 65. CMS will then match the RRB data with data maintained in the MBD, System No. 09–70–0536 published in the **Federal Register** at 66 FR 63392 (December 6, 2001).

*E. Inclusive Dates of the Matching Program*

The matching program will become effective upon signing of the agreement by both parties to the agreement and approval of the agreement by the Data Integrity Boards of the respective agencies, but no sooner than 40 days after notice of the matching program is sent to Congress and the Office of Management and Budget, or 30 days after publication of this notice in the **Federal Register**, whichever date is later. The matching program will continue for 18 months from the effective date and may be extended for an additional 12 months thereafter, if certain conditions are met.

[FR Doc. 04–7953 Filed 4–7–04; 8:45 am]

**BILLING CODE 4191–02–P**

## SOCIAL SECURITY ADMINISTRATION

### Privacy Act of 1974 as Amended; Computer Matching Program (SSA/Department of Veterans Affairs (VA), Veterans Benefit Administration (VA/VBA)/Centers for Medicare & Medicaid Services (CMS))—Match Number 1303

**AGENCY:** Social Security Administration (SSA).

**ACTION:** Notice of a new computer matching program.

**SUMMARY:** In accordance with the provisions of the Privacy Act, as amended, this notice announces a new computer matching program that SSA will conduct with VA/VBA and CMS.

**DATES:** SSA will file a report of the subject matching program with the Committee on Governmental Affairs of the Senate, the Committee on Government Reform of the House of Representatives and the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). The matching program will be effective as indicated below.

**ADDRESSES:** Interested parties may comment on this notice by either telefax to (410) 965–8582 or writing to the Associate Commissioner for Income Security Programs, 245 Altmeyer Building, 6401 Security Boulevard, Baltimore, MD 21235–6401. All comments received will be available for public inspection at this address.

**FOR FURTHER INFORMATION CONTACT:** The Associate Commissioner for Income Security Programs as shown above.

**SUPPLEMENTARY INFORMATION:**

**A. General**

The Computer Matching and Privacy Protection Act of 1988 (Public Law (Pub. L.) 100–503), amended the Privacy Act (5 U.S.C. 552a) by describing the manner in which computer matching involving Federal agencies could be performed and adding certain protections for individuals applying for and receiving Federal benefits. Section 7201 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508) further amended the Privacy Act regarding protections for such individuals.

The Privacy Act, as amended, regulates the use of computer matching by Federal agencies when records in a system of records are matched with other Federal, State, or local government records. It requires Federal agencies involved in computer matching programs to:

(1) Negotiate written agreements with the other agency or agencies participating in the matching programs;

(2) Obtain the approval of the matching agreement by the Data Integrity Boards (DIB) of the participating Federal agencies;

(3) Publish notice of the computer matching program in the **Federal Register**;

(4) Furnish detailed reports about matching programs to Congress and OMB;

(5) Notify applicants and beneficiaries that their records are subject to matching; and

(6) Verify match findings before reducing, suspending, terminating or denying an individual's benefits or payments.

**B. SSA Computer Matches Subject to the Privacy Act**

We have taken action to ensure that all of SSA's computer matching programs comply with the requirements of the Privacy Act, as amended.

Dated: April 2, 2004.

**Martin H. Gerry,**

*Deputy Commissioner for Disability and Income Security Programs.*

### Notice of Computer Matching Program, Social Security Administration (SSA) With the Department of Veterans Affairs (VA), Veterans Benefit Administration (VA/VBA) and the Centers for Medicare & Medicaid Services (CMS)

*A. Participating Agencies*

SSA/VA/VBA/CMS.

*B. Purpose of the Matching Program*

The purpose of this matching program is to establish conditions under which VA/VBA agrees to the disclosure of Federal compensation and pension payment data to CMS via SSA. These disclosures will provide CMS with information to use in verifying an individual's self-certification of eligibility for Transitional Assistance under the Medicare Prescription Drug Discount Card Program provided under the Medicare Prescription Drug, Improvement and Modernization Act of 2003. SSA receives pertinent data from VA/VBA for existing computer matches, and is in a position to provide this data to CMS upon approval of the appropriate computer matching agreements.

*C. Authority for Conducting the Matching Program*

The legal authority for this computer matching program is contained in the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. 108–173, section 101, 117 Stat. 2066 (2003) and section 1106 (42 U.S.C. 1306) of the Social Security Act.

*D. Categories of Records and Individuals Covered by the Matching Program*

**1. Specified Data Elements Used in the Match**

a. VA/VBA will electronically furnish CMS (transmitted via SSA) with the following Federal compensation and pension payment data: SSN, name, date of birth and VA claim number on both

the VA file and the SSR, and the payment date.

b. To increase the efficiency and effectiveness of the program, SSA will receive the data from VA/VBA and transmit it to CMS.

c. CMS will match this file against their database of prescription benefit participants and/or applicants.

**2. Systems of Records**

VA/VBA will provide CMS (transmitted via SSA) with electronic files containing compensation and pension payment data from its system of records entitled the Compensation, Pension, Education and Rehabilitation Records-VA (58VA21/22). Routine use 21 of 58VA21/22 and routine use 3 of 60–0103 permits disclosure of the subject records for matching purposes. CMS will match the VA/VBA information with the electronic data from the following system of records: Medicare Beneficiary Data Base, System Number 09–70–0536, published at 67 FR 63392 (December 6, 2001).

*E. Inclusive Dates of the Matching Program*

The matching program will become effective upon signing of the agreement by all parties to the agreement and approval of the agreement by the Data Integrity Boards of the respective agencies, but no sooner than 40 days after notice of the matching program is sent to Congress and the Office of Management and Budget, or 30 days after publication of this notice in the **Federal Register**, whichever date is later. The matching program will continue for 18 months from the effective date and may be extended for an additional 12 months thereafter, if certain conditions are met.

[FR Doc. 04–7954 Filed 4–7–04; 8:45 am]

BILLING CODE 4191–02–P

## DEPARTMENT OF STATE

**[Public Notice 4683]**

## Bureau of Educational and Cultural Affairs Request for Grant Proposals: International Sports Programming Initiative

**SUMMARY:** The Office of Citizen Exchanges of the Bureau of Educational and Cultural Affairs announces an open competition for International Sports Programming Initiative. Public and private non-profit organizations meeting the provisions described in Internal Revenue Code section 26 U.S.C. 501(c)(3) may submit proposals to discuss approaches designed to enhance and improve the infrastructure of youth sports programs in the countries of Africa, South East Asia, Near East, and South Asia with significant Muslim populations.

In Africa, the following countries are eligible: Senegal, Mali, Nigeria, Benin, Chad, Mauritania, Niger and Cameroon. The eligible countries in South East Asia are: Indonesia, Malaysia, Philippines and Thailand. In the Near East and North Africa eligible countries are: Algeria, Bahrain, Egypt, Iraq; Jordan, Kuwait, Lebanon, Morocco, Oman, Qatar, Saudi Arabia, Syria, Tunisia, the United Arab Emirates (UAE), the West Bank/Gaza, and Yemen. Eligible countries in South Asia are Afghanistan, Bangladesh, and Pakistan.

**Important Note:** This Request for Grant Proposals contains language in the "Shipment and Deadline for Proposals'' section that is significantly different from that used in the past. Please pay special attention to procedural changes as outlined.

*Announcement Name and Number:* All correspondence with the Bureau concerning this RFGP should reference the "Open Competition for International Sports Programming Initiative'' and reference number: ECA/PE/C/WHAEAP–04–61. Please refer to title and number in all correspondence or telephone calls to the Office of Citizen Exchanges.

**FOR FURTHER INFORMATION CONTACT:** Interested organizations/institutions may contact the Office of Citizen Exchanges, room 216, SA–44, U.S. Department of State, 301 4th Street, SW., Washington, DC 20547, telephone number 202/260–5491, fax number 202/260–0440, or *HarveyRH@state.gov* to request a Solicitation Package. The Solicitation Package contains detailed award criteria, required application forms, specific budget instructions, and standard guidelines for proposal preparation. Please specify Bureau Program Officer, Raymond H. Harvey, on all other inquiries and correspondence. Please read the complete **Federal Register** announcement before sending inquiries or submitting proposals. Once the RFGP deadline has passed, Bureau staff may not discuss this competition with applicants until the proposal review process has been completed.

*To Download a Solicitation Package Via Internet:* The entire Solicitation Package also may be downloaded from the Bureau's Web site at *http://exchanges.state.gov/education/RFGPs.* Please read all information before downloading.

**Program Information**

*Overview*

The Office of Citizen Exchanges welcomes proposals that directly respond to the following thematic areas. Given budgetary limitations, projects for other themes and other countries will not be eligible for consideration under the FY–2004 International Sports Program Initiative.

*Training Sports Coaches*

The World Summit on Physical Education (Berlin, 1999) stated that a "quality physical education helps children to develop the patterns of interest in physical activity, which are essential for healthy development and which lay the foundation for healthy, adult lifestyles.'' Coaches are critical to the accomplishment of this goal. A coach not only needs to be qualified to provide the technical assistance required by young athletes to improve, but must also understand how to aid a young person to discover how success in athletics can be translated into achievement in the development of life skills and in the classroom. Projects submitted in response to this theme would be aimed at aiding youth, secondary school and university coaches in the target countries in the development and implementation of appropriate training methodologies, through seminars and outreach. The goal is to ensure the optimal technical proficiency among the coaches participating in the program while also emphasizing the role sports can play in the long-term economic well being of youth.

*Youth Sports Management Exchange*

Exchanges funded under this theme would help American and foreign youth sport coaches, adult sponsors, and sports associations officials share their experience in managing and organizing youth sports activities, particularly in financially challenging circumstances, and would contribute to better understanding of role of sports as a significant factor in educational success. Americans are in a good position to convey to the foreign counterparts the importance of linking success in sports to educational achievement and how these two factors can contribute to short-term and long-term economic prospects.

*Youth With Disability*

Exchanges supported by this theme are designed to promote and sponsor sports, recreation, fitness and leisure events for children and adults with physical disabilities. Project goals

include improving the quality of life for people with disabilities by providing affordable inclusive sports and recreational experiences that build self-esteem and confidence, enhancing active participation in community life and making a significant contribution to the physical and psychological health of people with disabilities. Physically and developmentally challenged individuals will be fully included in the sports and recreation opportunities in our communities.

*Sports and Health*

Projects funded under this category will focus on effective and practical ways to use sport personalities and sports health professionals to increase awareness among young people of the importance of following a healthy life style to reduce illness, prevent injuries and speed rehabilitation and recovery. Emphasis will be on the responsibility of the broader community to support healthy behavior. The project goals are to promote and integrate scientific research, education, and practical applications of sports medicine and exercise science to maintain and enhance physical performance, fitness, health, and quality of life. (Actual medical training and dispensing of medications are outside the purview of this theme.)

*Guidelines*

The Office seeks proposals that provide professional experience and exposure to American life and culture through internships, workshops and other learning-sharing experiences hosted by local institutions. The experiences also will provide Americans the opportunity to learn about culture and the social and economic challenges young athletes face today. Travel under these grants should ideally provide for a two-way exchange but may focus primarily on U.S.-based activities for countries with heightened security concerns. Projects should not simply focus on athletic training; they should be designed to provide practical, hands-on experience in U.S. public/private sector settings that may be adapted to an individual's institution upon return home. Proposals may combine elements of professional enrichment, job shadowing and internships appropriate to the language ability and interests of the participants.

**General Program Guidelines**

Applicants must identify the local organizations and individuals in the counterpart country with whom they are proposing to collaborate and describe in detail previous cooperative programming and/or contacts. Specific information about the counterpart organizations' activities and accomplishments is required and must be included in the section on Institutional Capacity. All proposals must contain letters of support tailored to the project being proposed from all foreign-country partner organizations.

Exchanges and training programs supported by institutional grants from the Bureau should operate at two levels: they should enhance institutional partnerships, and they should offer practical information and experience to individuals and groups to assist them with their professional responsibilities. Strong proposals usually have the following characteristics:

- A proven track record of working in the proposed issue area;
- An experienced staff with language facility and a commitment by the staff to monitor projects locally to improve accountability;
- A clear, convincing plan showing how permanent results will be accomplished as a result of the activity funded by the grant; and
- A follow-on plan beyond the scope of the Bureau grant.

Proposal narratives must demonstrate an organization's willingness to consult closely with the Public Affairs Section and other officers at the U.S. Embassy. Proposal narratives must confirm that all materials developed for the project will acknowledge USG funding for the program as well as a commitment to invite representatives of the Embassy and/or Consulate to participate in various program sessions/site visits. Please note that this will be a formal requirement in all final grant awards.

**Program Data Requirements**

Organizations awarded grants will be required to maintain specific data on program participants and activities in an electronically accessible database format that can be shared with the Bureau of Educational and Cultural Affairs as required. As a minimum, the data must include the following:

- Name, address, contact information and biographic sketch of all persons who travel internationally on funds provided by the grant or who benefit from the grant funding but do not travel.
- Itineraries of international and domestic travel, providing dates of travel and cities in which exchange experiences take place.

**Selection of Participants**

All grant proposals should clearly describe the type of persons who will participate in the program as well as the process by which participants will be selected. It is recommended that for programs including U.S. internships, grant applicants submit letters tentatively committing host institutions to support the internships. In the selection of foreign participants, the Department and U.S. Embassies retain the right to review all participant nominations and to accept or refuse participants recommended by grantee institutions. When participants are selected, grantee institutions will provide the names of American participants and brief (two pages) biographical data on each American participant to the Office of Citizen Exchanges for information purposes. Priority in two-way exchange proposals will be given to foreign participants who have not previously traveled to the United States. (*See* section below on requirements for maintenance of and provision to ECA of data on participants and program activities.)

**Suggested Program Designs**

Bureau-supported exchanges may include internships; study tours; short-term, non-technical experiential learning, extended and intensive workshops and seminars taking place in the United States or overseas. Examples of possible program activities include.

1. A U.S.-based program that includes: orientation to program purposes and to U.S. society; study tour/site visits; professional internships/placements; interaction and dialogue; hands-on training; professional development; and action plan development.

2. Capacity-building/training-of-trainer (TOT) workshops to help participants to identify priorities, create work plans, strengthen professional and volunteer skills, share their experience to committed people within each country, and become active in a practical and valuable way.

3. Seed/small grants to indigenous non-profit organizations to support community-based educational projects that build upon exchange activities and that address issues of local concern. Proposals may include a component for a Seed/Small Grants Competition (often referred to as 'sub-grants' or 'secondary grants'). This requires a detailed plan for recruitment and advertising; description of the proposal review and award mechanism; a plan for how the grantee would monitor and evaluate small grant activity; and a proposed amount for an average grant. The small grants should be directly linked to exchange activities. Small/seed grants may not be used for micro-credit or re-loaning purposes. Small/seed grants may not exceed 10%

of the total value of the grant funds sought from ECA.

4. Site visits by U.S. facilitators/experts to monitor projects in the region and to provide additional training and consultations as needed.

5. Content-based Internet training/cyber-training to encourage citizen participation in workshops, fora, chats, and/or discussions via the Internet that will stimulate communication and information sharing among key opinion leaders on priority topics as a form of cost sharing.

Proposals that include Internet utilization must reflect knowledge of the opportunities and obstacles that exist for use of information technologies in the target country or countries, and, if needed, provide hardware, software and servers, preferably as a form of cost sharing. Federal standards are under review and their adoption may impact on the implementation of these programs.

**Adherence to All Regulations Governing the J Visa**

The Office of Citizen Exchanges of the Bureau of Educational and Cultural Affairs is the official program sponsor of the exchange program covered by this RFGP, and an employee of the Bureau will be the "Responsible Officer'' for the program under the terms of 22 CFR 62, which covers the administration of the Exchange Visitor Program (J visa program). Under the terms of 22 CFR 62, organizations receiving grants under this RFGP will be third parties "cooperating with or assisting the sponsor in the conduct of the sponsor's program.'' The actions of grantee program organizations shall be "imputed to the sponsor in evaluating the sponsor's compliance with'' 22 CFR 62. Therefore, the Bureau expects that any organization receiving a grant under this competition will render all assistance necessary to enable the Bureau to fully comply with 22 CFR 62 *et seq.*

The Bureau of Educational and Cultural Affairs places great emphasis on the secure and proper administration of Exchange Visitor (J visa) Programs and adherence by grantee program organizations and program participants to all regulations governing the J visa program status. Therefore, proposals should *explicitly state in writing* that the applicant is prepared to assist the Bureau in meeting all requirements governing the administration of Exchange Visitor Programs as set forth in 22 CFR 62. If your organization has experience as a designated Exchange Visitor Program Sponsor, the applicant should discuss their record of compliance with 22 CFR 62 *et. seq.,* including the oversight of their Responsible Officers and Alternate Responsible Officers, screening and selection of program participants, provision of pre-arrival information and orientation to participants, monitoring of participants, proper maintenance and security of forms, record-keeping, reporting and other requirements.

The Office of Citizen Exchanges of ECA will be responsible for issuing DS–2019 forms to participants in this program.

A copy of the complete regulations governing the administration of Exchange Visitor (J) programs is available at *http://exchanges.state.gov* or from: United States Department of State, Office of Exchange Coordination and Designation, ECA/EC/ECD—SA–44, Room 734, 301 4th Street, SW., Washington, DC 20547, Telephone: (202) 401–9810, FAX: (202) 401–9809.

**New OMB Requirement**

An OMB policy directive published in the **Federal Register** on Friday, June 27, 2003, requires that all organizations applying for Federal grants or cooperative agreements must provide a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number when applying for all Federal grants or cooperative agreements on or after October 1, 2003. The complete OMB policy directive can be referenced at *http://www.whitehouse.gov/omb/fedreg/062703_grant_identifier.pdf.* Please also visit the ECA Web site at *http://exchanges.state.gov/education/rfgps/menu.htm* for additional information on how to comply with this new directive.

**Program Data Requirements**

Organizations awarded grants will be required to maintain specific data on program participants and activities in an electronically accessible database format that can be shared with the Bureau of Educational and Cultural Affairs as required. As a minimum, the data must include the following: name, address, contact information and biographic sketch of all persons who travel internationally on funds provided by the grant or who benefit from the grant funding but do not travel.

**Budget Guidelines**

The Bureau has an overall budget of $400,000 for this competition. Grants awarded to eligible organizations with less than four years of experience in conducting international exchange programs will be limited to $60,000. The Bureau has set a ceiling of $135,000 for proposals funded under this competition. The Bureau encourages applicants to provide maximum levels of cost sharing and funding from private sources in support of its programs.

Applicants must submit a comprehensive budget for the entire program. Grant awards may not exceed $135,000. There must be a summary budget as well as breakdowns reflecting both administrative and program budgets. Applicants may provide separate sub-budgets for each program component, phase, location, or activity to provide clarification.

Since Bureau grant assistance constitutes only a portion of total project funding, proposals should list and provide evidence of other anticipated sources of financial and in-kind support. Proposals must provide a minimum 30% cost sharing of the amount requested from ECA to be eligible for consideration in this competition. Proposals with higher cost-sharing levels are welcome.

*Example:* A proposal requests $125,000 in grant funds from ECA, for a project with a total budget of $500,000. The required minimum allowable cost sharing offered must amount to at least $37,500. In this case, the cost sharing far exceeds the minimum, since actual cost sharing is $375,000. When cost sharing is offered, it is understood and agreed that the applicant must provide the minimum amount of cost sharing as stipulated in this RFGP and later included in an approved grant agreement. Cost sharing may be in the form of allowable direct or indirect costs. For accountability, you must maintain written records to support all allowable costs, which are claimed as being your contribution to cost participation, as well as costs to be paid by the Federal government. Such records are subject to audit. The basis for determining the value of cash and in-kind contributions must be in accordance with OMB Circular A–110, (Revised), Subpart C.23—Cost Sharing and Matching. In the event you do not provide the minimum amount of cost sharing as stipulated in the approved budget, ECA's contribution will be reduced proportionately to the contribution.

The following project costs are eligible for consideration for funding:

*Travel costs*

International and domestic airfares; visas; transit costs; ground transportation costs. Please note that all air travel must be in compliance with the Fly America Act. There is no charge for J–1 visas for participants in Bureau sponsored programs. Please note that Tibetan participants may not travel to the U.S. primarily for English language instruction.

*Per Diem*

For the U.S. program, organizations have the option of using a flat $160/day for program participants or the

published U.S. Federal per diem rates for individual American cities. For activities outside the U.S., the published Federal per diem rates must be used.

**Note:** U.S. escorting staff must use the published Federal per diem rates, not the flat rate. Per diem rates may be accessed at *http://www.policyworks.gov/.*

*Interpreters*

If needed, interpreters for the U.S. program are available through the U.S. Department of State Language Services Division. Typically, a pair of simultaneous interpreters is provided for every four visitors who need interpretation. Bureau grants do not pay for foreign interpreters to accompany delegations from their home country. Grant proposal budgets should contain a flat $160/day per diem for each Department of State interpreter, as well as home-program-home air transportation of $400 per interpreter plus any U.S. travel expenses during the program. Salary expenses are covered centrally and should not be part of an applicant's proposed budget. Locally arranged interpreters with adequate skills and experience may be used by the grantee in lieu of State Department interpreters, with the same 1:4 interpreter to participant ratio. Costs associated with using their services may not exceed rates for U.S. Department of State interpreters.

*Book and Cultural Allowance*

Foreign participants are entitled to and escorts are reimbursed a one-time cultural allowance of $150 per person, plus a participant book allowance of $50. U.S. program staff members are not eligible to receive these benefits.

*Consultants*

Consultants may be used to provide specialized expertise, design or manage development projects or to make presentations. Honoraria generally do not exceed $250 per day. Subcontracting organizations may also be used, in which case the written agreement between the prospective grantee and subcontractor should be included in the proposal. Subcontracts should be itemized in the budget.

*Room Rental*

Room rental may not exceed $250 per day.

*Materials Development*

Proposals may contain costs to purchase, develop, and translate materials for participants.

*Equipment*

Proposals may contain limited costs to purchase equipment crucial to the success of the program, such as computers, fax machines and copy machines. However, equipment costs must be kept to a minimum, and costs for furniture are not allowed.

*Working Meal*

The grant budget may provide for only one working meal during the program. Per capita costs may not exceed $5–8 for a lunch and $14–20 for a dinner, excluding room rental. The number of invited guests may not exceed participants by more than a factor of two-to-one. Interpreters must be included as participants.

*Return Travel Allowance*

A return travel allowance of $70 for each foreign participant may be included in the budget. This may be used for incidental expenses incurred during international travel.

*Health Insurance*

Foreign participants will be covered under the terms of a U.S. Department of State-sponsored health insurance policy. The premium is paid by the U.S. Department of State directly to the insurance company. Applicants are permitted to included costs for travel insurance for U.S. participants in the budget.

*Administrative Costs*

Costs necessary for the effective administration of the program may include salaries for grant organization employees, benefits, and other direct or indirect costs per detailed instructions in the proposal submission instructions.

Please refer to the proposal submission instructions for complete budget guidelines and formatting instructions.

**Deadline for Proposals**

**Important Note:** The deadline for this submission is Friday, May 21, 2004. In light of recent events and heightened security measures, proposal submissions must be sent via a nationally recognized overnight delivery service (*i.e.*, Airborne Express, DHL, Federal Express, UPS, or U.S. Postal Service Express Overnight Mail, etc.) and be shipped no later than above deadline. The delivery services used by applicants must have in-place, centralized shipping identification and tracking systems that may be accessed via the Internet and delivery people who are identifiable by commonly recognized uniforms and delivery vehicles. It is each applicant's responsibility to ensure that each package is marked with a legible tracking number and to monitor and confirm delivery via the Internet. Neither faxed documents nor documents postmarked after the above deadline will be accepted.

Applicants must follow all instructions in the Solicitation Package. The original and twelve copies of the application should be sent to: U.S. Department of State, SA–44, Bureau of Educational and Cultural Affairs, Ref.: ECA/PE/C/WHAEAP–04–61, Program Management, ECA/EX/PM, Room 534, 301 4th Street, SW., Washington, DC 20547.

Please also submit the Executive Summary, Proposal Narrative, and Budget sections of the proposal as e-mail attachments in Microsoft Word and Excel to the program officer at *HarveyRH@state.gov.* The Bureau will transmit these files electronically to the Public Affairs section at the U.S. Embassy for its review, with the goal of reducing the time it takes to get embassy comments for the Bureau's grants review process.

**Diversity, Freedom and Democracy Guidelines**

Pursuant to the Bureau's authorizing legislation, programs must maintain a non-political character and should be balanced and representative of the diversity of American political, social, and cultural life. "Diversity'' should be interpreted in the broadest sense and encompass differences including, but not limited to ethnicity, race, gender, religion, geographic location, socio-economic status, and physical challenges. Applicants are strongly encouraged to adhere to the advancement of this principle both in program administration and in program content. Please refer to the review criteria under the 'Support for Diversity' section for specific suggestions on incorporating diversity into the total proposal. Public Law 104–319 provides that "in carrying out programs of educational and cultural exchange in countries whose people do not fully enjoy freedom and democracy,'' the Bureau "shall take appropriate steps to provide opportunities for participation in such programs to human rights and democracy leaders of such countries.'' Public Law 106–113 requires that the governments of the countries described above do not have inappropriate influence in the selection process. Proposals should reflect advancement of these goals in their program contents, to the full extent deemed feasible.

**Review Process**

The Bureau will acknowledge receipt of all proposals and will review them for technical eligibility. Proposals will be deemed ineligible if they do not fully adhere to the guidelines stated herein

and in the Solicitation Package. The Program Office and the Public Diplomacy section overseas will review all eligible proposals. Eligible proposals will be subject to compliance with Federal and Bureau regulations and guidelines and forwarded to Bureau grant panels for advisory review. Proposals may also be reviewed by the Office of the Legal Adviser or by other Department elements. Final funding decisions are at the discretion of the Department of State's Assistant Secretary for Educational and Cultural Affairs. Final technical authority for assistance awards resides with the Bureau's Grants Officer.

**Review Criteria**

Technically eligible applications will be competitively reviewed according to the criteria stated below. These criteria are not rank ordered and all carry equal weight in the proposal evaluation:

1. *Program planning to achieve program objectives:* Proposals should clearly demonstrate how the institution plans to achieve the program's objectives. Objectives should be reasonable, feasible, and flexible. The proposal should contain a detailed agenda and relevant work plan that demonstrates substantive undertakings and logistical capacity. Agenda and plan should adhere to the program overview and guidelines described above.

2. *Institutional Capacity/Record/Ability:* Proposed personnel and institutional resources should be adequate and appropriate to achieve the program or project's goals. For technical projects, foreign experts and their local partners will be required to have the necessary education, training and experience for the work to be undertaken, in addition to language skills where applicable. Proposals should demonstrate an institutional record of successful development or exchange programs, including responsible fiscal management and full compliance with all reporting requirements for past Bureau grants as determined by Bureau Grant Staff. The Bureau will consider the past performance of prior recipients and the demonstrated potential of new applicants. Many successful applicants will have a multiyear track record of successful work in the selected country or within the region.

3. *Multiplier effect/impact:* Proposed programs should strengthen long-term mutual understanding, including maximum sharing of information and establishment of long-term institutional and individual linkages.

4. *Support of Diversity:* Proposals should demonstrate substantive support of the Bureau's policy on diversity. Achievable and relevant features should be cited in both program administration (selection of participants, program venue and program evaluation) and program content (orientation and wrap-up sessions, program meetings, resource materials and follow-up activities).

5. *Follow-on Activities:* Proposals should identify other types of exchanges or linkages that might be undertaken after completion of the Bureau supported activity.

6. *Monitoring and Project Evaluation Plan:* Proposals should provide a detailed plan for monitoring and evaluating the program. The evaluation plan should identify anticipated outcomes and performance requirements clearly related to program objectives and activities and include procedures for ongoing monitoring and corrective action when necessary the identification of best practices relating to project administration is also encouraged, as is the discussion of unforeseen difficulties.

7. *Cost-effectiveness/Cost-sharing:* The overhead and administrative components of the proposal, including salaries and honoraria, should be kept as low as possible. All other items should be necessary and appropriate.

Proposals must have 30% cost sharing of the amount of grant funds requested from ECA through other private sector support as well as institutional direct funding contributions.

**Authority:** Overall grant making authority for this program is contained in the Mutual Educational and Cultural Exchange Act of 1961, Pub. L. 87–256, as amended, also known as the Fulbright-Hays Act. The purpose of the Act is "to enable the Government of the United States to increase mutual understanding between the people of the United States and the people of other countries * * *; to strengthen the ties which unite us with other nations by demonstrating the educational and cultural interests, developments, and achievements of the people of the United States and other nations * * * and thus to assist in the development of friendly, sympathetic and peaceful relations between the United States and the other countries of the world.'' The funding authority for the program above is provided through legislation.

**Notice**

The terms and conditions published in this RFGP are binding and may not be modified by any Bureau representative. Explanatory information provided by the Bureau that contradicts published language will not be binding. Issuance of the RFGP does not constitute an award commitment on the part of the Government. The Bureau reserves the right to reduce, revise, or increase proposal budgets in accordance with the needs of the program and the availability of funds. Awards made will be subject to periodic reporting and evaluation requirements.

**Notification**

Final awards cannot be made until funds have been appropriated by Congress, allocated and committed through internal Bureau procedures.

Dated: April 1, 2004.

**Patricia S. Harrison,**

*Assistant Secretary for Educational and Cultural Affairs, Department of State.*

[FR Doc. 04–7976 Filed 4–7–04; 8:45 am]

BILLING CODE 4710–05–P

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## DEPARTMENT OF STATE

**[Public Notice 4645]**

## Advisory Committee on Labor Diplomacy; Notice of Meeting

The Advisory Committee on Labor Diplomacy (ACLD) will hold a meeting beginning at 9 a.m. on April 26, 2004 in room 1107, U.S. Department of State, 2201 C Street, NW., Washington, DC 20520. Committee Chairman Thomas R. Donahue, Former President of the AFL–CIO, will chair the meeting.

The ACLD is composed of prominent persons with expertise in the area of International labor policy and labor diplomacy. The ACLD advises the Secretary of State and the President on the resources and policies necessary to implement labor diplomacy programs efficiently, effectively and in a manner that ensures success in promoting the objectives and ideals of U.S. labor policies in the 21st century. The ACLD makes recommendations on how to strengthen the Department of State's ability to respond to the many challenges facing the United States and the federal government in international labor matters. These challenges include the protection of worker rights, the elimination of exploitative child labor, and the prevention of abusive working conditions.

The agenda for the April 26 meeting includes:

(1) Reading of the minutes of the last ACLD meeting;

(2) Review of the Committee's forthcoming report on U.S. labor diplomacy in the Middle East and elsewhere.

Members of the public are welcome to attend the meeting as seating capacity allows. As access to the Department of State is controlled, persons wishing to attend the meeting must be pre-cleared by calling or faxing the following

information, by close of business April 20, to Executive Secretariat, ACLD, Robin DeLoatch at tel. (202) 647–3204, or fax (202) 647–3779, e-mail *DeloatchRJ@state.gov;* name, company or organization affiliation (if any); date of birth; and social security number. Pre-cleared persons should use the C Street entrance to the State Department and have a driver's license with photo, a passport, a U.S. Government ID or other valid photo identification.

Members of the public may, if they wish, submit a brief statement to the Committee in writing. Those wishing further information should contact Ms. DeLoatch at the phone and fax numbers provided above.

Dated: April 2, 2004.

**Lorne Craner,**

*Assistant Secretary, Bureau of Democracy, Human Rights and Labor, Department of State.*

[FR Doc. 04–7975 Filed 4–7–04; 8:45 am]

**BILLING CODE 4710–18–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### Aging Transport Systems Rulemaking Advisory Committee Meeting

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of public meeting.

**SUMMARY:** This notice announces a public meeting of the FAA's Aging Transport Systems Rulemaking Advisory Committee (ATSRAC).

**DATES:** The ATSRAC will meet April 28 and 29, 2004, from 8:30 a.m. to 5 p.m.

**ADDRESSES:** Radisson Hotel Hampton, 700 Settlers Landing Road, Hampton, Virginia 23669.

**FOR FURTHER INFORMATION CONTACT:** Shirley Stroman, Office of Rulemaking, ARM–208, FAA, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–7470; fax (202) 267–5075; or e-mail *shirley.stroman@faa.gov.*

**SUPPLEMENTARY INFORMATION:** This notice announces a meeting of the Aging Transport Systems Rulemaking Advisory Committee. The FAA will hold the meeting at the location listed under the **ADDRESSES** heading of this notice. The agenda topics for the meeting include—

- Status report of the tasks (68 FR 31741, May 28, 2003) assigned to Harmonization Working Groups 11, 12, and 13; and
- Presentation on resetting circuit breakers by Airbus, Boeing, and Dassault Aviation.

The meeting is open to the public; however, attendance will be limited by the size of the meeting room. The FAA will make the following services available if you request them by April 16, 2004:

- Teleconferencing
- Sign and oral interpretation
- A listening device

Individuals using the teleconferencing service and calling from outside the Washington, DC metropolitan area will be responsible for paying long-distance charges. To arrange for any of these services, contact the person listed under the **FOR FURTHER INFORMATION CONTACT** heading of this notice.

The public may present written statements to the Committee by providing 20 copies to the Committee's Executive Director or by bringing the copies to the meeting. Public statements will be considered if time allows.

Issued in Washington, DC, on April 5, 2004.

**Ida M. Klepper**

*Acting Director, Office of Rulemaking.*

[FR Doc. 04–7997 Filed 4–7–04; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

**[Docket No. FHWA–2004–17256]**

### Agency Information Collection Activities; Request for Comments; Renewed Approval of Eight Information Collections

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Notice and request for comments.

**SUMMARY:** The FHWA invites public comments about our intention to request the Office of Management and Budget's (OMB) approval to renew eight information collections, which are summarized below under Supplementary Information. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

**DATES:** Please submit comments by June 7, 2004.

**ADDRESSES:** You may submit comments identified by DOT DMS Docket Number FHWA–2004–17256 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.
- 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, D.C., between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**SUPPLEMENTARY INFORMATION:**

1. *Title:* Structure Inventory and Appraisal Sheet.

*OMB Control Number:* 2125–0501 (Expiration Date: July 31, 2004).

*Abstract:* The collection of the bridge information contained on the Structure Inventory and Appraisal Sheet (SI&A) is necessary to satisfy the requirements of Title 23 United States Code 144 and 151, and the Code of Federal Regulations, 23 Highways—Part 650, Subpart C—National Bridge Inspection Standards (NBIS) and Subpart D—Highway Bridge Replacement and Rehabilitation Program. The NBIS requires bridge inspection and reporting at regular intervals for all bridges located on public roads. The NBIS information is used as a basis for setting priorities for the replacement or rehabilitation of bridges under the Highway Bridge Replacement and Rehabilitation Program (HBRRP) and for apportioning HBRRP funds to the States for bridge replacement or rehabilitation. In addition, the information is used for strategic national defense needs and for preparing the report to Congress on the status of the Nation's highway bridges and funding under the HBRRP.

*Respondents:* 52 State Transportation Departments, including the District of Columbia and Puerto Rico.

*Frequency:* Biannual inspections and annual reporting.

*Estimated Total Annual Burden:* 540,000 hours. The average burden is two hours to complete each SI&A sheet on the approximate 300,000 bridges that are inspected annually. The total bridge inventory (rounded to 600,000) requires biannual inspections. Some States voluntarily inspect bridges more frequently; however, these estimates do not include this information.

**FOR FURTHER INFORMATION CONTACT:** Ms. Ann Shemaka, 202–366–1575, Department of Transportation, Federal

Highway Administration, Office of Infrastructure, Office of Bridge Technology, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:30 a.m. to 4:30 p.m., Monday through Friday, except Federal holidays.

2. *Title:* Planning and Research Program Administration.

*OMB Control Number:* 2125–0039 (Expiration Date: July 31, 2004).

*Abstract:* Under the provisions of Title 23, United States Code, Section 505, two percent of Federal-aid highway funds in certain categories that are apportioned to the States are set aside to be used only for State Planning and Research (SPR funds). At least 25 percent of the SPR funds apportioned annually must be used for research, development, and technology transfer activities. In accordance with government-wide grant management procedures, a grant application must be submitted for these funds. In addition, recipients must submit periodic progress and financial reports. In lieu of Standard Form 424, Application for Federal Assistance, the FHWA uses a work program as the grant application. This includes a scope of work and budget for activities to be undertaken with FHWA planning and research funds during the next one- or two-year period. The information contained in the work program includes task descriptions, assignments of responsibility for conducting the work effort, and estimated costs for the tasks. This information is necessary to determine how FHWA planning and research funds will be utilized by the State Transportation Departments and if the proposed work is eligible for Federal participation. The content and frequency of submission of progress and financial reports specified in 23 CFR Part 420 is as specified in OMB Circular A–102 and the companion common grant management regulations.

*Respondents:* 52 State Transportation Departments, including the District of Columbia and Puerto Rico.

*Estimated Total Annual Burden:* 29,120 hours (560 hours per respondent).

**FOR FURTHER INFORMATION CONTACT:** Mr. Tony Solury, 202–366–5003, Department of Transportation, Federal Highway Administration, Office of Planning, Environment, and Realty, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:30 a.m. to 4:30 p.m., Monday through Friday, except Federal holidays.

3. *Title:* Heavy Vehicle Travel Information System (HVTIS).

*OMB Control Number:* 2125–0587 (Expiration Date: July 31, 2004).

*Abstract:* Title 49, United States Code, Section 301, authorizes the Department of Transportation (DOT) to collect statistical information relevant to domestic transportation. Title 23, United States Code, Section 307, authorizes the DOT to engage in studies to collect data for planning future highway programs. The FHWA has developed the HVTIS to house data that would be used to analyze the amount and nature of truck travel at the national and regional levels. The information would be used by the FHWA and other DOT administrations to evaluate changes in truck travel in order to assess: impacts on highway safety; the role of travel in economic productivity; and the impacts of changes in truck travel on infrastructure condition; and to maintain our mobility while protecting the human and natural environment. The increasing dependence on truck transportation requires that data be available to better assess its overall contribution to the Nation's well-being. In conducting the data collection, the FHWA will request the State Departments of Transportation to provide periodic reporting of vehicle classification and weight data, which they collect as part of their existing traffic data collection programs. The majority of States collect this vehicle weight data periodically throughout the year using weigh-in-motion devices and the States also continuously collect vehicle classification data. The data will allow transportation professionals at the Federal, state and metropolitan levels to make informed decisions about policies and plans.

*Respondents:* 51 State Transportation Departments, including the District of Columbia.

*Frequency:* Continuous vehicle classification and total volume data will be reported on a monthly basis to assure timely information that can be compared to monthly reports of economic activity. Based on data collection practices in common use by the State Transportation Departments, truck weight data collected using weigh-in-motion devices and site description data will be submitted to FHWA annually.

*Estimated Average Burden per Response:* The average State Transportation Department operates 40 continuous vehicle classification installations, 10 total volume sites, and 10 truck weight (weigh-in-motion) sites. It is estimated that the additional processing necessary to make 48 hours of weigh-in-motion data available to FHWA would be 6 minutes per site per year, processing the site description data would take 1 minute per site per year, processing one month of vehicle classification data would take 5 minutes per site per month, and processing one month of total volume data would take 4 minutes per site per month.

*Estimated Total Annual Burden Hours:* 50 per State; 2,550 total.

**FOR FURTHER INFORMATION CONTACT:** Mr. Ralph Gillmann, 202–366–0160, Department of Transportation, Federal Highway Administration, Office of Highway Policy Information, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 8 a.m. to 4:30 p.m., Monday through Friday, except Federal holidays.

4. *Title:* Bid Price Data.

*OMB Control Number:* 2125–0010 (Expiration Date: June 30, 2004).

*Abstract:* Information collected on Form FHWA–45, Bid Price Data, is needed for the FHWA to monitor trends in purchasing power of the Federal-aid construction dollar. FHWA follows these trends so that changes in highway construction prices can be measured and funding level recommendations to Congress can be justified. The Federal share of the cost of certain projects constructed by the States in advance of regular apportionments is adjusted based on the bid price index (Title 23 United States Code 115). Form FHWA–45 is prepared for Federal-aid highway construction contracts greater than $0.5 million in the 50 States plus Washington, DC, and Puerto Rico. Data is reported on six major items of highway construction, together with the total materials and labor costs of the project, taken from the bid tabulation of construction items submitted by the lowest or winning bidder to the State Transportation Department. The State Transportation Departments furnish copies of the bid tabulation to the FHWA that uses the data to produce the national FHWA bid price index and related statistics.

*Respondents:* 52 State Transportation Departments, including the District of Columbia and Puerto Rico.

*Frequency:* The data is collected by the States and submitted to FHWA one time, within two weeks after the project has been awarded.

*Estimated Total Annual Burden:* 975 hours. There are approximately 1,300 annual projects that require about 37 of the State DOTs to complete the form. It takes an average of 45 minutes for each form.

**FOR FURTHER INFORMATION CONTACT:** Ms. Claretta Duren, 202–366–4636, Department of Transportation, Federal Highway Administration, Office of Pavement Technology, 400 Seventh Street, SW., Washington, DC 20590.

Office hours are from 7:30 a.m. to 4:30 p.m., Monday through Friday, except Federal holidays.

5. *Title:* Highway Safety Improvement Programs.

*OMB Control Number:* 2125–0025 (Expiration Date: May 31, 2004).

*Abstract:* Under Sections 130(g) and 152(g) of Title 23, United States Code, each State is required to report annually to the Secretary of Transportation on the progress being made in implementing the Highway Safety Improvement Programs (Highway-Rail Grade Crossings and Hazard Elimination) and on the effectiveness of these programs. This information provides FHWA with a means for monitoring the effectiveness of these programs. It will also be used by the Congress for determining funding levels for the Highway Safety Improvement Programs and for modifying these programs. States are also required under Sections 130(d) and 152(a) of Title 23 to conduct and systematically maintain surveys to identify highway-rail grade crossings in need of improvements and to identify hazardous highway locations, sections, and elements. These surveys are the basis for establishing priorities for corrective measures, for scheduling improvements, and for evaluating the effectiveness of improvements. The States collect safety information by surveying highway-rail grade crossings and public roads for potential safety hazards. In addition, motor vehicle crash data, traffic volume data, and other highway inventory data are used by the States to identify hazards and determine which hazards would be the most cost-effective to improve.

*Respondents:* 52 State Transportation Departments, including the District of Columbia and Puerto Rico.

*Frequency:* Annually.

*Estimated Total Annual Burden:* 10,400 hours. It is estimated that each State, the District of Columbia and Puerto Rico spend 200 hours to provide this information to the FHWA.

**FOR FURTHER INFORMATION CONTACT:** Mr. Kenneth Epstein, 202–366–2157, Department of Transportation, Federal Highway Administration, Office of Safety, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:30 a.m. to 4:30 p.m., Monday through Friday, except Federal holidays.

6. *Title:* Emergency Relief Funding Applications.

*OMB Control Number:* 2125–0525 (Expiration Date: May 31, 2004).

*Abstract:* Section 125 of Title 23 United States Code requires States to submit applications to the FHWA for Emergency Relief (ER) funds. The ER funds are established for the repair or reconstruction of Federal-aid highways and Federal roads, which have suffered serious damage by natural disasters over a wide area or serious damage from catastrophic failures. The information is needed for the FHWA to fulfill its statutory obligations regarding funding determinations on emergency work to repair highway facilities. The requirements covering the FHWA ER program are contained in 23 CFR Part 668.

*Respondents:* 52 State Transportation Departments, including the District of Columbia and Puerto Rico.

*Frequency:* As required.

*Estimated Total Annual Burden:* 6,000 hours. 200 hours per application for an average of 30 annual applications.

**FOR FURTHER INFORMATION CONTACT:** Mr. Greg Wolf, 202–366–4655, Department of Transportation, Federal Highway Administration, Office of Program Administration, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., Monday through Friday, except Federal holidays.

7. *Title:* Preparation and Execution of the Project Agreement and Modifications.

*OMB Control Number:* 2125–0529 (Expiration Date: June 30, 2004).

*Abstract:* Formal agreements between State Transportation Departments and the FHWA are required for Federal-aid highway projects. These agreements, referred to as "project agreements'' are written contracts between the State and the Federal government that define the extent of work to be undertaken and commitments made concerning a highway project. Section 1305 of the Transportation Equity Act for the 21st Century (TEA–21, Public Law 105–178) amended 23 U.S.C. 106(a) and combined authorization of work and execution of the project agreement for a Federal-aid project into a single action. States continue to have the flexibility to use whatever format is suitable to provide the statutory information required, and burden estimates for this information collection are not changed.

*Respondents:* There are 56 respondents, including 50 State Transportation Departments, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, and the Territories of Guam, the Virgin Islands and American Samoa.

*Estimated Total Annual Burden:* 12,040 hours. There are an average of 215 annual agreements per respondent. Each agreement requires approximately one hour to complete.

**FOR FURTHER INFORMATION CONTACT:** Mr. Don West, 202–366–4652, Department of Transportation, Federal Highway Administration, Office of Pavement Technology, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:30 a.m. to 4:30 p.m., Monday through Friday, except Federal holidays.

8. *Title:* Drug Offender's Drivers' License Suspension Certification.

*OMB Control No:* 2125–0579 (Expiration Date: June 30, 2004).

*Abstract:* States are legally required to enact and enforce laws that revoke or suspend the drivers' licenses of any individual convicted of a drug offense and to make annual certifications to the FHWA on their actions. The implementing regulations of the Department of Transportation and Related Agencies Appropriation Act, 1993 (Pubic Law 102–388, October 6, 1992) require annual certifications by the Governors. In this regard, the State must submit by January 1 of each year either a written certification, signed by the Governor, stating that the State is in compliance with 23 U.S.C. 159; or a written certification stating that the Governor is opposed to the enactment or enforcement, and that the State legislature has adopted a resolution expressing its opposition to 23 U.S.C. 159.

Beginning in fiscal year 1996, States' failure to comply by October 1 of each fiscal year resulted in a withholding penalty of 10-percent from major categories of Federal-aid funds (*i.e.*, National Highway System, Surface Transportation Program and Interstate) from States' apportionments for the fiscal year. Any funds withheld in FY 1996 and thereafter cannot be restored and will be redistributed.

*Respondents:* 50 States and the District of Columbia and Puerto Rico.

*Estimated Annual Burden Hours:* Annual average of 5 hours for each respondent; 260 total annual burden hours.

**FOR FURTHER INFORMATION CONTACT:** John Balser, 202–366–9212, Department of Transportation, Federal Highway Administration, Office of Safety, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

*Public Comments Invited:* You are asked to comment on any aspect of these information collections, including: (1) Whether the proposed collections are necessary for the FHWA's performance; (2) the accuracy of the estimated burdens; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and

(4) ways that the burdens could be minimized, including use of electronic technology, without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of these information collections.

*Privacy Act:* Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

**Authority:** The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

**James R. Kabel,**

*Chief, Management Programs and Analysis Division.*

[FR Doc. 04–7961 Filed 4–7–04; 8:45 am]

BILLING CODE 4910–22–P

## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

### Environmental Impact Statement; Maricopa County, AZ

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Notice of intent; correction.

**SUMMARY:** The FHWA is issuing this notice to advise the public that an environmental impact statement (EIS) will be prepared for a proposed highway project within Maricopa County, Arizona.

**FOR FURTHER INFORMATION CONTACT:** Kenneth H. Davis, District Engineer, Federal Highway Administration, 400 E Van Buren Street, Suite 410, Phoenix, AZ 85004, Telephone (602) 379–3646.

**Correction**

In the **Federal Register** of Tuesday, May 14, 2002, in FR Doc 02–11968, filed 2–1–02, 8:45 a.m. on page 34513, in the third column, correct the project limits to read as follows:

**SUPPLEMENTARY INFORMATION:** The FHWA in cooperation with the Arizona Department of Transportation is preparing an EIS for a proposal to build improvements on Interstate 10 from the south ramp of the I–10/SR 51/202L (Red Mountain Freeway) Traffic Interchange to the north ramps of the I–10/202L (Santan Freeway) Traffic Interchange in Maricopa County, Arizona. One addition to the project limits is as follows: (1) US60 from Hardy Drive to Mill Avenue.

*Additional Correction*: the address and telephone number for Federal Highway Administration has been changed to: 400 E. Van Buren Street, Suite 410, One Arizona Center, Phoenix, Arizona 85004, Telephone (602) 379–3646.

Dated: March 30, 2004.

**Kenneth H. Davis,**

*District Engineer, Phoenix.*

[FR Doc. 04–7955 Filed 4–7–04; 8:45 am]

BILLING CODE 4910–22–M

## DEPARTMENT OF TRANSPORTATION

### Research and Special Programs Administration

**[Docket RSPA–98–4957; Notice 04–04]**

### Renewal of Existing Information Collection

**AGENCY:** Research and Special Programs Administration, DOT.

**ACTION:** Request for Public Comments and OMB Approval.

**SUMMARY:** As required by the Paperwork Reduction Act of 1995, the Research and Special Programs Administration (RSPA) published a notice on January 13, 2004 (69 FR 2042) requesting public comments on a request for renewal of an information collection, *Incorporation by Reference of Industry Standard on Leak Detection*. This information collection requires hazardous liquid pipeline operators who have leak detection systems to maintain records of those systems. No comments were received. RSPA is now requesting OMB to approve renewal of this information collection and the public is offered another opportunity to comment.

**DATES:** Comments on this notice must be received no later than May 10, 2004 to be assured of consideration.

**ADDRESSES:** You must identify the docket number RSPA–98–4957, at the beginning of your comments. Comments should be mailed directly to Office of Information and Regulatory Affairs, Office of Management and Budget, 726 Jackson Place, NW., Washington, DC 20503, ATTN: Desk Officer for the Department of Transportation.

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

**FOR FURTHER INFORMATION CONTACT:** Marvin Fell, Office of Pipeline Safety, Research and Special Programs Administration, Department of Transportation, 400 Seventh Street, SW. Washington, DC 20950, (202) 366–6205 or by electronic mail at *marvin.fell@rspa.dot.gov.*

**SUPPLEMENTARY INFORMATION:**

*Title:* Incorporation by Reference of Industry Standard on Leak Detection

*OMB Number:* 2137–0598.

*Type of Request:* Renewal of an existing information collection.

*Respondents:* Hazardous liquid pipeline operators that use computational pipeline monitoring systems (CPM) for leak detection.

*Estimate of Burden:* 2 hours per operator.

*Estimated Number of Responses per Respondent:* 1.

*Estimated Total Burden:* 100 hours.

*Estimated Number of Respondents:* 50.

*Abstract:* The hazardous liquid pipeline safety regulations at 49 CFR Part 195 do not require hazardous liquid pipeline operators to use software-based, CPM leak detection systems. However, if an operator does use CPM leak detection systems they must comply with the national consensus technical standard, American Petroleum Institute (API) 1130, as required at 49 CFR 195.134. This standard provides guidance for operating, maintaining, and testing CPM systems. Records documenting the operations, maintenance, and testing of CPM systems must be maintained by all hazardous liquid pipeline operators.

Comments are invited on: (a) The need for the proposed collection of information for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) 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; (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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques.

Issued in Washington, DC on April 2, 2004.

**Richard D. Huriaux,**

*Regulations Manager, Office of Pipeline Safety.*

[FR Doc. 04–7964 Filed 4–7–04; 8:45 am]

**BILLING CODE 4910–60–P**

## DEPARTMENT OF TRANSPORTATION

### Research and Special Programs Administration

**[Docket No. RSPA–00–7666]**

### Pipeline Safety: Workshop on Gas Pipeline Integrity Management

**AGENCY:** Office of Pipeline Safety, Research and Special Programs Administration, DOT.

**ACTION:** Notice of workshop on gas pipeline integrity management.

**SUMMARY:** The Research and Special Programs Administration's (RSPA) Office of Pipeline Safety (OPS) and the National Association of Pipeline Safety Representatives (NAPSR) will cosponsor a workshop to discuss the Gas Pipeline Integrity Management final rule issued on December 15, 2003. The workshop will provide a detailed review and discussion of gas pipeline integrity management program requirements. Comments and issues discussed at the workshop will help RSPA/OPS and NAPSR implement oversight of operators' compliance with the gas pipeline integrity management rule. RSPA/OPS and NAPSR will hold another workshop in 2004 to provide further guidance on the oversight process to be used. OPS will also provide written guidance material to help operators prepare for compliance.

**DATES:** Tuesday, May 11, 2004, from 8 a.m. to 5:30 p.m. and Wednesday, May 12, 2004, from 8 a.m. to Noon.

**ADDRESSES:** The Westin Galleria, 5060 West Alabama, Houston, Texas, Phone: 713–960–8100; fax: 713–960–6549. For discounted rates, please refer to the USDOT Gas IMP Workshop block when making reservations. The deadline for reserving accommodations is April 19, 2004. For additional information on hotel accommodations, contact Janice Morgan at 202–366–2392 or *janice.morgan@rspa.dot.gov.*

**Information on Services for Individuals with Disabilities**

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact Juan Carlos Martinez (tel: 202–366–1933; E-mail: *juan.martinez@rspa.dot.gov).*

**FOR FURTHER INFORMATION CONTACT:** Zach Barrett, (tel: 405–954–5559; E-mail *zach.barrett@tsi.jccbi.gov*), or Jeff Wiese (tel: 202–366–2036; E-mail *jeff.wiese@rspa.dot.gov* regarding the subject matter of this notice. Additional information about gas integrity management can be found at *http://primis.rspa.dot.gov/gasimp.* You can read comments and other material in the docket on the Internet at: *http://dms.dot.gov.*

This meeting is open to all interested parties. However, operators of natural gas transmission pipelines are urged to attend either in person or to observe the workshop via the Internet. RSPA/OPS will webcast this meeting. To facilitate meeting planning and to obtain additional information regarding the webcast, advance registration for the meeting is strongly encouraged and can be accomplished online at the following Web site: *http://primis/rspa.dot.gov/meetings.* Internet links to the webcast will also be available through this Web site, or from the front page of the OPS Web site: *http://ops.dot.gov.* Those planning to "attend'' this meeting through the webcast are strongly encouraged to review our "tips'' for ensuring successful viewing in advance, as well as to register through our Web site. Registration both ensures that we can accommodate all attendees and provide additional information to them via the internet. The deadline for online meeting registration is May 5, 2004. Walk-in registration will be accommodated on a first-come, first-served basis.

Attendees will be provided the opportunity, at scheduled times during the workshop, to ask questions or make short statements on the topics under discussion. You may submit written comments by mail or deliver to the Dockets Facility, U.S. Department of Transportation (DOT), Room PL–401, 400 Seventh Street, SW., Washington, DC 20590–0001. It is open from 10 a.m. to 5 p.m., Monday through Friday, except Federal holidays. You also may submit written comments to the docket electronically. To do so, log onto the following Internet Web address: *http://dms.dot.gov.* Click on "Help & Information'' for instructions on how to file a document electronically. All written comments should identify the docket and notice numbers which appear in the heading of this notice. Anyone who would like confirmation of mailed comments must include a self-addressed stamped postcard.

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the April 11, 2000, issue of the FR (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

**SUPPLEMENTARY INFORMATION:** The Pipeline Safety Improvement Act of 2002 (codified at 49 U.S.C. 60101) required RSPA/OPS to prescribe standards by December 17, 2003, to direct a pipeline operator's conduct of a risk analysis and the adoption and implementation of an integrity management program. In compliance with the statute, on December 15, 2003, RSPA/OPS issued a final rule on Gas Transmission Pipeline Integrity Management (68 FR 69778). Similar to the final rule for integrity management of hazardous liquid pipelines, RSPA/OPS has four fundamental objectives for the Gas Integrity Management final rule:

(1) To increase the level of integrity assessments (*i.e.*, in-line inspection, pressure testing or direct assessment) for pipelines that can affect high consequence areas; (2) to improve operator integrity management systems; (3) to improve government oversight of operator integrity management programs; and (4) to improve public assurance in pipeline safety.

The Gas Transmission Pipeline Integrity Management rule provides the foundation for RSPA/OPS to move beyond an assessment of the current metallurgical condition of the pipe to assess the overall management and systems used by an operator to implement effective and timely actions to maintain pipeline safety. Specific requirements of the final rule and extensive information on its implementation and enforcement can be found at: *http://primis.rspa.dot.gov/gasimp.*

**Authority:** 49 U.S.C. 60102, 60109, 60117.

Issued in Washington, DC on April 2, 2004.

**Stacey L. Gerard,**

*Associate Administrator for Pipeline Safety.*

[FR Doc. 04–7963 Filed 4–7–04; 8:45 am]

**BILLING CODE 4910–60–P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### Proposed Collection; Comment Request for Form 4852

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 4852, Substitute for Form W–2, Wage and Tax Statement, or Form 1099–R, Distributions From Pensions, Annuities, Retirement or Profit-Sharing Plans, IRAs, Insurance Contracts, Etc.

**DATES:** Written comments should be received on or before June 7, 2004, to be assured of consideration.

**ADDRESSES:** Direct all written comments to Glenn P. Kirkland, Internal Revenue Service, room 6411, 1111 Constitution Avenue NW., Washington, DC 20224.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the form and instructions should be directed to Carol Savage at Internal Revenue Service, room 6407, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 622–3945, or through the Internet at *CAROL.A.SAVAGE@irs.gov.*

**SUPPLEMENTARY INFORMATION:**

*Title:* Substitute for Form W–2, Wage and Tax Statement, or Form 1099–R, Distributions From Pensions, Annuities, Retirement or Profit-Sharing Plans, IRAs, Insurance Contracts, Etc.

*OMB Number:* 1545–0458.

*Form Number:* Form 4852.

*Abstract:* In the absence of a Form W–2 or 1099R from the employer or payer, Form 4852 is used by the taxpayer to estimate gross wages, pensions, annuities, retirement or IRA payments received as well as income or FICA tax withheld during the year. The form is attached to the tax return so the return can be processed through normal channels the same as those with Forms W–2 or 1099R attached.

*Current Actions:* There are no changes being made to the form at this time.

*Type of Review:* Extension of a currently approved collection.

*Affected Public:* Individuals or households, business or other for-profit organizations, farms, and Federal, state, local or tribal governments.

*Estimated Number of Responses:* 1,500,000.

*Estimated Time Per Response:* 18 minutes.

*Estimated Total Annual Burden Hours:* 450,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may 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.

*Request for Comments:* Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the 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 collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: April 1, 2004.

**Glenn P. Kirkland,**

*IRS Reports Clearance Officer.*

[FR Doc. 04–8000 Filed 4–7–04; 8:45 am]

**BILLING CODE 4830–01–P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

**[Regulation Section 31.6001]**

### Proposed Collection; Comment Request for Regulation Project

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning existing regulations, 26 CFR 31.6001–1, Records in general; 26 CFR 31.6001–2 Additional Records under FICA; 26 CFR 31.6001–3, Additional records under Railroad Retirement Tax Act; 26 CFR 31.6001–5, Additional records in connection with collection of income tax at source on wages; 26 CFR 31.6001–6, Notice by District Director requiring returns, statements, or the keeping of records.

**DATES:** Written comments should be received on or before June 7, 2004, to be assured of consideration.

**ADDRESSES:** Direct all written comments to Glenn P. Kirkland, Internal Revenue Service, room 6411, 1111 Constitution Avenue NW., Washington, DC 20224.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of regulation sections should be directed to Carol Savage at Internal Revenue Service, room 6407, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 622–3945, or through the Internet at *CAROL.A.SAVAGE@irs.gov.*

**SUPPLEMENTARY INFORMATION:**

*Title:* 26 CFR 31.6001–1, Records in general; 26 CFR 31.6001–2, Additional Records under FICA; 26 CFR 31.6001–3, Additional records under Railroad Retirement Tax Act; 26 CFR 31.6001–5, Additional records in connection with collection of income tax at source on wages; 26 CFR 31.6001–6, Notice by District Director requiring returns, statements, or the keeping of records.

*OMB Number:* 1545–0798.

*Abstract:* Internal Revenue Code section 6001 requires, in part, that every person liable for tax, or for the collection of that tax must keep such records and comply with such rules and regulations as the Secretary may from time to time prescribe. The recordkeeping requirements under 26 CRF 31.6001 have special application to employment taxes (and to employers) and are needed to ensure proper compliance with the Code. Upon examination, the records are needed by the taxpayer to establish the employment tax liability claimed on any tax return.

*Current Actions:* There is no change to these existing regulations.

*Type of Review:* Extension of a currently approved collection.

*Affected Public:* Individuals or households, business or other for-profit organizations, not-for-profit institutions, farms, and Federal, state, local or tribal governments.

*Estimated Number of Recordkeepers:* 5,676,263.

*Estimated Time Per Recordkeeper:* 5 hours, 20 minutes.

*Estimated Total Annual Recordkeeping Hours:* 30,273,950.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may 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.

*Request for Comments:* Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the 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 collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: April 2, 2004.

**Glenn P. Kirkland,**

*IRS Reports Clearance Officer.*

[FR Doc. 04–8001 Filed 4–7–04; 8:45 am]

**BILLING CODE 4830–01–P**

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

**[LR 2013 and EE–155–78]**

### Proposed Collection; Comment Request for Regulation Project

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning existing final regulations, LR 2013 (TD 7533), Disc Rules on Procedure and Administration; Rules on Export Trade Corporations, and EE–155–78 (TD 7896), Income From Trade Shows (§§ 1.6071–1 and 1.6072–2).

**DATES:** Written comments should be received on or before June 7, 2004, to be assured of consideration.

**ADDRESSES:** Direct all written comments to Glenn P. Kirkland, Internal Revenue Service, room 6411, 1111 Constitution Avenue NW., Washington, DC 20224.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the regulations should be directed to Carol Savage at Internal Revenue Service, room 6407, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 622–3945, or through the Internet at *CAROL.A.SAVAGE@irs.gov.*

**SUPPLEMENTARY INFORMATION:**

*Title:* LR 2013 (TD 7533), Disc Rules on Procedure and Administration; Rules on Export Trade Corporations, and EE–155–78 (TD 7896), Income From Trade Shows.

*OMB Number:* 1545–0807.

*Regulation Project Numbers:* LR 2013 and EE–155–78.

*Abstract:* Regulation section 1.6071–1(b) requires that when a taxpayer files a late return for a short period, proof of unusual circumstances for late filing must be given to the District Director. Sections 6072(b), (c), (d), and (e) of the Internal Revenue Code deal with the filing dates of certain corporate returns. Regulation section 1.6072–2 provides additional information concerning these filing dates.

*Current Actions:* There is no change to these existing regulations.

*Type of Review:* Extension of OMB approval.

*Affected Public:* Individual or households, business or other for-profit organizations, not-for-profit institutions, farms, and state, local or tribal governments.

*Estimated Number of Respondents:* 12,417.

*Estimated Time Per Respondent:* 15 minutes.

*Estimated Total Annual Burden Hours:* 3,104.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may 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.

*Request for Comments:* Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the 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 collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: April 1, 2004.

**Glenn P. Kirkland,**

*IRS Reports Clearance Officer.*

[FR Doc. 04–8002 Filed 4–7–04; 8:45 am]

**BILLING CODE 4830–01–P**

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### Proposed Collection; Comment Request for Form 8855

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is

soliciting comments concerning Form 8855, Election To Treat a Qualified Revocable Trust as Party of an Estate.

**DATES:** Written comments should be received on or before June 7, 2004, to be assured of consideration.

**ADDRESSES:** Direct all written comments to Glenn P. Kirkland, Internal Revenue Service, room 6411, 1111 Constitution Avenue, NW., Washington, DC 20224.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the form and instructions should be directed to Carol Savage at Internal Revenue Service, room 6407, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 622–3945, or through the Internet at *CAROL.A.SAVAGE@irs.gov*.

**SUPPLEMENTARY INFORMATION:**

*Title:* Election To Treat a Qualified Revocable Trust as Party of an Estate.

*OMB Number:* 1545–1881.

*Form Number:* 8855.

*Abstract:* Form 8855 is used to make a section 645 election that allows a qualified revocable trust to be treated and taxed (for income tax purposes) as part of its related estate during the election period.

*Current Actions:* There are no changes being made to the form at this time.

*Type of Review:* Extension of a currently approved collection.

*Affected Public:* Business or other for-profit organizations.

*Estimated Number of Respondents:* 5,000.

*Estimated Time Per Respondent:* 5 hours, 38 minutes.

*Estimated Total Annual Burden Hours:* 28,200.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may 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.

*Request for Comments:* Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the 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 collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: April 2, 2004.

**Glenn P. Kirkland,**

*IRS Reports Clearance Officer.*

[FR Doc. 04–8003 Filed 4–7–04; 8:45 am]

**BILLING CODE 4830–01–P**

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### Proposed Collection; Comment Request for Regulation Project; Regulations Under Tax Conventions—Ireland

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing regulation, Regulations Under Tax Conventions—Ireland (26 CFR Part 513).

**DATES:** Written comments should be received on or before June 7, 2004, to be assured of consideration.

**ADDRESSES:** Direct all written comments to Glenn P. Kirkland, Internal Revenue Service, room 6411, 1111 Constitution Avenue, NW., Washington, DC 20224.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of income tax treaty should be directed to Carol Savage at Internal Revenue Service, room 6407, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 622–3945, or through the Internet at *CAROL.A.SAVAGE@irs.gov*.

**SUPPLEMENTARY INFORMATION:**

*Title:* Regulations Under Tax Conventions—Ireland.

*OMB Number:* 1545–0834.

*Abstract:* The information required by these regulations is needed to allow taxpayers to receive benefits under the tax treaty, and to allow withholding agents to permit those benefits to be immediately realized by the taxpayers. The information is used by the Internal Revenue Service to determine if the treaty benefits are being used properly, to aid in determining whether income is being reported accurately, and to prevent evasion of income taxes.

*Current Actions:* There is no change to these existing regulations.

*Type of Review:* Extension of a currently approved collection.

*Affected Public:* Individuals or households, and business or other for-profit organizations.

*Estimated Number of Respondents:* 20.

*Estimated Time Per Respondent:* 15 minutes.

*Estimated Total Annual Burden Hours:* 5.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may 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.

*Request for Comments:* Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the 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 collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: April 2, 2004.

**Glenn P. Kirkland,**

*IRS Reports Clearance Officer.*

[FR Doc. 04–8004 Filed 4–7–04; 8:45 am]

**BILLING CODE 4830–01–P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

**[REG–209446–82]**

### Proposed Collection; Comment Request for Regulation Project

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing final regulation, REG–209446–82 (TD 8852), Passthrough of Items of an S Corporation to its Shareholders (§ 1.1366–1).

**DATES:** Written comments should be received on or before June 7, 2004, to be assured of consideration.

**ADDRESSES:** Direct all written comments to Glenn P. Kirkland, Internal Revenue Service, room 6411, 1111 Constitution Avenue NW., Washington, DC 20224.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of regulation should be directed to Carol Savage at Internal Revenue Service, room 6407, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 622–3945, or through the Internet at *CAROL.A.SAVAGE@irs.gov.*

**SUPPLEMENTARY INFORMATION:**

*Title:* Passthrough of Items of an S Corporation to its Shareholders.

*OMB Number:* 1545–1613.

*Regulation Project Number:* REG–209446–82.

*Abstract:* Section 1366 requires shareholders of an S corporation to take into account their pro rata share of separately stated items of the S corporation and nonseparately computed income or loss. Section 1.1366–1 of the regulation provides that an S corporation must report, and a shareholder is required to take into account in the shareholder's return, the shareholder's pro rata share, whether or not distributed, of the S corporation's items of income, loss, deduction, or credit.

*Current Actions:* There is no change to this existing regulation.

*Type of Review:* Extension of a currently approved collection.

*Affected Public:* Business or other for-profit organizations, and individuals or households.

This reporting requirement is reflected in the burden of Form 1040, U.S. Individual Income Tax Return, and Form 1120S, U.S. Income Tax Return for an S Corporation.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may 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.

**Request for Comments**

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the 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 collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: April 2, 2004.

**Glenn P. Kirkland,**

*IRS Reports Clearance Officer.*

[FR Doc. 04–8005 Filed 4–7–04; 8:45 am]

**BILLING CODE 4830–01–P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### Proposed Collection; Comment Request for Form 6524

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 6524, Office of Chief Counsel—Application.

**DATES:** Written comments should be received on or before June 7, 2004, to be assured of consideration.

**ADDRESSES:** Direct all written comments to Glenn P. Kirkland, Internal Revenue Service, room 6411, 1111 Constitution Avenue NW., Washington, DC 20224.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the form and instructions should be directed to Carol Savage at Internal Revenue Service, room 6407, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 622–3945, or through the Internet at *CAROL.A.SAVAGE@irs.gov.*

**SUPPLEMENTARY INFORMATION:**

*Title:* Office of Chief Counsel—Application.

*OMB Number:* 1545–0796.

*Form Number:* 6524.

*Abstract:* Form 6524 is used as a screening device to evaluate an applicant's qualifications for employment as an attorney with the Office of Chief Counsel. It provides data deemed critical for evaluating an applicant's qualifications such as Law School Admission Test (LSAT) score, bar admission status, type of work preference, law school, and class standing.

*Current Actions:* There are no changes being made to the form at this time.

*Type of Review:* Extension of a currently approved collection.

*Affected Public:* Individuals.

*Estimated Number of Respondents:* 3,000.

*Estimated Time Per Respondent:* 18 minutes.

*Estimated Total Annual Burden Hours:* 900.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may 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.

*Request for Comments:* Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the 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 collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: April 2, 2004.

**Glenn P. Kirkland,**

*IRS Reports Clearance Officer.*

[FR Doc. 04–8006 Filed 4–7–04; 8:45 am]

**BILLING CODE 4830–01–P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

**[Regulation Section 1.6001–1]**

### Proposed Collection; Comment Request for Regulation Project

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing final regulation, regulation section 1.6001–1, Records.

**DATES:** Written comments should be received on or before June 7, 2004, to be assured of consideration.

**ADDRESSES:** Direct all written comments to Glenn P. Kirkland, Internal Revenue Service, room 6411, 1111 Constitution Avenue NW., Washington, DC 20224.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the regulation section should be directed to Carol Savage at Internal Revenue Service, room 6407, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 622–3945, or through the internet at *CAROL.A.SAVAGE@irs.gov*.

**SUPPLEMENTARY INFORMATION:**

*Title:* Records.

*OMB Number:* 1545–1156.

*Regulation Project Number:* Regulation section 1.6001–1.

*Abstract:* Internal Revenue Code section 6001 requires, in part, that every person liable for tax, or for the collection of that tax, keep such records and comply with such rules and regulations as the Secretary (of the Treasury) may from time to time prescribe. It also allows the Secretary, in his or her judgement, to require any person to keep such records that are sufficient to show whether or not that person is liable for tax. Under regulation section 1.6001–1, in general, any person subject to tax, or any person required to file an information return, must keep permanent books of account or records, including inventories, that are sufficient to establish the amount of gross income, deductions, credits or other matters required to be shown by such person in any tax return or information return. Books and records are to be kept available for inspection by authorized internal revenue officers or employees and are to be retained so long as their contents any became material in the administration of any internal revenue law.

*Current Actions:* There is no change to these existing regulations.

*Type of Review:* Extension of a currently approved collection.

*Affected Public:* Individuals or households, and business or other for-profit organizations, not-for-profit institutions, farms, and Federal, state, local or tribal governments.

The recordkeeping burden in this regulation is already reflected in the burden of all tax forms.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may 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.

*Request for Comments:* Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the 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 collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: April 1, 2004.

**Glenn P. Kirkland,**

*IRS Reports Clearance Officer.*

[FR Doc. 04–8007 Filed 4–7–04; 8:45 am]

**BILLING CODE 4830–01–P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### Proposed Collection; Comment Request for Form 5500 and Schedules

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is

soliciting comments concerning Form 5500 and Schedules, Annual Return/Report of Employee Benefit Plan.

**DATES:** Written comments should be received on or before June 7, 2004, to be assured of consideration.

**ADDRESSES:** Direct all written comments to Glenn P. Kirkland, Internal Revenue Service, room 6411, 1111 Constitution Avenue, NW., Washington, DC 20224.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the forms and instructions should be directed to Carol Savage at Internal Revenue Service, room 6407, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 622–3945, or through the Internet at *CAROL.A.SAVAGE@irs.gov*.

**SUPPLEMENTARY INFORMATION:**

*Title:* Annual Return/Report of Employee Benefit Plan.

*OMB Number:* 1545–1610.

*Form Number:* 5500 and Schedules.

*Abstract:* Form 5500 is an annual information return filed by employee benefit plans. The IRS uses this information to determine if the plan appears to be operating properly as required under the law or whether the plan should be audited.

*Current Actions:* There are no changes being made to the form at this time.

*Type of Review:* Extension of a currently approved collection.

*Affected Public:* Business or other for-profit organizations, individuals and households, not-for profit institutions, and farms.

*Estimated Number of Respondents:* 998,682.

*Estimated Time Per Respondent:* Varies.

*Estimated Total Annual Burden Hours:* 4,978,724.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may 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.

*Request for Comments:* Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the 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 collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: April 1, 2004.

**Glenn P. Kirkland,**

*IRS Reports Clearance Officer.*

[FR Doc. 04–8008 Filed 4–7–04; 8:45 am]

**BILLING CODE 4830–01–P**

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### Proposed Collection; Comment Request for Form 4598

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 4598, Form W–2, 1098, or 1099 Not Received, Incorrect or Lost.

**DATES:** Written comments should be received on or before June 7, 2004, to be assured of consideration.

**ADDRESSES:** Direct all written comments to Glenn P. Kirkland, Internal Revenue Service, room 6411, 1111 Constitution Avenue, NW., Washington, DC 20224.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the form and instructions should be directed to Carol Savage at Internal Revenue Service, room 6407, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 622–3945, or through the Internet at *CAROL.A.SAVAGE@irs.gov*.

**SUPPLEMENTARY INFORMATION:**

*Title:* Form W–2, 1098, or 1099 Not Received, Incorrect or Lost.

*OMB Number:* 1545–0597.

*Form Number:* 4598.

*Abstract:* Form 4598 is used to resolve taxpayer inquiries concerning the non-receipt of, incorrect or lost, Forms W–2, 1098 or 1099. Part one of Form 4598 is mailed to the employer or payer for response to the IRS and, if necessary, to the taxpayer. Part two is mailed to the taxpayer advising the taxpayer of the action taken on their behalf.

*Current Actions:* There are no changes being made to the form at this time.

*Type of Review:* Extension of a currently approved collection.

*Affected Public:* Individuals, business or other for-profit organizations, farms, and Federal, state, local or tribal governments.

*Estimated Number of Responses:* 850,000.

*Estimated Time Per Respondent:* 15 minutes.

*Estimated Total Annual Burden Hours:* 212,500.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may 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.

*Request for Comments:* Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the 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 collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: April 1, 2004.

**Glenn P. Kirkland,**

*IRS Reports Clearance Officer.*

[FR Doc. 04–8009 Filed 4–7–04; 8:45 am]

BILLING CODE 4830–01–P

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### Proposed Collection; Comment Request for Revenue Procedure 2000–12

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Revenue Procedure 2000–12, Application Procedures for Qualified Intermediary Status Under Section 1441; Final Qualified Intermediary Withholding Agreement.

**DATES:** Written comments should be received on or before June 7, 2004, to be assured of consideration.

**ADDRESSES:** Direct all written comments to Glenn P. Kirkland, Internal Revenue Service, room 6411, 1111 Constitution Avenue, NW., Washington, DC 20224.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the revenue procedure should be directed to Carol Savage at Internal Revenue Service, room 6407, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 622–3945, or through the Internet at *CAROL.A.SAVAGE@irs.gov.*

**SUPPLEMENTARY INFORMATION:**

*Title:* Application Procedures for Qualified Intermediary Status Under Section 1441; Final Qualified Intermediary Withholding Agreement.

*OMB Number:* 1545–1597.

*Revenue Procedure Number:* Revenue Procedure 2000–12.

*Abstract:* This revenue procedure gives guidance for entering into a withholding agreement with the IRS to be treated as a Qualified Intermediary (QI) under regulation section 1.1441–1(e)(5). It describes the application procedures for becoming a QI and the terms that the IRS will ordinarily require in a QI withholding agreement. The objective of a QI withholding agreement is to simplify withholding and reporting obligations with respect to payments of income made to an account holder through one or more foreign intermediaries.

*Current Actions:* There are no changes being made to Revenue Procedure 2000–12 at this time.

*Type of Review:* Extension of a currently approved collection.

*Affected Public:* Business or other for-profit organizations.

*Estimated Number of Respondents/Recordkeepers:* 88,504.

*Estimated Time for QI Account Holder:* 30 minutes.

*Estimated Time for a QI:* 2,093 hours.

*Estimated Total Annual Reporting/Recordkeeping Hours:* 301,018.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may 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.

*Request for Comments:* Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the 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 collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: April 2, 2004.

**Glenn P. Kirkland,**

*IRS Reports Clearance Officer.*

[FR Doc. 04–8010 Filed 4–7–04; 8:45 am]

BILLING CODE 4830–01–P

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### Open Meeting of the Small Business/Self Employed—Payroll Committee of the Taxpayer Advocacy Panel

**AGENCY:** Internal Revenue Service (IRS) Treasury.

**ACTION:** Notice.

**SUMMARY:** An open meeting of the Small Business/Self Employed—Payroll Committee of the Taxpayer Advocacy Panel will be conducted (via teleconference). The TAP will be discussing issues pertaining to increasing compliance and lessoning the burden for Small Business/Self Employed individuals. Recommendations for IRS systemic changes will be developed.

**DATES:** The meeting will be held Wednesday, May 5, 2004.

**FOR FURTHER INFORMATION CONTACT:** Mary O'Brien at 1–888–912–1227, or (206) 220–6096.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Small Business/Self Employed-Payroll Committee of the Taxpayer Advocacy Panel will be held Wednesday, May 5, 2004, from 3 p.m. e.d.t. to 4:30 p.m. e.d.t. via a telephone conference call. If you would like to have the TAP consider a written statement, please call 1–888–912–1227 or (206) 220–6096, or write to Mary O'Brien, TAP Office, 915 2nd Avenue, MS W–406, Seattle, WA 98174 or you can contact us at *http://www.improveirs.org.* Due to limited conference lines, notification of intent to participate in the telephone conference call meeting must be made with Mary O'Brien. Ms O'Brien can be reached at 1–888–912–1227 or (206) 220–6096.

The agenda will include the following: various IRS issues.

Dated: April 5, 2004.

**Bernard Coston,**

*Director, Taxpayer Advocacy Panel.*

[FR Doc. 04–7998 Filed 4–7–04; 8:45 am]

BILLING CODE 4830–01–P

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### Open Meeting of the Area 7 Taxpayer Advocacy Panel (Including the State of California)

**AGENCY:** Internal Revenue Service (IRS) Treasury.

**ACTION:** Notice.

**SUMMARY:** An open meeting of the Area 7 committee of the Taxpayer Advocacy Panel will be conducted (via teleconference). The Taxpayer Advocacy Panel (TAP) is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service. The TAP will use citizen input to make recommendations to the Internal Revenue Service.

**DATES:** The meeting will be held Tuesday, May 4, 2004.

**FOR FURTHER INFORMATION CONTACT:** Mary Peterson O'Brien at 1–888–912–1227, or (206) 220–6096.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Area 7 Taxpayer Advocacy Panel will be held Tuesday, May 4, 2004, from 9 a.m. Pacific time to 10 a.m. Pacific time via a telephone conference call. The public is invited to make oral comments. Individual comments will be limited to 5 minutes. If you would like to have the TAP consider a written statement, please call 1–888–912–1227 or (206) 220–6096, or write to Mary Peterson O'Brien, TAP Office, 915 2nd Avenue, MS W–406, Seattle, WA 98174 or you can contact us at *http://www.improveirs.org.* Due to limited conference lines, notification of intent to participate in the telephone conference call meeting must be made with Mary Peterson O'Brien. Ms. O'Brien can be reached at 1–888–912–1227 or (206) 220–6096.

The agenda will include the following: Various IRS issues.

Dated: April 5, 2004.

**Bernard Coston,**

*Director, Taxpayer Advocacy Panel.*

[FR Doc. 04–7999 Filed 4–7–04; 8:45 am]

BILLING CODE 4830–01–P

## DEPARTMENT OF VETERANS AFFAIRS

### Advisory Committee on Former Prisoners of War, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under Public Law 92–463 (Federal Advisory Committee Act) that a meeting of the Advisory Committee on Former Prisoners of War (FPOW) will be held on April 26–28, 2004, at the Department of Veterans Affairs, Central Office, 810 Vermont Avenue, NW., Washington, DC 20420. On April 26 and 27, the meeting will be in Room 730. On April 28, the Committee will meet in Room 630. Each day the meeting will convene at 9 am. and end at 4:30 p.m. The meeting is open to the public.

The purpose of the Committee is to advise the Secretary of Veterans Affairs on the administration of benefits under Title 38, United States Code, for veterans who are former prisoners of war and to make recommendations on the needs of such veterans for compensation, health care, and rehabilitation.

The agenda for April 26 will begin with a review of Committee reports, an update of activities since the last meeting, and a period for FPOW veterans and/or the public to address the Committee. VA's Compensation and Pension Service will provide a briefing on the progress of outreach initiatives to FPOWs and initiatives to reduce the number of old pending disability claims, as well as a progress report from VA's FPOW Medical Presumptive Workgroup. The agenda on April 27 will include a presentation from the Director of the Robert E. Mitchell Center for Prisoners of War Studies and reports on expanded VA outreach efforts to FPOWs and the continuing FPOW Case Management Training Courses. The Committee will also hear presentations on the overview of the Veterans Health Administration. The day will conclude with new business and general discussion. On April 28, the Committee's Medical and Administrative work groups will break out to discuss their activities and report to the Committee. Additionally, the Committee will review the comments discussed throughout the meeting and compile a final report of the Secretary.

Members of the public may direct questions or submit written statements for review by the Committee in advance of the meeting to Mr. Ronald J. Henke, Director, Compensation and Pension Service (21), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420.

Dated: April 1, 2004.

By Direction of the Secretary.

**E. Philip Riggin,**

*Committee Management Officer.*

[FR Doc. 04–7912 Filed 4–7–04; 8:45 am]

BILLING CODE 8320–01–M

Federal Register

Thursday,
April 8, 2004

# Part II

# Federal Trade Commission

## 16 CFR Parts 801, 802 and 803

## Premerger Notification; Reporting and Waiting Period Requirements; Proposed Rule

## FEDERAL TRADE COMMISSION

### 16 CFR Parts 801, 802 and 803

### Premerger Notification; Reporting and Waiting Period Requirements

**AGENCY:** Federal Trade Commission.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Commission is proposing amendments to the premerger notification rules ("the rules") that attempt to reconcile, as far as is practical, the current disparate treatment of corporations, partnerships, limited liability companies and other types of non-corporate entities under the rules. The rules require the parties to certain mergers and acquisitions to file reports with the Federal Trade Commission ("the Commission") and the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice ("the Assistant Attorney General") and to wait a specified period of time before consummating such transactions. The reporting and waiting period requirements are intended to enable these enforcement agencies to determine whether a proposed merger or acquisition may violate the antitrust laws if consummated and, when appropriate, to seek a preliminary injunction in federal court to prevent consummation. This proposed rulemaking introduces a number of changes that attempt to reconcile, as far as is practical, the current disparate treatment of corporations, partnerships, limited liability companies and other types of non-corporate entities under the rules, particularly in the areas of acquisitions of interests in these entities; formations of the entities; and the application of certain exemptions, including the intraperson exemption.

**DATES:** Comments must be received on or before June 4, 2004.

**ADDRESSES:** Interested parties are invited to submit written comments. Comments should refer to "HSR Proposed Rulemaking, Project No. P989316," to facilitate the organization of comments. A comment filed in paper form should include this reference both in the text and on the envelope, and should be mailed or delivered to the following address: Federal Trade Commission/Office of the Secretary, Room H–159 (Annex E), 600 Pennsylvania Avenue, NW., Washington, DC 20580. Comments containing confidential material must be filed in paper form. The FTC is requesting that any comment filed in paper form be sent by courier or overnight service, if possible, because U.S. postal mail in the Washington area and at the Commission is subject to delay due to heightened security precautions.

An electronic comment can be filed by (1) clicking on *http://www.regulations.gov;* (2) selecting "Federal Trade Commission" at "Search for Open Regulations;" (3) locating the summary of this Notice of Proposed Rulemaking ("NPR"); (4) clicking on "Submit a Comment on this Regulation;" and (5) completing the form. For a given electronic comment, any information placed in the following fields—"Title," "First Name," "Last Name," "Organization Name," "State," "Comment," and "Attachment"—will be publicly available on the FTC Web site. The fields marked with an asterisk on the form are required in order for the FTC to fully consider a particular comment. Commenters may choose not to fill in one or more of these fields, but if they do so, their comments may not be considered.

Comments on any proposed filing, recordkeeping, or disclosure requirements that are subject to paperwork burden review under the Paperwork Reduction Act should additionally be submitted to: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10102, Washington, DC 20503, Attention: Carolyn Lovett, Desk Officer for Federal Trade Commission. Such comments should also be mailed to the following address: Federal Trade Commission/Office of the Secretary, Room H–159 (Annex E), 600 Pennsylvania Avenue, NW., Washington, DC 20580.

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. All timely and responsive public comments, whether filed in paper or electronic form, will be considered by the Commission, and will be available to the public on the FTC Web site, to the extent practicable, at *http://www.ftc.gov.* As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC Web site. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

**FOR FURTHER INFORMATION CONTACT:** Marian R. Bruno, Assistant Director, Karen E. Berg, Attorney, B. Michael Verne, Compliance Specialist, or Nancy M. Ovuka, Compliance Specialist, Premerger Notification Office, Bureau of Competition, Room 303, Federal Trade Commission, Washington, DC 20580. Telephone: (202) 326–3100.

**SUPPLEMENTARY INFORMATION:** Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by the Hart-Scott-Rodino Antitrust Improvements Act of 1976, Public Law 94–435, 90 Stat. 1390 ("the Act"), requires all persons contemplating certain mergers or acquisitions to file notification with the Commission and the Assistant Attorney General and to wait a designated period of time before consummating such transactions. Congress empowered the Commission, with the concurrence of the Assistant Attorney General, to require "that the notification * * * be in such form and contain such documentary material and information * * * as is necessary and appropriate" to enable the agencies "to determine whether such acquisitions may, if consummated, violate the antitrust laws." Congress similarly granted rulemaking authority to, inter alia, "prescribe such other rules as may be necessary and appropriate to carry out the purposes of this section." 15 U.S.C. 18a(d).

Pursuant to that section, the Commission, with the concurrence of the Assistant Attorney General, developed the Antitrust Improvements Act Rules ("the HSR rules") and Notification and Report Form for Certain Mergers and Acquisitions ("the Form"), and has amended or revised the HSR rules and the Form on numerous occasions, and now proposes these further changes to the HSR rules.

The Commission invites interested members of the public to submit written data, views, facts, and arguments addressing the issues raised by this NPR. Written comments must be submitted on or before June 4, 2004. Comments should refer to "HSR Proposed Rulemaking, Project No. P989316," to facilitate the organization of comments. A comment filed in paper form should include this reference both in the text and on the envelope, and should be mailed or delivered to the following address: Federal Trade Commission/Office of the Secretary, Room H–159 (Annex E), 600 Pennsylvania Avenue, NW., Washington, DC 20580. If the comment contains any material for which confidential treatment is requested, it must be filed in paper (rather than electronic) form, and the first page of the document must be clearly labeled "Confidential." [1] The FTC is requesting

[1] Commission Rule 4.2(d), 16 CFR 4.2(d). The comment must be accompanied by an explicit

that any comment filed in paper form be sent by courier or overnight service, if possible, because U.S. postal mail in the Washington area and at the Commission is subject to delay due to heightened security precautions.

Comments on any proposed filing, recordkeeping, or disclosure requirements that are subject to paperwork burden review under the Paperwork Reduction Act should additionally be submitted to: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10102, Washington, DC 20503, Attention: Carolyn Lovett, Desk Officer for Federal Trade Commission. Such comments should also be mailed to the following address: Federal Trade Commission/ Office of the Secretary, Room H–159 (Annex E), 600 Pennsylvania Avenue, NW., Washington, DC 20580.

An electronic comment can be filed by (1) clicking on *http://www.regulations.gov;* (2) selecting "Federal Trade Commission'' at "Search for Open Regulations;'' (3) locating the summary of this Notice of Proposed Rulemaking; (4) clicking on "Submit a Comment on this Regulation;'' and (5) completing the form. For a given electronic comment, any information placed in the following fields—"Title,'' "First Name,'' "Last Name,'' "Organization Name,'' "State,'' "Comment,'' and "Attachment''—will be publicly available on the FTC Web site. The fields marked with an asterisk on the form are required in order for the FTC to fully consider a particular comment. Commenters may choose not to fill in one or more of these fields, but if they do so, their comments may not be considered.

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. All timely and responsive public comments, whether filed in paper or electronic form, will be considered by the Commission, and will be available to the public on the FTC Web site, to the extent practicable, at *http://www.ftc.gov.* As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC Web site. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

**Background**

The Act applies to acquisitions of voting securities or assets. Whether a transaction must be reported is determined by applying the statute, supporting regulations, and formal and informal staff interpretations. Neither the Act nor the HSR rules specifically address whether interests in unincorporated entities are deemed to be voting securities or assets. The Premerger Notification Office, by informal interpretation, has long taken the position that partnership interests, and, by extension, interests in other types of unincorporated entities, are neither assets nor voting securities. Thus, any acquisition of such interests has not been deemed a reportable event unless 100 percent of the interests are acquired, in which case the acquisition is deemed to be that of all of the underlying assets of the partnership or other unincorporated entity.

When promulgating the original HSR rules, the Commission recognized the possible applicability of the Act to acquisitions of less than 100 percent of the interests in such entities. Although the Commission did not extend the coverage of § 801.40 regarding formations of corporations to unincorporated entities, the Statement of Basis and Purpose to Section 801.40 reads:

"There is evidence that Congress intended coverage of acquisitions by or of noncorporate entities. Section 7A(b)(3)(A) states:

The term "voting securities'' means any securities which * * * entitle the owner or holders thereof to vote for the election of directors of the issuer, or, *with respect to unincorporated issuers,* persons exercising similar functions. (Emphasis supplied).

However, the Commission has instructed its staff to monitor the formation of joint business arrangements of all types and forms and to determine, after a year of operation, whether the rules provide appropriate coverage. The fact that persons contributing to the formation of a noncorporate joint venture are not required to report and wait prior to the transaction should not, of course, be construed as a Commission statement that such transactions are free from antitrust concerns.'' [2]

At the end of the one year period, further modifications to the rules were not made.

The language of the Act cited above suggests that unincorporated entities can have voting securities. Voting securities, under the Act, must entitle the holder to vote either for the election of directors or to vote for the election of individuals exercising similar functions with respect to unincorporated entities.[3] The Commission did not apply this approach to unincorporated entities in 1978 and does not propose to do so in these proposed amendments. In the 1987 rulemaking that redefined control of partnerships, which is discussed in more detail below, the Commission stated:

"* * * [t]he Commission staff concluded that partnerships do not possess 'individuals exercising similar functions' to directors; * * *'' [4]

Because the Commission concluded that partnerships do not have directors or individuals exercising similar functions, partnerships cannot have voting securities as defined in the Act.

In 1987, the Commission revised a longstanding staff position that a partnership was never controlled by its partners and thus was always its own ultimate parent entity. The rules were amended to incorporate the current control tests for partnerships.[5] In the Statement of Basis and Purpose accompanying that rulemaking, the Commission addressed the possibility of making the acquisition of control of a partnership a reportable event.

"* * * the Commission is considering whether, in light of its adoption of the 'partnership control' rule, it should also revise its rules to require reporting the acquisition of control of a partnership. Currently, the staff interpretation makes acquisition of less than a 100 percent interest in a partnership not reportable, because a partnership interest is deemed to be neither a voting security nor an asset.'' [6]

The Commission also raised the possibility of applying the intraperson exemption to partnerships should the acquisition of control be made a reportable event. Responding to a comment from the ABA Section of Antitrust Law asking whether an acquisition of assets from a partnership by a person who controlled that partnership would be an exempt transaction, the Commission replied:

"As a general matter, the Commission agrees it would be logical to exempt such transactions if acquisition of control of the partnership were a reportable event. However, as is noted above, under current staff interpretations, acquisition of control is

request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission's General Counsel, consistent with applicable law and the public interest. *See* Commission Rule 4.9(c), 16 CFR 4.9(c).

[2] 43 FR 33487 (July 31, 1978).

[3] Section 7A(b)(3)(A).

[4] 52 FR 20062 (May 29, 1987).

[5] 16 CFR 801.1(b)(1)(ii) ("In the case of an entity that has no outstanding voting securities, having the right to 50 percent or more of the profits of the entity, or having the right in the event of dissolution to 50 percent or more of the assets of the entity * * *'').

[6] 52 FR 20061 (May 29, 1987).

not normally a reportable event. Consequently, the Commission is not prepared now to exempt the asset acquisition. It will consider such an exemption as it considers making the acquisition of control of a partnership a reportable event.''[7]

In developing these proposed rule amendments, the Commission considered changing the control test for unincorporated entities from an equity test (having the right to 50 percent or more of the profits of the entity, or having the right in the event of dissolution to 50 percent or more of the assets of the entity)[8] to a governance test (the general partner(s) of a partnership, the person(s) who designate the general partner, the managing member(s) of a limited liability company (''LLC''), or the person(s) who designate the management committee of an LLC, etc.). Such a change would conform the control test for unincorporated entities more closely to the control test for corporations (either holding 50 percent more of the outstanding voting securities of the issuer or having the contractual power presently to designate 50 percent or more of the directors of a corporation)[9]. However, the application of a governance test of control to an unincorporated entity would be difficult to apply consistently. The Commission has decided that changing the control rule in such a manner would create confusion and make the control test more ambiguous than the current rule. Therefore, these proposed amendments do not include such a change to the control test, and the current rule will remain unchanged with one exception. The proposed amendment to § 801.1(b)(2) would remove the alternate test of control for unincorporated entities which provides for control through having the contractual power presently to designate individuals exercising similar functions to those of directors of a corporation. This is discussed further in the narrative accompanying the proposed amendments to § 801.1.

Finally, in February, 1999 the Commission issued Formal Interpretation 15, which defined circumstances under which the formation of LLCs would be reportable. At that time, the Commission recognized that the use of LLCs had evolved, and while LLCs were still used to some extent as vehicles for start-up enterprises, they were also often being used to combine competing businesses under common control. To address the combination of businesses, Formal Interpretation 15 construed the Act and rules to require reporting when two or more ongoing businesses were combined under common control. Formal Interpretation 15 covers only LLCs, leaving other non-corporate ventures unaddressed, and has been complicated to apply.

In its commentary in Formal Interpretation 15, the Commission again indicated the possibility of making formations of partnerships reportable under the same reasoning that it used for LLCs.

> ''Some of the reasons for concluding that the formation of certain LLCs should be treated as reportable may apply equally well to partnerships * * *. [t]he [PreMerger Notification Office] has decided not to change its treatment of partnerships at this time, but may re-visit this issue in the future as developments require.''[10]

The use of unincorporated entities is expanding, and such entities are increasingly engaging in acquiring interests in other corporate and unincorporated entities. For example, the number of corporate income tax filings increased from 4,630,000 to 5,711,000 (23%) between 1994 and 2002, while the number of partnership returns[11], including LLCs taxed as partnerships, increased from 1,550,000 to 2,236,000 (44%) during the same period.[12] In addition, a number of states have amended their statutes in recent years to allow limited liability companies to merge with other types of legal entities.

Delaware has traditionally led the nation in incorporations and has now achieved the same position with unincorporated entities. According to the Delaware Secretary of State, 1,499 statutory trusts, 5,717 limited partnerships (''LPs'') and more than 47,000 LLCs were formed in 2002.[13]

Professor Susan Pace Hamill comments in the Michigan Law Review ''[r]egardless of whether the motivation is tax or business related, the use and acceptance of LLCs as a serious alternative to the partnership and the corporation [has] exponentially increased * * * and will probably grow more each year. Indeed, some commentators believe the LLC will largely replace the partnership and the closely held corporation and emerge as the dominant form of business for non-publicly traded entities.'' She further observes that ''[c]ommentators are just starting to speculate on the future popularity of the LLP (limited liability partnership). Some believe that LLPs will evolve as the business form of choice for many transactions and may even surpass the LLC.''[14]

Consequently, as a result of the increased usage of non-corporate entities in transaction structures, the Commission believes that this is the appropriate time to review its application of the Act and the HSR rules to non-corporate entities and to propose amendments that will revise the Commission's historic treatment of these entities.

**Current Interpretations**

Staff informal interpretations of the current rules with respect to unincorporated entities lead to several anomalies which do not occur with corporations. These inconsistencies relate primarily to three areas: changes of control, intraperson transfers of assets, and formations.

*(a) Changes of Control*

Section 801.2(a) states ''[a]ny person which, as a result of an acquisition, will hold voting securities or assets * * * is an acquiring person.'' Section 801.1(c)(8) further states ''* * * in addition to its own holding, an entity holds all assets and voting securities held by the entities which it controls * * *''. Despite this language, under current application of the rules, if a minority interest holder or a person who holds no interests at all acquires a controlling, but less than 100 percent interest in an existing unincorporated entity, the transaction is never reportable because the person who will control the unincorporated entity is not deemed to be acquiring the assets of the entity and no reportable acquisition occurs. However, under the rules, the person is immediately deemed to hold those same assets for purposes of determining the size-of-person test by virtue of having the right to 50% of the profits and assets upon dissolution of the entity. Further, if the person who now controls the unincorporated entity, who is deemed to hold all of the assets of the entity under § 801.1(c)(8), were to acquire the remaining interests, it would be required to file notification to acquire the same assets it is deemed to currently

[7] *Ibid.*

[8] 16 CFR 801.1(b)(1)(ii).

[9] 16 CFR 801.1(b).

[10] 64 FR 5808 (February 5, 1999).

[11] Partnership return of income forms (Form 1065) are not strictly income tax returns because partnerships are not taxed directly.

[12] Internal Revenue Service, *FY 1994 and FY 2002 Data Books, Summary of Number of Returns by Type of Return.*

[13] BNA's Corporate Counsel Weekly Newsletter Analysis, ''*Delaware Law: 2003 Amendments to Delaware's Alternative Entity Statutes*'', Turthill and Hering (October 8, 2003).

[14] Hamill, *The Limited Liability Company: A Catalyst Exposing the Corporate Integration Question,* 95 Mich. L. Rev. 393 (November, 1996).

hold, assuming the jurisdictional thresholds are met. The intraperson exemption provided in § 802.30 prevents this result in the context of a corporation but is not available to unincorporated entities because the exemption requires that the acquiring and acquired person be the same by reason of holdings of voting securities.

Under this approach, if a person who currently holds no interests or a minority position in a non-corporate entity acquires 100 percent of the interests, the person is required to file, but if the person acquires 99 percent it does not. A person who controls a non-corporate entity and acquires the remainder of the interests must also file. Both situations are anomalous: a filing is required after control is obtained, yet no filing is required to gain control.

Consistent with the treatment of corporate entities, meaningful antitrust review should occur at the time that control of an unincorporated entity changes and not after control is already acquired. Currently, if a person who controls a partnership or other unincorporated entity is acquiring the remaining interests, that interest holder is deemed both the acquiring and acquired person and files notification to acquire the assets which, according to a literal reading of the rules, it already holds.[15] For example, a 90 percent partner acquiring the remaining 10 percent of the interest in a partnership must file. An HSR filing for this type of transaction appears to be of little antitrust significance. The Commission receives a significant number of such filings each year and believes that other such transactions are not reported as required due to the counterintuitive nature of the current application of the rules.[16]

*(b) Intraperson Transfers*

In the context of corporations, any transfer of assets from a corporation to a controlling shareholder, or a transfer of assets from one corporate subsidiary of a parent to another corporate subsidiary of the same parent is exempt.[17] However, because partnerships and other unincorporated entities are not controlled through the holding of voting securities, similar transfers involving such entities are reportable. This results, for example, in a reportable transaction when assets are transferred from a partnership to a partner that holds a 90 percent interest in the partnership, irrespective of the fact that the controlling partner is already deemed to hold those assets. Similarly, if a person controls two different partnerships and transfers assets from one to the other, that person would have a filing requirement despite the fact that it holds the assets under the rules both before and after the transfer. This result conflicts with the definition in § 801.2 which defines an acquiring person as "Any person which, *as a result of an acquisition* will hold voting securities or assets * * *'' (emphasis supplied).

*(c) Formations*

With the exception of certain limited liability company formations, as noted above,[18] formations of non-corporate entities are not reportable events. This leads to a number of transactions where de facto change of control of assets can occur without notification. For example, A and B form a non-corporate entity to which B will contribute a business in exchange for a 40 percent interest and A will contribute cash in exchange for a 60 percent interest. Although A now holds assets which were previously held by B, current application of the rules does not require notification because A will not hold 100 percent of the interests in the non-corporate entity nor are two pre-existing businesses being combined in an LLC. This would not be reportable in an LLC or partnership formation but would be reportable in the formation of a corporation. While Formal Interpretation 15 was an attempt to address this inconsistency in the context of limited liability company formations, its application still results in non-reportable transactions which could have significant antitrust implications.

**Proposed Amendments**

These proposed rules attempt to apply the Act as consistently as possible to all forms of legal entities, requiring filings for transactions which are likely to present antitrust concerns and exempting transactions which are not. The Commission particularly seeks information on the number and types of transactions that would become reportable and whether changes in the proposal, including additional exemptions, could limit any undesirable effects.

Proposed changes to the coverage rules include a revision to § 801.1(b) to remove the alternate control test for unincorporated entities; an amendment to § 801.1(f) to define a "non-corporate interest''; revising § 801.2(d) to clarify the consolidation rule; amending § 801.2(f) to define when acquiring interests in unincorporated entities may constitute an acquisition; adding a new subsection to § 801.10 to define how to value such an acquisition; adding a new subsection to § 801.13 to address aggregation of non-corporate interests; and adding a new § 801.50 which makes certain formations of unincorporated entities a reportable event. There are also ministerial changes to §§ 801.4, 802.40 and 802.41 to adapt their application to both corporations and unincorporated entities. Additionally, there are minor changes to the Notification and Report Form to require that Item 5(d) be completed in connection with the formation of an unincorporated entity and to reflect the applicability of Items 7 and 8 to unincorporated entities and to change the reporting requirement in Item 7 with regard to the formation of new entities.

Proposed changes to the exemption rules include modifying § 802.4 to eliminate the dissimilar treatment of asset and voting securities acquisitions which are substantively the same; codifying in § 802.10 a longstanding informal interpretation that pro-rata reformations (*i.e.* reincorporation in a new jurisdiction) are exempt transactions; changing § 802.30 to apply the intraperson exemption to entities which are held other than through holdings of voting securities; and adding a new § 802.65 to exempt acquisitions of non-corporate interests in entities which are formed in connection with financing transactions.

If the Commission adopts the proposed rules, it will revoke Formal Interpretation 15 and issue a new Formal Interpretation 18 because LLCs will then be treated like any other unincorporated entity under the rules.[19]

[15] 16 CFR 801.1(c)(8) (A person holds all assets and voting securities held by the entities included within it; in addition to its own holding, an entity holds all assets and voting securities held by the entities *which it controls* directly or indirectly). (emphasis supplied).

[16] Between 1997 and 2002, the Commission received 248 filings in which the acquiring person and the acquired person were the same.

[17] "An acquisition (other than the formation of a joint venture or other corporation the voting securities of which will be held by two or more persons) in which, by reason of holdings of voting securities, the acquiring and acquired persons are (or as a result of formation of a wholly owned entity will be) the same person, shall be exempt from the requirements of the Act.'' 16 CFR 802.30.

[18] Formal Interpretation (64 FR 5808 (February 5, 1999)) treats as reportable the formation of an LLC if (1) two or more pre-existing, separately controlled businesses will be contributed, and (2) at least one of the members will control the LLC. The formation of all other LLCs is treated similar to the formation of a partnership which is not reportable.

[19] Text of proposed Formal Interpretation 18:

1. This formal interpretation of the Premerger Notification Rules concerning limited liability companies is issued by the Federal Trade Commission pursuant to 16 CFR 803.30. It supersedes a formal interpretation issued by the

Continued

In addition to amendments concerning unincorporated entities, there are technical corrections to §§ 801.13, 801.15 and 802.2.

**Part 801—Coverage Rules**

*Section 801.1 Definitions*

The proposed amendment to § 801.1(b)(2) would remove the alternate test of control for unincorporated entities, which provides for control through having the contractual power presently to designate individuals exercising similar functions to those of directors of a corporation. This deletion simplifies the test of control for unincorporated entities, which is defined as having the right to 50 percent or more of the profits of the entity, or having the right in the event of dissolution to 50 percent or more of the assets of the entity. The elimination of the alternate control test insures that an acquisition involving an unincorporated entity is reportable only when control is acquired through an acquisition of non-corporate interests which confer the right to profits or assets upon dissolution of the entity, not when obtaining the right to designate individuals exercising functions similar to those of directors of a corporation, such as the management committee of an LLC. The proposed amendment also clarifies that the only test for control of a not-for-profit corporation which does not issue voting securities is the right to designate 50 percent or more of the board of directors.

Proposed new § 801.1(f)(1)(ii) would define the term "non-corporate interest'' as an interest in any unincorporated entity which gives the holder the right to any profits of the entity or the right to any assets of the entity in the event of dissolution of that entity. This term is used throughout the proposed rule changes.

*Section 801.2 Acquiring and Acquired Persons*

The proposed amendment to § 801.2(d) would codify a longstanding informal staff position that the combination of any two entities into a new holding company is the functional equivalent of a consolidation and should be treated in the same manner regardless of whether the entities are corporations or non-corporate entities. It also clarifies that even if the two entities are retaining their separate legal identities, either by becoming subsidiaries of the new holding company or through arrangements such as dual-listing agreements, the transactions would be treated the same.

Proposed new § 801.2(f)(1) provides that an acquisition occurs at the time non-corporate interests which confer control of an unincorporated entity are acquired. At this point the person who controls the entity is deemed to hold all of the assets of the entity. Thus the proposed rules would shift reporting from when 100% of the interest in an unincorporated entity is received to the more significant point when control is obtained.[20] This change would be consistent with Section 801.2(a) which defines an acquiring person as "[a]ny person which, as a result of an acquisition, will hold voting securities or assets, either directly or indirectly * * * is an acquiring person.''

Proposed new § 801.2(f)(2) would clarify that a contribution of assets or voting securities to an existing unincorporated entity is an acquisition by that entity and that such a transaction would not be governed by new § 801.50, even if all or part of the consideration is interests in the entity. This differs from Formal Interpretation 15 which views the contribution of a business to an existing LLC in exchange for membership interests as a new formation of that LLC. Note that when a person acquires control of an existing non-corporate entity as a result of a contribution made to that non-corporate entity, the acquisition by the non-corporate entity from the contributing person is not separately reportable. If the rule is amended as proposed, Formal Interpretation 15 will be repealed.

Proposed § 801.2(f)(3) would also codify a longstanding informal position that acquiring the right to designate 50 percent or more of the board of directors of a not-for-profit corporation is an acquisition of all of the underlying assets of such an entity. This is generally accomplished by becoming a member with the right to designate 50 percent or more of the board of directors.

*Section 801.4 Secondary Acquisitions*

The proposed amendment to § 801.4 would clarify that any indirect acquisition of voting securities of an issuer that is not controlled by the acquired entity in the primary acquisition is deemed a secondary acquisition and is separately subject to the reporting requirements of the Act. This is true whether the primary acquisition confers control of a corporation or an unincorporated entity. Again, the Commission intends to elevate substance over form in the application of this rule to different types of legal entities. A separately reportable acquisition of an unincorporated entity may also occur through an indirect acquisition of minority non-corporate interests if the acquiring person already holds non-corporate interests in that entity that in aggregate would result in control.

*Section 801.10 Value of Voting Securities, Assets and Non-Corporate Interests To Be Acquired*

Proposed § 801.10(d) would specify the method of valuing a transaction in which non-corporate interests which confer control of an existing unincorporated entity are acquired. Under the proposed rules, an acquisition of non-corporate interests is potentially reportable where a change of control results in the acquiring person being deemed to hold all of the assets of the unincorporated entity. That said, it appears inequitable to require the acquiring person in such a transaction to value all of the underlying assets of the unincorporated entity if less than 100 percent of the interests are being acquired. Under the current rules, in an acquisition of voting securities of a non-publicly traded corporation, where a person acquires 50 percent or more of the corporation's voting securities, that person is deemed to hold all of the assets of the corporation. However, the value of the transaction is the value of the percentage interest held in the corporation, not the value of 100 percent of the underlying assets. The Commission believes that it is appropriate to similarly value an acquisition of non-corporate interests. Rather than treating such a transaction as a stand-alone acquisition of assets, which would be valued in accordance with § 801.10(b), the new rule establishes the value of the transaction by using the same methodology employed in valuing voting securities of a non-publicly traded corporation. Therefore, the value of any non-corporate interests which are being acquired is the acquisition price if determined or if undetermined, the fair market value of those interests. The value of any non-corporate interests in the same unincorporated entity which are already held prior to the instant

staff of the Federal Trade Commission on February 5, 1999.

2. The formal interpretation issued on February 5, 1999, will no longer be used to analyze the reportability of transactions involving limited liability companies. Such transactions will now be analyzed under parts 801–803 of the Premerger Notification Rules in the same manner as any other non-corporate entities.

[20] See § 801.1(c)(8), which provides that a "person holds all assets and voting securities held by the entities included within it; in addition to its own holdings, an entity holds all assets and voting securities held by the entities which it controls directly or indirectly.''

acquisition is the fair market value of those interests.

*Section 801.13 Aggregation of Voting Securities, Assets and Non-Corporate Interests*

The proposed amendment to § 801.13(b) would correct a drafting oversight that has existed since the original rulemaking in 1978.[21] Because this section only requires aggregation of a current acquisition of assets with an earlier acquisition of assets from the same acquired person if the earlier transaction has been consummated, incongruous unintended results are produced in many instances.

Under the current rule, the value of a past and current asset acquisition must be aggregated if the acquiring person has signed a letter of intent or entered into a contract or agreement in principle to acquire assets from the acquired person, and if the acquiring person has acquired assets from the acquired person within 180 calendar days preceding the signing of such agreement. This requirement applies if the prior acquisition was not previously subject to the requirements of the Act.

A problem arises when the acquiring person has not consummated the prior acquisition of assets at the time the subsequent acquisition letter of intent or agreement has been entered into. In that situation, aggregation is not required yet the combination of assets may exceed the reporting thresholds. As a result, an earlier planned non-reportable acquisition which is the subject of a letter of intent or agreement that is still valid, but has not closed would not be aggregated with assets to be acquired from the same acquired person pursuant to a new letter of intent or agreement executed within 180 days of the original transaction. For example, if A enters into an agreement with B to acquire $30 million in assets on day one, and enters into a second agreement with B to acquire $30 million in additional assets on day 60, aggregation of the two sets of assets would not be required if the first acquisition has not closed, but would be required if it has closed.

To correct this anomaly, amended § 801.13(b) would require aggregation if within the 180 days preceding the execution of a letter of intent or agreement, either (1) a still valid letter of intent or agreement which has not been consummated was entered into with the same acquired person; or (2) assets were acquired from the same acquired person and are still held by the acquiring person. No aggregation is required if the earlier contemplated or consummated acquisition was subject to the requirements of the Act. The reference to § 801.1(h)(1) would also be removed because that part of the rule is no longer applicable to asset acquisitions.

Proposed new § 801.13(c) would require that any new acquisition of non-corporate interests be aggregated with any previously acquired non-corporate interests in the same unincorporated entity for purposes of determining the value of the transaction in accordance with new § 801.10(d). An acquisition of non-corporate interests that does not confer control of the unincorporated entity is not aggregated with any other assets or voting securities which have been or are currently being acquired from the same acquired person.

*Section 801.15 Aggregation of Voting Securities and Assets the Acquisition of Which Was Exempt*

The proposed amendment to § 801.15 would correct a drafting oversight in the rulemaking promulgated in March, 2002 [22], which, among other things, reorganized the foreign exemptions found in § § 802.50 and 802.51. The foreign exemptions were originally organized by nationality of the acquiring person such that § 802.50 covered acquisitions of both assets located outside of the U.S. and voting securities of foreign issuers by U.S. persons. Section 802.51 likewise covered both types of acquisitions by foreign persons. The 2002 rulemaking reorganized the two rules by type of transaction. Section 802.50 now covers acquisitions of assets located outside of the U.S. by any person and § 802.51 covers acquisitions of voting securities of foreign issuers by any person.

Both rules proscribe the use of the exemption if the foreign assets or foreign issuer generated sales in or into the U.S. in excess of $50 million in the most recent year or if the foreign issuer has assets located in the U.S. valued in excess of $50 million. Section 801.15(b) states that any assets or voting securities exempted under § 802.50 or § 802.51 are not held as a result of an acquisition unless the $50 million limitation in the relevant section is exceeded.

The original rules each referenced both assets and voting securities and thus covered aggregation of the U.S. sales attributable to foreign assets and voting securities that are acquired from the same acquired person in the same transaction. However, the rules as amended present a problem when applied without change to § 801.15. Because § 801.15(b) is applied separately to each exemption to determine whether the limitation in that exemption has been exceeded, under the current aggregation rule, §§ 802.50 and 802.51 are each analyzed separately to determine if the limitation in each has been exceeded independent of the other. This produced the unintended result that an acquisition can be made of voting securities of foreign issuers and assets located outside of the U.S. from the same acquired person, which in aggregate have sales in or into the U.S. in excess of $50 million, which will not be reportable if both the assets and the issuers do not individually exceed the limitation. For example, an acquisition of assets located outside of the U.S. with $30 million in sales into the U.S. coupled with an acquisition of voting securities of a subsidiary of the same acquired person with $30 million of sales into the U.S. would not currently be reportable. This is obviously not the intended result because the requisite nexus with U.S. commerce has been satisfied.

To correct this earlier drafting omission, the proposed amendment to § 801.15 would remove §§ 802.50 and 802.51 from paragraph (b) and move them to new paragraph (d) which requires that sales in or into the U.S. be aggregated under both foreign exemptions to determine if the $50 million limitation is exceeded. This proposed revision would insure consistent application of the foreign exemptions to transactions which are substantively the same but different in form.

*Section 801.50 Formation of Unincorporated Entities*

Because the formation of an entity presents the same potential antitrust concerns regardless of whether its legal form is that of a corporation or a non-corporate entity, the Commission believes that all such formations should be treated as similarly as possible under the rules. Thus, proposed new § 801.50 would mirror § 801.40, which governs the formation of corporations, with two exceptions. Most importantly, like any potentially reportable acquisition of an existing unincorporated entity, acquisitions of non-corporate interests which confer control must be reported. Because acquiring control is the triggering event in such a formation, the special size of person test in § 801.40 that requires that two acquiring persons and the newly formed corporation have sufficient size to satisfy the jurisdictional requirements, appears to be unnecessary. It might be inconsistent with the structure of the proposed rule, because there may well be only one

[21] 43 FR 33487 (July 31, 1978).

[22] 67 FR 11898 (March 18, 2002).

acquiring person (*i.e.*, only one person who will control the entity) in a formation of an unincorporated entity even though there are other minority interest holders. Therefore, this test is omitted in proposed new § 801.50 and the standard size of person test specified in section 7A(a)(2) of the Act is used.

Outside parties have raised questions concerning the determination of the right of profits or assets upon dissolution in a new unincorporated entity that has a formulaic distribution of profits based upon variables that cannot be determined at the time of the formation of the entity. If a formation agreement designates a fixed percentage of profits and assets upon dissolution for each person contributing to the formation of the entity, the analysis is straightforward. If however, the profit distribution depends on the level of profit, for instance, the analysis is more complex.

Thus far, staff in the Premerger Notification Office has learned of two profit sharing arrangements that raise complications when the control test is applied. In the first instance, the profit distribution is based on the level of cumulative profits. For example, the first $10 million in profits is distributed 80% to A and 20% to B. The second $10 million is distributed 50% to each. Any profits above $20 million are distributed 20% to A and 80% to B. Thus, the eventual distribution of profit cannot be determined in advance. At different points the right to 50% or more of the profits shifts from A to B and at one point they each have that right. Given the uncertainty that any of the profit targets will be achieved, the analysis of rights to profits becomes extremely difficult. Does A control because it has the right to more than 50% in the first 10 million, does B control because it has the same right to profits above $20 million, or do both control because they each have the right to 50% or more at different times? Does only A control because the only certainty is that the entity will have less than $10 million in profits, if indeed it ever generates any profits, at some point in its life cycle? Or does neither control?

A second arrangement is even more problematic. In this scenario, the percentage of profits distributed to each of the persons contributing to the formation is recalculated based on the level of profits achieved since the last distribution. Thus, each time there is a new distribution, a different person may have the right to more than 50% of that distribution.

To address these problems, the Commission proposes that any profit distribution arrangement that cannot be determined at the time of the formation of the entity will result in the right to profits of the entity being deemed undetermined. The control test in such a scenario will be the right to residual assets of the entity. Under the formation agreement, if any person contributing to the formation receives the right to 50% or more of the assets of the entity once all its debt has been repaid, then that person is deemed to have acquired control of the entity at the time of its formation. If no such right is conferred, the entity is deemed to be its own ultimate parent entity and its formation will not be reportable.

Proposed § 801.50 is intended to cover only the formation of unincorporated entities, not other contractual arrangements that may confer rights to profits of a joint enterprise that does not involve the formation of an entity, nor any existing contractual arrangement deemed by a court to be a partnership under rule of law.

## PART 802—EXEMPTION RULES

### *Section 802.2 Certain Acquisitions of Real Property Assets*

Section 802.2 of the rules was promulgated in 1996 to exempt eight categories of real property acquisitions, including office and residential property, unproductive real property, hotels and motels, and agricultural property, that the agencies concluded were unlikely to violate the antitrust laws.[23]

Section 802.2(g) of the 1996 version of the rule exempted acquisitions of agricultural property and stated:

> "Agricultural property is real property and assets that primarily generate revenues from the production of crops, fruits, vegetables, livestock, poultry, milk, and eggs (activities within SIC[24] Major Groups 01 and 02)."

SIC major groups 01 and 02 did not include timber tracts (08) or logging (24).

At the time § 802.2 was originally adopted, the agencies explained that three comments had proposed "an exemption for acquisitions of timberland, noting that the raw material supply and manufacturing resources in the forestry industry are abundant, and ownership of timberland is fragmented." The agencies expressly rejected creating such an exemption:

> "However, because there has been enforcement interest in a number of transactions involving timberland in the western United States, the Commission declined to include an exemption for acquisitions of timberland to insure that the enforcement agencies continue to receive notification of those acquisitions of timberland that may present competitive concerns."[25]

In 2001, the FTC amended the HSR Form and Instructions to require reporting of revenue data by NAICS[26] rather than by SIC code.[27] At the same time, the two HSR Rules that had referenced SIC codes were amended so as to replace those references with "the applicable NAICS sector." Accordingly, the parenthetical in the agricultural property exemption was amended to read:

> "(activities within NAICS sector 11)."

The Statement of Basis and Purpose simply stated: "This amendment is necessary to update the definition to the applicable NAICS sector rather than the SIC industry code."[28]

The agencies have since discovered that timberland, which was in SIC major group 08 and thus not originally referenced in the parenthetical at issue, is in NAICS sector 11, which is captioned "Agriculture, Forestry, Fishing and Hunting." Within sector 11 are "timber tract operations", "forest nurseries and gathering of forest products", and "logging." Thus, the change to NAICS sector 11 inadvertently expanded the exemption beyond the agricultural property originally intended.

To clarify that timberland acquisitions are not exempted by § 802.2(g), the proposed amendment to this rule would make two changes. First, the parenthetical at issue would be revised to make it clear that only real property and assets that primarily generate revenues from "certain" activities within NAICS sector 11, *i.e.*, activities named in the text of the rule (the production of crops, fruits, vegetables, livestock, poultry, milk and eggs), are exempted. Second, the amendment would add a new subsection under the exceptions to the rule providing that timberland or other real property that generate revenues from activities within NAICS subsector 113 (Forestry and logging) and NAICS industry group 1153 (Support activities for forestry and logging) do not qualify for the agricultural property exemption.

[23] 61 FR 13666 (March 28, 1996).

[24] Standard Industrial Classification.

[25] 61 FR 13679 (March 28, 1996).

[26] North American Industry Classification System.

[27] 66 FR 23561 (May 9, 2001) (interim rules); 66 FR 35541 (July 6, 2001) (finalizing interim rules).

[28] *Ibid.*

*Section 802.4 Acquisitions of Voting Securities of Issuers or Non-Corporate Interests in Unincorporated Entities Holding Certain Assets the Acquisition of Which Is Exempt*

Section 802.4 in its current form was promulgated in connection with the 1996 rulemaking that exempted the acquisition of certain real property and goods acquired in the ordinary course of business. Consequently, its scope is limited to such acquisitions. This limitation of the exemption requires filings even for transactions of a type that the Commission has now deemed unlikely to create antitrust concerns.

For example, the current rule does not exempt the acquisition of voting securities of a U.S. issuer whose only assets are foreign with no nexus to the U.S., while the direct acquisition of those foreign assets would be exempt under § 802.50. Another example would be the acquisition of an issuer whose only assets consisted of cash and cash equivalents. While the direct acquisition of the assets would not be reportable under § 801.21, the acquisition of the voting securities is not exempted by the current version of the rule. It seems unlikely that a filing in such acquisitions of voting securities would prove useful if the direct acquisition of the same assets of the issuer would be exempt.

The exemption in § 802.4 applies to acquisitions of voting securities of issuers that hold certain assets that are exempt from the notification requirements if acquired directly. The exemption is only available if the acquired issuer or issuers do not in the aggregate hold non-exempt assets exceeding the $50 million notification threshold. The Commission now believes that this exemption should be expanded in two ways. First, consistent with the other proposed amendments to the rules, the proposed amendments to this exemption would apply to both acquisitions of voting securities and to acquisitions of non-corporate interests in an unincorporated entity. Second, the proposed exemption would be broadened to include acquisitions of voting securities of an issuer or of non-corporate interests which confer control of a non-corporate entity whose assets are exempt under any section of part 802 of the rules or section 7A(c) of the Act or are specified under § 802.21 of the rules. The Commission has concluded that if the direct acquisition of an asset is already exempt, it appears logical to extend that exemption to an acquisition of voting securities of an issuer or of non-corporate interests in a unincorporated entity whose only holding is that same asset.

The proposed rule would also codify another informal staff position that the value of any minority interests in either corporations or unincorporated entities does not count toward the $50 million limitation for non-exempt assets. However, the indirect acquisitions of such minority interests could be separately reportable as a secondary acquisition in the case of voting securities or if the acquiring person already has a minority interest in an unincorporated entity that, when combined with the interest being indirectly acquired, would result in control of that entity. The Commission believes that expanding coverage of § 802.4 would ensure that all of the exemptions are applied consistently to the substance of a transaction regardless of whether it is structured as an asset or a voting securities acquisition.

*Section 802.10 Stock Dividends and Splits; Reorganizations*

Proposed new § 802.10(b) would expand the existing exemption to codify another longstanding informal position that exempts the reincorporation or formation of an upstream holding company by an existing corporation, as long as two conditions are met: (1) no new assets will be introduced as a result of the conversion, and (2) the interests that will be held by an acquiring person in the new entity will be pro-rata to or less than the holdings in the original entity or the acquiring person was a controlling shareholder or interest holder prior to the conversion. The reorganization will be exempt for a person that controlled the original entity regardless of its holdings in the new entity as long as the first condition is met.

*Section 802.30 Intraperson Transactions*

Section 802.30 in its present form exempts acquisitions in which, by reason of holdings of voting securities, the acquiring and acquired person are the same person. Current § 802.30 produces another inconsistent application of an exemption dependent on whether a corporation or an unincorporated entity is involved in the transaction. Because of the qualifying phrase "by reason of holdings of voting securities'', entities that do not issue voting securities are excluded from the exemption. For example, if a corporate subsidiary transfers assets to its controlling shareholder, no filing is required. If an unincorporated subsidiary made the same transfer to a person who controlled it, the exemption would not apply. Similarly, if a parent controlled two corporations and transferred assets from one to the other, no filing is required. If a parent controlled two partnerships and made the same transfer between them, the exemption is inapplicable and a filing would be required. These scenarios seem at odds with the HSR rules' definition of "control'' and "hold'' because the parent holds the assets of the controlled entities both before and after each transaction.

Proposed § 802.30(a) would eliminate the requirement that control be through the holding of voting securities, and instead applies the appropriate control test in § 801.1(b)(1) to any type of entity. This proposed section also adds the provision that the exemption would apply if "at least one of the acquired persons'' is the same person. This insures that the proposed exemption would be available in an acquisition where there are two acquired ultimate parent entities as in proposed Example 1. These proposed changes would ensure that this prong of the intraperson exemption is applied consistently to all types of entities.

The proposed amendment to § 802.30(b) would restate the existing exemption for formation of wholly owned subsidiaries, but would change the language slightly to exempt the formation of any type of wholly-owned entity.

Proposed new § 802.30(c) would provide that assets which will be contributed to a new entity upon its formation would not be subject to the requirements of the Act with respect to the person contributing the assets to the formation. This is intended to eliminate a filing requirement where the assets contributed to the formation by other persons would not on their own be subject to the Act, such as when the controlling person contributes assets and the non-controlling person contributes only cash. This proposed exemption would be applicable to the formations of both unincorporated entities and corporations.

*Section 802.40 Exempt Formation of Corporations or Unincorporated Entities*

Section 802.40 is intended to exempt the formation of not-for-profit corporations, but its requirement that the acquisition be of voting securities of the not-for-profit is anomalous in that the vast majority of not-for-profit corporations do not issue voting securities. The proposed amendment to § 802.40 would correct this by removing the reference to voting securities, thereby extending the exemption to the formation of any not-for-profit entity

within the meaning of the cited sections of the Internal Revenue Code.

*Section 802.41 Corporations or Unincorporated Entities at the Time of Formation*

Section 802.41 states that in a formation of a joint venture or other corporation under § 801.40, only the acquiring persons need file notification and not the new entity being formed. The new corporation being formed is not required to file as an acquired person. The proposed amendment to § 802.41 would extend the same treatment to new unincorporated entities being formed under proposed new § 801.50.

*Section 802.65 Exempt Acquisition in Formation of Unincorporated Entity*

Proposed new § 802.65 would exempt certain acquisitions in financing transactions involving the formation of unincorporated entities. In some financing transactions, a new unincorporated entity is formed into which one party contributes assets and another contributes only cash. Initially, the cash investor will have a preferred return in order to recover its investment. As a result, that person may have the right to 50 percent or more of the profits of the entity for some period of time following the formation. Although this right to profits constitutes control of the entity under § 801.1(b), the investor has no operational control of the entity. This type of transaction is analogous to a creditor acquiring secured debt in the entity, an event which is not subject to the Act. Rather than taking back secured debt, however, the investor acquires an equity interest in the entity to obtain its return on investment. For these reasons, the Commission believes that such a financing arrangement is unlikely to raise antitrust concerns.

The proposed new exemption would be applicable if four conditions are met: (1) The acquiring person is contributing only cash to the formation of the entity; (2) the formation transaction is in the ordinary course of the acquiring person's business; (3) the terms of the formation agreement are such that the acquiring person will no longer control the entity after it realizes its preferred return; and (4) the acquiring person will not be a competitor of the new entity. While the investor's acquisition of control of the new entity at its formation would be exempt, the investor would be deemed to control the new entity for all other purposes following the formation.

**Part 803—Transmittal Rules**

*Appendix: Premerger Notification and Report Form*

Item 5(d) Corporations and Unincorporated Entities at the Time of Formation

Current Item 5(d) requires that certain additional information be provided when the Notification and Report Form is being submitted in connection with the formation of a new corporation. The proposed amendment to the Item 5(d) instructions would require that the same information be provided in connection with the formation of a new unincorporated entity pursuant to new § 801.50. Item 5(d) on the Notification and Report Form would be amended to include reference to unincorporated entities as well as corporations.

Item 7 NAICS Code Overlaps

The instructions to Item 7 currently require the reporting of any NAICS codes in which the person filing notification and any other person that is a party to the transaction also derived revenues in the most recent year. This language implies that in the formation of a new entity, overlaps among the acquiring persons contributing to the formation must be reported. The Commission believes that is overly burdensome and provides little helpful information because the only relevant overlap is between the person filing notification as an acquiring person and the newly formed entity. The proposed new language would also clarify that this information is provided in connection with the formation of new corporations and new unincorporated entities.

Item 8 Previous Acquisitions

The instructions to Item 8 would also be amended to include reference to newly formed unincorporated entities as well as corporations.

**Communications by Outside Parties to Commissioners and Their Advisors**

Written communications and summaries or transcripts of oral communications respecting the merits of this proceeding from any outside party to any Commissioner or Commissioner's advisor will be placed on the public record. 16 CFR 1.26(b)(5).

**Regulatory Flexibility Act**

The Regulatory Flexibility Act, 5 U.S.C. 601–612, requires that the agency conduct an initial and final regulatory analysis of the anticipated economic impact of the proposed amendments on small businesses, except where the Commission certifies that the regulatory action will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 605.

Because of the size of the transactions necessary to invoke a Hart-Scott-Rodino filing, the premerger notification rules rarely, if ever, affect small businesses. Indeed, the 2000 amendments to the Act were intended to reduce the burden of the premerger notification program by exempting all transactions valued at $50 million or less. Further, none of the proposed rule amendments expands the coverage of the premerger notification rules in a way that would affect small business. Accordingly, the Commission certifies that these proposed rules will not have a significant economic impact on a substantial number of small entities. This document serves as the required notice of this certification to the Small Business Administration.

**Paperwork Reduction Act**

The Paperwork Reduction Act, 44 U.S.C. 3501–3518, requires agencies to submit "collections of information'' to the Office of Management and Budget ("OMB'') and obtain clearance before instituting them. Such collections of information include reporting, recordkeeping, or disclosure requirements contained in regulations. The information collection requirements in the HSR rules and Form have been reviewed and approved by OMB under OMB Control No. 3084–0005. The current clearance expires on May 31, 2004, and the FTC is seeking a renewal clearance from OMB.[29] Because the rule amendments proposed in this NPR would change existing reporting requirements, the Commission has submitted a Supporting Statement for Information Collection Provisions to OMB.

*Increase in Filings Due to Proposed Change in Filing Requirements for Non-Corporate Entities*

The proposed amendments make certain acquisitions of controlling interests in existing and newly-formed non-corporate entities a reportable event. Currently, a filing is only required if 100 percent of the interests in a non-corporate entity are acquired.

Staff has estimated the increase in reportable transactions due to this aspect of the proposed rule by making reasonable deductions using publicly available statistics, from the State of Delaware, which is a leading domicile for U.S. and international corporations. More than half a million business entities have made Delaware their legal home including 280,000 corporations

[29] 69 FR 7225 (February 13, 2004).

and 250,000 limited liability companies and partnerships. More than 50% of all publicly-traded companies in the United States including 58% of the Fortune 500 have chosen Delaware as their legal home.[30] Based on the above estimates, unincorporated entities in Delaware represent a figure that is 47% of the total entities registered in Delaware. In the absence of other relevant available data, staff believes that this is approximately the same proportion nationwide.

The total number of transactions requiring HSR filings in FY 2003 in which a controlling interest in a corporation was acquired is 495. Applying the 47% figure from above, staff estimates a total of 233 transactions requiring HSR filings for acquisitions of a controlling interest in an unincorporated entity under the proposed rules (495 × .47 = 233).[31] This estimate is extremely conservative because HSR filings are already required for acquisitions of 100 percent of the interests in an unincorporated entity and for certain formations of LLCs. Using a conservative estimate that 50% of acquisitions of controlling interests in unincorporated entities are already reported at a different point than they will be under the proposed rules results in a projected increase of 117 transactions requiring HSR filings (233 × .50 = 117).

*Decrease Due to Proposed Broadening of the Exemptions*

The broadening of the exemptions in the proposed rules would eliminate the filing requirement for a number of the projected filings for unincorporated entities. The intraperson exemption in § 802.30 currently only applies to corporations. The proposed amendments would expand this exemption to cover non-corporate entities as well. Additionally, proposed new § 802.65 exempts the acquisition of a controlling interest in a non-corporate entity which is being formed in connection with a financing transaction. Applying an extremely conservative estimate of 50% of these transactions qualifying for exemption, the total projected decrease is 59 (117 × .50 = 59).

This estimate is conservative, because a number of filings for corporate transactions would also be exempted under the proposed rules which would require a filing under the current rules. In particular, § 802.4, which exempts acquisitions of voting securities of an issuer which holds exempt assets, is currently limited to a narrow range of real property and ordinary course of business related assets. The proposed amendment to this exemption would expand coverage to all assets exempted in any section of the HSR rules or the Act. Again, applying a conservative estimate that 10% of the total transactions involving acquiring a controlling interest in a corporation would now be exempted, a total of 50 transactions which currently require HSR filings would be exempted under the proposed rule (495 × .10 = 50).

*Net Effect*

Staff estimates that there will be an increase of 9 transactions requiring HSR filings due to the proposed rule change. This represents a less than 1% increase as a result of the proposed rules over the 968 total transactions that required HSR non-index filings in FY 2003 (9/968 = .009 or 0.9%).[32] Therefore, staff estimates that the total burden hours under the HSR rules as revised will be 87,530 hours, which is an increase of 702 hours from the staff's estimate of 86,828 hours for the current rules.[33] Similarly, staff estimate the labor costs under the proposed rules to be $37,200,000 (rounded to the nearest thousand), an increase of $300,000 from the estimate of $36,902,000.

The Commission invites comments that will enable it to: (1) Evaluate whether the proposed collections of information are necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) evaluate the accuracy of the Commission's estimate of the burden of the proposed collections 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 collections of information on those who must comply, including through the use of appropriate automated, electronic, mechanical, or other technological techniques or other forms of information technology.

**List of Subjects in 16 CFR Parts 801, 802 and 803**

Antitrust.

For the reasons stated in the preamble, the Federal Trade Commission proposes to amend 16 CFR parts 801, 802 and 803 as set forth below:

## PART 801—COVERAGE RULES

1. The authority citation for part 801 continues to read as follows:

**Authority:** 15 U.S.C. 18a(d).

2. Amend § 801.1 by revising paragraphs (b)(1)(ii) and (b)(2), redesignating paragraph (f)(1) as (f)(1)(i) and adding paragraph (f)(1)(ii) to read as follows:

**§ 801.1 Definitions.**

* * * * *

(b) * * *

(1) *Either.* (i) * * *

(ii) In the case of an unincorporated entity, having the right to 50 percent or more of the profits of the entity, or having the right in the event of dissolution to 50 percent or more of the assets of the entity; or

(2) Having the contractual power presently to designate 50 percent or more of the directors of a for-profit or not-for-profit corporation.

* * * * *

(f)(1)(i) *Voting securities.* * * *

(ii) *Non-corporate interest.* The term "non-corporate interest'' means an interest in any unincorporated entity which gives the holder the right to any profits of the entity or the right to any assets of the entity in the event of dissolution of that entity. These unincorporated entities include, but are not limited to, general partnerships, limited partnerships, limited liability partnerships, limited liability companies, cooperatives and business trusts; but these unincorporated entities do not include trusts described in paragraphs (c)(3) through (5) of this section and any interest in such a trust is not a non-corporate interest as defined by this rule.

* * * * *

3. Amend § 801.2 by revising paragraph (d)(2)(iii), adding an Example

[30] Delaware Division of Corporations *(www.state.de.us/corp/aboutagency.shtml).*

[31] All calculations in this section are rounded to the nearest whole number.

[32] Clayton Act sections 7A(c)(6) and (c)(8) exempt from the requirements of the premerger notification program certain transactions that are subject to the approval of other agencies, but only if copies of the information submitted to these other agencies are also submitted to the FTC and the Assistant Attorney General. Thus, parties must submit copies of these "index'' filings, but completing the task requires significantly less time than non-exempt transactions which require "non-index'' filings.

[33] As explained in the Notice that solicits comment on the renewal clearance for the rules, the staff estimated the hours burden under the current rules as 86,828 hours [(21 index filings × 2 hours) + (2,174 non-index filings × 39 hours) + (50 transactions requiring more precise valuation × 40 hours)]. *See* 69 FR 7225 (February 13, 2004). Staff estimates that the proposed rules will increase by 9 the number of transactions that require non-index filings, thereby increasing the number of non-index filings by 18 to 2,192 [2,174 + (9 transactions × 2 filings per transaction)]. Accordingly, staff estimates the hours burden for the proposed rule as 87,530 hours [(21 index filings × 2 hours) + (2,192 non-index filings × 39 hours) + (50 transactions × 40 hours)]. [(87,530 hours × $425/hour for executives and attorneys' wages) = $37,200,250].

6 and designating the Examples as Examples 1 through 6 to paragraph (d)(2)(iii), and by adding paragraph (f) to read as follows:

**§ 801.2 Acquiring and acquired persons.**

* * * * *

(d) * * *

(2) * * *

(iii) All persons party to a transaction as a result of which all parties will lose their separate pre-acquisition identities or will become wholly owned subsidiaries of a newly formed entity shall be both acquiring and acquired persons. This includes any combination of corporations and unincorporated entities consolidating into any newly formed entity. In such transactions, each consolidating entity is deemed to be acquiring all of the voting securities (in the case of a corporation) or interests (in the case of an unincorporated entity) of each of the others. Dual-listed company arrangements under which two entities effectively combine their assets and operations by agreement are governed by this rule.

*Examples to paragraph (d)(2)(iii):* * * *

6. Partnership A and Corporation B form a new LLC in which they combine their businesses. A and B cease to exist and partners of A and shareholders of B receive membership interests in the new LLC. For purposes of determining reportability, A is deemed to be acquiring 100 percent of the voting securities of B and B is deemed to be acquiring 100 percent of the interests of A. Pursuant to § 803.9(b) of this chapter, even if such a transaction consists of two reportable acquisitions, only one filing fee is required.

* * * * *

(f)(1)(i) In an acquisition of non-corporate interests which results in a person controlling the entity, that person is deemed to hold all of the assets of the entity as a result of the acquisition. The acquiring person is the person acquiring control of the entity and the acquired person is the pre-acquisition ultimate parent entity of the entity.

(ii) The value of an acquisition described in paragraph (f)(1)(i) of this section is determined in accordance with § 801.10(d).

(2) Any contribution of assets or voting securities to an existing unincorporated entity is deemed an acquisition of such voting securities or assets by the ultimate parent entity of that entity. If the only consideration for such contribution or acquisition is interests in the entity, neither the contribution nor the receipt of interests is subject to § 801.50.

*Examples to paragraph (f)(2):* 1. A, B and C each hold 33⅓ percent of the interests in Partnership X. D contributes assets valued in excess of $50 million to X and as a result D receives 40 percent of the interests in X and A, B and C are each reduced to 20 percent. Partnership X is deemed to be acquiring the assets from D, in a transaction which may be reportable. This is not treated as a formation of a new partnership. Because no person will control Partnership X, no additional filing is required by any of the four partners.

2. LLC X is its own ultimate parent entity. A contributes a manufacturing plant valued in excess of $200 million to X which issues new interests to A resulting in A having a 50% interest in X. A is acquiring non-corporate interests which confer control of X and therefore will file as an acquiring person. LLC X is not an acquiring person with respect to the contribution of the plant by A, because A held the plant prior to the transaction and continues to hold it through its acquisition of control of LLC X after the transaction is completed.

(3) Any person who acquires control of an existing not-for-profit corporation which has no outstanding voting securities is deemed to be acquiring all of the assets of that corporation.

*Example to paragraph (f)(3):* A becomes the sole corporate member of not-for-profit corporation B and accordingly has the right to designate all of the directors of B. A is deemed to be acquiring all of the assets of B as a result.

4. Amend § 801.4 by revising paragraph (a) to read as follows:

**§ 801.4 Secondary acquisitions.**

(a) Whenever as the result of an acquisition (the "primary acquisition") an acquiring person controls an entity which holds voting securities of an issuer that entity does not control, then the acquiring person's acquisition of the issuer's voting securities is a secondary acquisition and is separately subject to the act and these rules.

* * * * *

5. Amend § 801.10 by revising the heading and by adding paragraph (d) to read as follows:

**§ 801.10 Value of voting securities, non-corporate interests and assets to be acquired.**

* * * * *

(d) *Value of interests in an unincorporated entity.* In an acquisition of non-corporate interests that confers control of either an existing or a newly-formed unincorporated entity, the value of the non-corporate interests held as a result of the acquisition is the sum of the acquisition price of the interests to be acquired (provided the acquisition price has been determined), and the fair market value of any of the interests in the same unincorporated entity held by the acquiring person prior to the acquisition; or, if the acquisition price has not been determined, the fair market value of interests held as a result of the acquisition.

6. Amend § 801.13 by revising the heading, by revising paragraph (b)(2), by removing the Example following paragraph (b)(2) and adding four Examples in its place, and adding paragraph (c) and two examples to read as follows:

**§ 801.13 Aggregation of voting securities, assets and non-corporate interests.**

* * * * *

(b) *Assets.* * * *

(2) If the acquiring person signs a letter of intent or agreement in principle to acquire assets from an acquired person, and within the previous 180 days the acquiring person has:

(i) Signed a letter of intent or agreement in principle to acquire assets from the same acquired person, which is still in effect but has not been consummated, or has acquired assets from the same acquired person which it still holds; and

(ii) The contemplated or consummated previous acquisition was not subject to the requirements of the Act; then for purposes of the size-of-transaction test of Section 7A(a)(2), both the acquiring and the acquired persons shall treat the assets that were the subject of the earlier letter of intent or agreement in principal as though they are being acquired as part of the present acquisition. The value of any assets which are subject to this paragraph is determined in accordance with § 801.10(b).

*Examples to paragraph (b)(2):* 1. On day 1, A enters into an agreement with B to acquire assets valued at $40 million. On day 90, A and B sign a letter of intent pursuant to which A will acquire additional assets from B, valued at $20 million. The original transaction has not closed, however, the agreement is still in effect. For purposes of the size-of-transaction test in Section 7A(a)(2), A must aggregate the value of both of its acquisitions.

2. On March 30, A enters into a letter of intent to acquire assets of B valued at $45 million. On January 31, earlier the same year, A closed on an acquisition of assets of B valued at $10 million. For purposes of the size-of-transaction test in Section 7A(a)(2), A must aggregate the value of both of its acquisitions.

3. On day 1, A enters into an agreement with B to acquire assets valued at $60 million. A and B file notification and observe the waiting period. On day 60, A signs a letter of intent to acquire an additional $40 million of assets from B. Because the earlier acquisition was subject to the requirements of the Act, A does not aggregate the two acquisitions of assets.

4. On day 1, A consummates an acquisition of assets of B valued at $30 million. On day 60, A consummates a sale of the same assets to an unrelated third party. On day 120, A

enters into an agreement to acquire additional assets of B valued at $30 million. Because A no longer holds the assets from the previous acquisition, no aggregation of the two asset acquisitions is required.

(c) (1) *Non-corporate interests.* In an acquisition of non-corporate interests, any previously acquired non-corporate interests in the same unincorporated entity is aggregated with the newly acquired interests. The value of such an acquisition is determined in accordance with § 801.10(d) of these rules.

(2) *Other assets or voting securities of the same acquired person.* An acquisition of non-corporate interests which does not confer control of the unincorporated entity is not aggregated with any other assets or voting securities which have been or are currently being acquired from the same acquired person.

*Examples to paragraph (c)(2):* 1. A currently has the right to 30 percent of the profits in LLC. B has the right to the remaining 70 percent. A acquires an additional 30 percent interest in LLC from B for $60 million in cash. As a result of the acquisition, A is deemed to now have a 60 percent interest in LLC. The current acquisition is valued at $60 million, the acquisition price. The value of the 30 percent interest that A already holds is the fair market value of that interest. The value for size-of-transaction purposes is the sum of the two.

2. A acquires the following from B: (1) all of the assets of a subsidiary of B; (2) all of the voting securities of another subsidiary of B; and (3) a 30 percent interest in an LLC which is currently wholly-owned by B. In determining the size-of-transaction, A aggregates the value of the voting securities and assets of the subsidiaries that it is acquiring from B, but does not include the value of the 30 percent interest in the LLC, pursuant to § 801.13(c)(2).

7. Amend § 801.15 by revising paragraphs (b) and (c), adding paragraph (d), designating the Examples as Examples to the entire section, and adding example 9 to read as follows:

**§ 801.15 Aggregation of voting securities and assets the acquisition of which was exempt.**

* * * * *

(b) Assets or voting securities the acquisition of which was exempt at the time of acquisition (or would have been exempt, had the Act and these rules been in effect), or the present acquisition of which is exempt, under Section 7A(c)(9) and §§ 802.3, 802.4, and 802.64 of this chapter unless the limitations contained in Section 7A(c)(9) or those sections do not apply or as a result of the acquisition would be exceeded, in which case the assets or voting securities so acquired will be held; and

(c) Voting securities the acquisition of which was exempt at the time of acquisition (or would have been exempt, had the Act and these rules been in effect), or the present acquisition of which is exempt, under section 7A(c)(11)(A) unless additional voting securities of the same issuer have been or are being acquired; and

(d) Assets or voting securities the acquisition of which was exempt at the time of acquisition (or would have been exempt, had the Act and these rules been in effect), or the present acquisition of which is exempt, under §§ 802.50(a), 802.51(a), 802.51(b) of this chapter unless the limitations, in aggregate for §§ 802.50(a), 802.51(a), 802.51(b), do not apply or as a result of the acquisition would be exceeded, in which case the assets or voting securities so acquired will be held.

*Examples to this section:* * * *

9. A acquires assets of B located outside of the U.S. with sales into the U.S. of $20 million. It also acquires voting securities of B's foreign subsidiary X which has sales into the U.S. of $40 million. Both the assets and the voting securities of X are exempt under §§ 802.50 and 802.51 respectively when analyzed separately. However, because § 801.15(d) requires that the sales into the U.S. for both the assets and the voting securities be aggregated to determine whether the $50 million limitation has been exceeded, both are held as a result of the acquisition because the aggregate sales into the U.S. total $60 million.

8. Add new § 801.50 to read as follows:

**§ 801.50 Formation of unincorporated entities.**

(a) Unless exempted by the Act or any of these rules, upon the formation of an unincorporated entity, in a transaction meeting the criteria of section 7A(a)(1) and 7A(a)(2)(A), an acquiring person is subject to the requirements of the Act if it acquires control of the newly-formed entity.

(b) Unless exempted by the Act or any of these rules, upon the formation of an unincorporated entity, in a transaction meeting the criteria of section 7A(a)(1), the criteria of section 7A(a)(2)(B)(i), and the criteria of paragraph (a) of this section (other than in connection with a consolidation), an acquiring person is subject to the requirements of the Act if:

(1)(i) The acquiring person has annual net sales or total assets of $100 million or more;

(ii) The newly-formed entity has total assets of $10 million or more; and

(iii) The acquiring person acquires control of the newly-formed entity; or

(2)(i) The acquiring person has annual net sales or total assets of $10 million or more;

(ii) The newly-formed entity has total assets of $100 million or more; and

(iii) The acquiring person acquires control of the newly-formed entity.

(c) For purposes of paragraph (b) of this section, the total assets of the newly-formed entity is determined in accordance with § 801.40(d).

(d) Any person acquiring control of the newly-formed entity determines the value of its acquisition in accordance with § 801.10(d).

(e) The commerce criterion of section 7A(a)(1) is satisfied if either the Activities of any acquiring person are in or affect commerce, or the person filing notification should reasonably believe that the Activities of the newly-formed entity will be in or will affect commerce.

## PART 802—EXEMPTION RULES

9. The authority citation for part 802 continues to read as follows:

**Authority:** 15 U.S.C. 18a(d).

10. Amend § 802.2 by revising the introductory language in paragraph (g), by revising (g)(1)(ii), and by adding paragraph (g)(1)(iii) to read as follows:

**§ 802.2 Certain acquisitions of real property assets.**

* * * * *

(g) *Agricultural property.* An acquisition of agricultural property and assets incidental to the ownership of such property shall be exempt from the requirements of the Act. Agricultural property is real property that primarily generates revenues from the production of crops, fruits, vegetables, livestock, poultry, milk and eggs (certain activities within NAICS sector 11).

(1) * * *

(ii) Any real property and assets either adjacent to or used in conjunction with processing facilities that are included in the acquisition; or

(iii) Timberland or other real property that generates revenues from activities within NAICS subsector 113 (Forestry and logging) or NAICS industry group 1153 (Support activities for forestry and logging).

* * * * *

11. Amend § 802.4 by revising the heading and revising paragraph (a) and adding an example thereunder to read as follows:

**§ 802.4 Acquisitions of voting securities of issuers or non-corporate interests in unincorporated entities holding certain assets the acquisition of which is exempt.**

(a) An acquisition of voting securities of an issuer or non-corporate interests in an unincorporated entity whose assets together with those of all entities it

controls consist or will consist of assets whose acquisition is exempt from the requirements of the Act pursuant to section 7A(c) of the Act, this part 802, or pursuant to § 801.21 of this chapter, is exempt from the reporting requirements if the acquired issuer or unincorporated entity and all entities it controls do not hold non-exempt assets with an aggregate fair market value of more than $50 million. The value of voting or non-voting securities of any other issuer or interests in any non-corporate entity not included within the acquired issuer does not count toward the $50 million limitation for non-exempt assets.

*Example to paragraph (a):* A and B form a new corporation as an acquisition vehicle to acquire all of the voting securities of C. Each contributes $250 million in cash. Because all of the cash is considered to be exempt assets pursuant to § 801.21, the new corporation does not have non-exempt assets valued in excess of $50 million, and the acquisition of its voting securities by A and B is exempt under § 802.4. Note that the result is the same if the acquisition vehicle is formed as an unincorporated entity. Also see the examples to § 802.30(c) for additional applications of § 802.4.

* * * * *

12. Revise § 802.10 to read as follows:

**§ 802.10 Stock dividends and splits; reorganizations.**

(a) The acquisition of voting securities pursuant to a stock split or pro rata stock dividend is exempt from the requirements of the Act under section 7A(c)(10).

(b) An acquisition of non-corporate interests or voting securities as a result of the conversion of a corporation or unincorporated entity into a new entity is exempt from the requirements of the Act if:

(1) No new assets will be contributed to the new entity as a result of the conversion; and

(2) Either:

(i) As a result of the transaction the acquiring person does not increase its per centum holdings in the new entity relative to its per centum holdings in the original entity; or

(ii) The acquiring person controlled the original entity.

*Examples to paragraph (b):* 1. Partners A and B hold 60 percent and 40 percent respectively of the partnership interests in C. C is converted to a corporation in which A and B hold 60 percent and 40 percent respectively of the voting securities. No new assets are contributed. The conversion to a corporation is exempt from notification for both A and B.

2. Shareholder A holds 55% and B holds 45% of the voting securities of corporation C. C is converted to a limited liability company in which A holds 60% and B holds 40% of the membership interests. No new assets are contributed. The conversion to a limited liability company is exempt from notification because A controlled the corporation. If however, B holds 55% and A holds 45% in the new limited liability company, the conversion is not exempt for B and may require notification because control changes.

3. Shareholders A, B and C each hold one third of the voting securities of corporation X. Pursuant to a reorganization agreement, A and B each contribute new assets to X and C contributes cash. X is then being reincorporated in a new state. Each of A, B and C receive one third of the voting securities of newly reincorporated C. The reincorporation is not exempt from notification and may be reportable for A, B and C because of the contribution of new assets.

13. Revise § 802.30 to read as follows:

**§ 802.30 Intraperson transactions.**

(a) An acquisition (other than the formation of a corporation or unincorporated entity under § 801.40 or § 801.50 of this chapter) in which the acquiring and at least one of the acquired persons are, the same person by reason of § 801.1(b)(1) of this chapter, or in the case of a not-for-profit corporation which has no outstanding voting securities, by reason of § 801.1(b)(2) of this chapter, is exempt from the requirements of the Act.

*Examples:* Examples to paragraph (a):

1. A and B each have the right to 50% of the profits of partnership X. A also holds 100% of the voting securities of corporation Y. A pays B $100 million in cash and transfers certain assets of X to Y. Because A is the acquiring person through its control of Y, pursuant to § 801.1(b)(1)(i), and one of the acquired persons through its control of X pursuant to § 801.1(b)(1)(ii) , the acquisition of assets is exempt under § 802.30(a).

2. A and B each have the right to 50% of the profits of partnership X. A contributes assets to X valued in excess of $50 million. B contributes cash to X. Because B is an acquiring person but not an acquired person, its acquisition of the assets contributed to X by A is not exempt under § 802.30(a). However, A is both an acquiring and acquired person, and its acquisition of the assets it is contributing to X is exempt under § 802.30(a).

(b) The formation of any wholly owned entity is exempt from the requirements of the Act.

(c) Assets contributed to a new entity upon its formation are not subject to the requirements of the Act with respect to the person contributing the assets to the formation.

*Examples to paragraph (c):* 1. A and B form a new partnership to which A contributes a manufacturing plant valued at $51 million and acquires a 51% interest in the partnership. B contributes $49 million in cash and acquires a 49% interest. B is not acquiring non-corporate interests which confer control of the partnership and therefore is not making a reportable acquisition. A is acquiring non-corporate interests which confer control of the partnership, however, the manufacturing plant it is contributing to the formation is exempt under § 802.30(c) and the cash contributed by B is excluded under § 801.21, therefore, the acquisition of non-corporate interests by A is exempt under § 802.4.

2. A and B form a new corporation to which A contributes a plant valued at $120 million and acquires 60% of the voting securities of the new corporation. B contributes a plant valued at $80 million and acquires 40% of the voting securities of the new corporation. While the assets contributed to the formation are exempted by § 802.30(c) for each of A and B, the new corporation holds more than $50 million in non-exempt assets (the plant contributed by the other person) with respect to both acquisitions. A is now acquiring voting securities of an issuer which holds $80 million in non-exempt assets (the plant contributed by B), and B is acquiring voting securities of an issuer which holds $120 million in non-exempt assets (the plant contributed by A). Therefore neither acquisition of voting securities is exempt under § 802.4. Note that in contrast to the formation of the partnership in Example 1, B is not required to acquire a controlling interest in the corporation in order to have a reportable transaction.

3. A and B form a 50/50 partnership. A contributes a plant valued at $60 million and B contributes a plant valued at $40 million and $20 million in cash. Because with respect to A, the new partnership has non-exempt assets of $40 million (the plant contributed by B), A's acquisition of non-corporate interests is exempt under § 802.4. With respect to B, the new partnership holds $60 million in non-exempt assets (the plant contributed by A), therefore B's acquisition of non-corporate interests would not be exempt under § 802.4.

14. Revise § 802.40 to read as follows:

**§ 802.40 Exempt formation of corporations or unincorporated entities.**

The formation of an entity is exempt from the requirements of the Act if the entity will be not-for-profit within the meaning of sections 501(c)(1)–(4), (6)–(15), (17)–(20) or (d) of the Internal Revenue Code.

15. Amend § 802.41 by revising the heading and the introductory text to read as follows:

**§ 802.41 Corporations or unincorporated entities at time of formation.**

Whenever any person(s) contributing to the formation of an entity are subject to the requirements of the Act by reason of § 801.40 or § 801.50 of this chapter, the new entity need not file the notification required by the Act and § 803.1 of this chapter.

*Examples:*

* * * * *

16. Add new § 802.65 to read as follows:

**§ 802.65 Exempt acquisition in formation of unincorporated entity.**

In a transaction to which § 801.50 of this chapter applies, an acquisition of non-corporate interests that confers control of the newly-formed unincorporated entity is exempt from the notification requirements of the Act if:

(a) The acquiring person is contributing only cash to the formation;

(b) The formation transaction is in the ordinary course of the acquiring person's business;

(c) The terms of the formation agreement are such that the acquiring person will no longer control the entity after it realizes its preferred return; and

(d) The acquiring person will not be a competitor to the new entity.

## PART 803—TRANSMITTAL RULES

17. The authority citation for part 803 continues to read as follows:

**Authority:** 15 U.S.C. 18a(d).

18. Revise the Appendix to part 803 to read as follows:

BILLING CODE 6750–01–P

## Appendix to Part 803

# ANTITRUST IMPROVEMENTS ACT NOTIFICATION AND REPORT FORM for Certain Mergers and Acquisitions

## INSTRUCTIONS

### GENERAL

The Answer Sheets (pp. 1-15) constitute the Notification and Report Form ("the Form") required to be submitted pursuant to § 803.1(a) of the premerger notification rules ("the rules"). Filing persons need not, however, record their responses on the Form.

These instructions specify the information which must be provided in response to the Items on the Answer Sheets. Only the completed Answer Sheets, together with all documentary attachments, are to be filed with the Federal Trade Commission and the Department of Justice.

Persons providing responses on attachment pages rather than on answer sheets must submit a complete set of attachment pages with each copy of the Form.

The term "documentary attachments" refers to materials supplied in responses to Item 3(d), Item 4 and to submissions pursuant to §§ 803.1(b) and 803.11 of the rules.

**Information**-The central office for information and assistance concerning the rules, 16 CFR Parts 801-803, and the Form is Room 303, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580, phone (202) 326-3100.

**Definitions**-The definitions and other provisions governing this Form are set forth in the rules, 16 CFR Parts 801-803. The governing statute, the rules, and the Statement of Basis and Purpose for the rules are set forth at 43 FR 33450 (July 31, 1978), 44 FR 66781 (November 22, 1979) 48 FR 34427 (July 29, 1983) and Pub. L. No. 106-533, 114 Stat. 2762.

**Affidavit**-Attach the affidavit required by § 803.5 to page 1 of the Form. Affidavits are not required if the person filing notification is an acquired person in a transaction covered by § 801.30. (See § 803.5(a)).

**Responses**-*Each answer* should identify the Item to which it is addressed. Use the reverse side of the corresponding answer sheet or attach separate additional sheets as necessary in answering each Item. Each additional sheet should identify at the top of the page the Item to which it is addressed. Voluntary submissions pursuant to § 803.1(b) should also be identified.

Enter the name of the person filing notification appearing in Item 1(a) on page 1 of the Form and the date on which the Form is completed at the top of each page of the Form, at the top of any sheets attached to complete the response to any Item, and at the top of the first or cover page of each documentary attachment.

If unable to answer any Item fully, give such information as is available and provide a statement of reasons for non-compliance as required by § 803.3. If exact answers to any Item cannot be given, enter best estimates and indicate the sources or bases of such estimates. Estimated data should be followed by the notation, "est." All information should be rounded to the nearest thousand dollars.

**Year**-All references to "year" refer to calendar year. If the data are not available on a calendar year basis, supply the requested data for the fiscal year reporting period which most nearly corresponds to the calendar year specified. References to "most recent year" mean the most recent calendar or fiscal year for which the requested information is available.

**North American Industry Classification System (NAICS) Data**-This Notification and Report Form requests information regarding dollar revenues and lines of commerce at three levels with respect to operations conducted within the United States. (See § 803.2(c)(1).) All persons must submit certain data at the 6-digit NAICS national industry code level. To the extent that dollar revenues are derived from *manufacturing operations* (NAICS Sectors 31-33), data must also be submitted at the *7-digit NAICS product class and 10-digit NAICS product code levels.* The term "dollar revenues" is defined in § 803.2(d).

**References**-In reporting information by 6-digit NAICS industry code refer to the *North American Industry Classification System - United States, 1997* (*1997 NAICS Manual*) published by the Executive Office of the President, Office of Management and Budget. In reporting information by 7-digit NAICS product class and 10-digit NAICS product code refer to the *1997 Numerical List of Manufactured and Mineral Products* (EC97M31R-NL) published by the Bureau of the Census. Information regarding NAICS also is available at www.census.gov.

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Privacy Act Statement-Section 18a(a) of Title 15 of the U.S. Code authorizes the collection of this information. The primary use of this information is to determine whether the merger or acquisition reported in the Notification and Report Form may violate the antitrust laws.

Furnishing the information on the Form is voluntary. Consummation of an acquisition required to be reported by the statute cited above without having provided this information may, however, render a person liable to civil penalties up to $11,000 per day.

**Items 5, 7, 8**-Supply information only with respect to operations conducted within the United States, including its commonwealths, territories, possessions and the District of Columbia. (See §§ 801.1(k); 803.2(c)(1).)

Information need not be supplied regarding assets or voting securities currently being acquired, when the acquisition is exempt under the statute or rules. (See § 803.2(c)(2).)

The acquired person should limit its response in the case of an acquisition of assets, to the assets being sold, and in the case of an acquisition of voting securities, to the issuer(s) whose voting securities are being acquired and all entities controlled by such issuer. Separate responses may be required where a person is both acquiring and acquired. (See § 803.2(b) and (c).)

**Filing**-Complete and return two copies (with one notarized original affidavit and certification and one set of documentary attachments) of this Notification and Report Form to the Premerger Notification Office, Bureau of Competition, Room 303, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Three copies (with one set of documentary attachments) should be sent to: Director of Operations, Antitrust Division, Department of Justice, Patrick Henry Bldg., 601 D Street, N.W., Room #10013, Washington, D.C. 20530. (For FEDEX airbills to the Department of Justice, do not use the 20530 zip code; use zip code 20004.)

**ITEM BY ITEM**

**Affidavit**-Attach the affidavit required by § 803.5 to page 1 of the Answer Sheets. Acquiring persons in transactions covered by § 801.30 are required to also submit a copy of the notice served on the acquired person pursuant to § 803.5(a)(1). (See § 803.5(a)(3).)

**Fee Information**-The fee for filing the Notification and Report Form is based on the aggregate total amount of assets and voting securities to be held as a result of the acquisition:

| Value of assets or voting securities to be held | Fee Amount |
|---|---|
| greater than $50 million but less than $100 million | $45,000 |
| $100 million or greater but less than $500 million | $125,000 |
| $500 million or greater | $280,000 |

**Amount Paid**-Indicate the amount of the filing fee paid. This amount should be net of any banking or financial institution charges. Where an explanatory attachment is required, include in your explanation any adjustments to the acquisition price that serve to lower the fee from that which would otherwise be due. If there is no acquisition price or if the acquisition price may fall within a range that straddles two filing fee thresholds, state the transaction value on which the fee is based and explain the valuation method used. Include in your explanation a description of any exempt assets, the value assigned to each, and the valuation method used.

A Valuation Worksheet available from the Premerger Notification Office will be helpful in determining the value of a transaction for filing and fee purposes. This Worksheet need not be submitted with the Notification and Report Form, but it or something similar should be utilized and retained by the acquiring person in the event
Commission staff has questions about the valuation of the transaction.

**Payer Identification**- Provide the 9-digit Taxpayer Identification Number (TIN) of the acquiring person and, if different from the filing person, the TIN of the payer(s) of the filing fee. A payer or filing person who is a natural person having no TIN must provide the name and social security number (SSN) of the payer. If the payer or filing person is a foreign person, only the name of the payer and the name of the filing person need be supplied if different.

**Method of Payment**-Check the box indicating the method of fee payment. If paying by electronic wire transfer (EWT), provide the name of the financial institution from which the EWT is being sent and the confirmation number.

To insure filing fees paid by EWT are attributed to the appropriate payer filing notification, the payer must provide the following information to the financial institution initiating the EWT:

The Department of Treasury's ABA Number: 021030004; and
The Federal Trade Commission's ALC Number: 29000001.

If the name used to transmit the EWT differs from the filer's name, provide the alternative name. If the confirmation number is unavailable at the time notification is filed, provide this information by letter within one business day of filing.

**Corrective Filing**-Put an X in the appropriate box to indicate whether the notification is a corrective filing being made for an acquisition that has already taken place in violation of the statute. Attach a detailed, written explanation signed by a company official explaining (1) how the violation occurred, (2) when and how the violation was discovered and (3) what steps will be taken to ensure compliance in the future.

**Transactions Subject to Foreign Antitrust Notification**-If to the knowledge or belief of the filing person at the time of filing this notification, a foreign antitrust or competition authority has been or will be notified of the proposed transaction, list the name of each such authority and the date or anticipated date of each such notification. Response to this item is voluntary.

**Cash Tender Offer**-Put an X in the appropriate box to indicate whether the acquisition is a cash tender offer.

**Bankruptcy**-Put an X in the appropriate box to indicate whether the acquired person's filing is being made by a trustee in bankruptcy or a debtor-in-possession for a transaction that is subject to section 363(b) of the Bankruptcy Code (11USC § 363).

**Early Termination**-Put an X in the yes box to request early termination of the waiting period. Notification of each grant of early termination will be published in the Federal Register as required by § 7A(b)(2) of the Clayton Act and on the FTC web site www.ftc.gov.

## ITEM 1

**Item 1(a)**-Give the name and headquarters address of the person filing notification. The name of the person is the name of the ultimate parent entity included within that person.

**Item 1(b)**-Indicate whether the person filing notification is an acquiring person, an acquired person, or both an acquiring and acquired person. (See § 801.2.)

**Item 1(c)**-Put an X in the appropriate box to indicate whether the person in Item 1(a) is a corporation, partnership or other (specify).

**Item 1(d)**-Put an X in the appropriate box to indicate whether data furnished is by calendar year or fiscal year. If fiscal year, specify period.

**Item 1(e)**-Put an X in the appropriate box to indicate if this Form is being filed on behalf of the ultimate parent entity by another entity within the same person authorized by it to file notification on its behalf pursuant to § 803.2(a), or if this Form is being filed pursuant to § 803.4 on behalf of a foreign person. Then provide the name and mailing address of the entity filing notification on behalf of the reporting person named in Item 1(a) of the Form.

**Item 1(f)**-If an entity within the person filing notification other than the ultimate parent entity listed in Item 1(a) is the entity which is making the acquisition, or if the assets or voting securities of an entity other than the ultimate parent entity listed in Item 1(a) are being acquired, provide the name and mailing address of that entity and the percentage of its voting securities held by the person named in Item 1(a) above. (If control is effected by means other than the direct holding of the entity's voting securities, describe the intermediaries or the contract through which control is effected (see § 801.1(b)).

**Item 1(g)**-Print or type the name and title, firm name, address, telephone number, fax number and e-mail address of the individual to contact regarding this Notification and Report Form. (See § 803.20(b)(2)(ii).)

**Item 1(h)**-Foreign filing persons print or type the name and title, firm name, address, telephone number, fax number and e-mail address of an individual located in the United States designated for the limited purpose of receiving notice of the issuance of a request for additional information or documentary material. (See § 803.20(b)(2)(iii).)

## ITEM 2

**Item 2(a)**-Give the names of all ultimate parent entities of acquiring and acquired person which are parties to the acquisition whether or not they are required to file notification.

**Item 2(b)**-Put an X in all the boxes that apply to this acquisition.

**Item 2(c)**-*Acquiring persons* put an X in the box to indicate the highest threshold for which notification is being filed (see § 801.1(h)): $50 million, $100 million, $500 million, 25% (if value of voting securities to be held is greater than $1 billion), or 50%. The notification threshold selected should be based on voting securities only that will be held as a result of the acquisition.

**Item 2(d)**-*Assets and voting securities held as a result of the acquisition* (to be completed by both acquiring and acquired persons). State:

**Item 2(d)(i)**-the value of voting securities;

**Item 2(d)(ii)**-the percentage of voting securities;

**Item 2(d)(iii)**-the value of assets:

**Item 2(d)(iv)**-the aggregate total amount of voting securities and assets of the acquired person to be held by each acquiring person, as a result of the acquisition (see §§ 801.12, 801.13, and 801.14).

**Item 2(e)**-Acquiring persons must provide the name(s) of the person(s) who performed any fair market valuation used to determine the aggregate total value of the transaction reported in Item 2(d)(iv).

## ITEM 3

**Item 3(a)**-*Description of acquisition.* Briefly describe the transaction. Include a list of the name and mailing address of each acquiring and acquired person, whether or not required to file notification. Indicate for each party whether assets or voting securities (or both) are to be acquired. Also indicate what consideration will be received by each party. In describing the acquisition, include the expected dates of any major events required to consummate the transaction (e.g., stockholders' meetings, filing of requests for approval, other public filings, terminations of tender offers) and the scheduled consummation date of the transaction.

If the voting securities are to be acquired from a holder other than the issuer (or an entity within the same person as the issuer) separately identify (if known) such holder and the issuer of the voting securities. Acquiring persons involved in tender offers should describe the terms of the offer.

**Item 3(b)(i)**-*Assets to be acquired.* This Item is to be completed only to the extent that the transaction is an acquisition of assets. Describe all general classes of assets (other than cash and securities) to be acquired by each party to the transaction, giving dollar values thereof.

Give the total value of the assets to be acquired in this transaction.

Examples of general classes of assets other than cash and securities are land, merchandising inventory, manufacturing plants (specify location and products produced), and retail stores. For each general class of assets, indicate the page or paragraph number of the contract or other document submitted with this Form in which the assets are more particularly described.

**Item 3(b)(ii)**-*Assets held by acquiring person.* (To be completed by acquiring persons). If assets of the acquired person (see § 801.13) are presently held by the person filing notification, furnish a description of each general class of such assets in the manner required by Item 3(b)(i), and the dollar value or estimated dollar value at the time they were acquired.

**Item 3(c)**-*Voting securities to be acquired.* Furnish the following information separately for each issuer whose voting securities will be acquired in the acquisition: (If, as a result of the acquisition, the acquiring person will hold 100 percent of the voting securities of the acquired issuer or if the acquisition is a merger or consolidation (see § 801.2(d)), the parties may so state and provide the total dollar value of the transaction instead of responding to Items 3(c)(i)-3(c)(vi).

**Item 3(c)(i)**-List each class of voting securities (including convertible voting securities) which will be outstanding after the acquisition has been completed. If there is more than one class of voting securities, include a description of the voting rights of each class. Also list each class of non-voting securities which will be acquired in the acquisition;

**Item 3(c)(ii)**-Total number of shares of each class of securities listed which will be outstanding after the acquisition has been completed;

**Item 3(c)(iii)**-Total number of shares of each class of securities listed which will be acquired in this acquisition. If there is more than one acquiring person for any class of securities, show data separately for each acquiring person;

**Item 3(c)(iv)**-Identity of each person acquiring any securities of any class listed. If there is more than one acquiring person for any class of securities, show data separately for each acquiring person;

**Item 3(c)(v)**-Dollar value of securities of each class listed to be acquired in this transaction (see § 801.10). If there is more than one acquiring person of any class of securities, show data separately for each acquiring person (If the exact dollar value cannot be determined at the time of filing, provide an estimated value and indicate the basis on which the estimate was made);

**Item 3(c)(vi)**-Total number of each class of securities listed which will be held by acquiring person(s) after the acquisition has been accomplished. If there is more than one acquiring person for any class of securities, show data separately for each acquiring person;

**Item 3(d)**-Furnish copies of final or most recent versions of all documents which constitute the agreement among the acquiring person(s) and the person(s) whose voting securities or assets are to be acquired. (Do not attach these documents to the Answer Sheets.)

**ITEM 4**

Furnish one copy of each of the following documents. For each entity included within the person filing notification which has prepared its own such documents different from those prepared by the person filing notification, furnish, in addition, one copy of each document from each such other entity. Furnish copies of:

**Item 4(a)**-all of the following documents which have been filed with the United States Securities and Exchange Commission (or are to be filed contemporaneously in connection with this acquisition); the most recent proxy statement and Form 10-K, each dated not more than three years prior to the date of this Notification and Report Form; all Forms 10-Q and 8-K filed since the end of the period reflected by the Form 10-K being supplied; any registration statement filed in connection with the transaction for which notification is being filed; if the acquisition is a tender offer, Schedule TO. Alternatively, if the person filing notification does not have copies of responsive documents readily available, identification of such documents and citation to date and place of filing will constitute compliance;

**NOTE:** In response to Item 4(a), the person filing notification may incorporate by reference documents submitted with an earlier filing as explained in the staff formal interpretations dated April 10, 1979, and April 7, 1981, and in § 803.2(e).

**Item 4(b)**-the most recent annual reports and most recent annual audit reports (of person filing notification and of each unconsolidated United States issuer included within such person) and, if different, the most recently regularly prepared balance sheet of the person filing notification and of each unconsolidated United States issuer included within such person;

**Item 4(c)**-all studies, surveys, analyses and reports which were prepared by or for any officer(s) or director(s) (or, in the case of unincorporated entities, individuals exercising similar functions) for the purpose of evaluating or analyzing the acquisition with respect to market shares, competition, competitors, markets, potential for sales growth or expansion into product or geographic markets, and indicate (if not contained in the document itself) the date of preparation, and the name and title of each individual who prepared each such document.

Persons filing notification may provide an optional index of documents called for by Item 4 of the Answer Sheets.

**NOTE:** If the person filing notification withholds any documents called for by Item 4(c) based on a claim of privilege, the person must provide a statement of reasons for such noncompliance as specified in the staff formal interpretation dated September 13, 1979, and § 803.3(d).

**ITEMS 5 through 8**

**NOTE:** For Items 5 through 8, the acquired person should limit its response in the case of an acquisition of assets, to the assets to be sold, and in the case of an acquisition of voting securities, to the issuer(s) whose voting securities are being acquired and all entities controlled by such issuer. A person filing as both acquiring and acquired may be required to provide a separate response to these items in each capacity so that it can properly limit its response as an acquired person. (See § 803.2(b) and (c).)

**Items 5(a)-5(c):** These items request information regarding dollar revenues and lines of commerce at three NAICS levels with respect to operations conducted within the United States. (See § 803.2(c)(1).) All persons must submit certain data at the 6-digit NAICS industry code level. To the extent that dollar revenues are derived from manufacturing operations (NAICS Sectors 31-33), data must also be submitted at the 7-digit product class level and 10-digit product code level (NAICS-based codes). Where certain published NAICS industry codes contain only 5 digits, the filing person should add a zero (0) after the fifth ($5^{th}$) digit.

**NOTE:** See "References" listed in the General Instructions to the Form. Refer to the *1997 NAICS Manual* for the 6-digit industry codes and the *1997 Numerical List of Manufactured and Mineral Products (1997 Numerical List)* for the 7-digit product classes and 10-digit product codes. Report revenues for the 7-digit NAICS product classes and 10-digit NAICS product codes using the codes in the columns labeled "Product code" in the *1997 Numerical List.*

Nondepository credit intermediation (NAICS Industry Group Code 5222); securities, commodity contracts, and other financial investments (NAICS Subsector 523); funds, trusts, and other financial vehicles (NAICS Subsector 525); real estate (NAICS Subsector 531); lessors of nonfinancial intangible assets, except copyright works (NAICS Subsector 533); and management of companies and enterprises (NAICS Subsector 551) should identify or explain the revenues reported (e.g. dollar sales receipts).

Persons filing notification should include the total dollar revenues for all entities included within the person filing notification at the time this Notification and Report Form is prepared (even if such entities have become included within the person since 1997). For example, if the person filing notification acquired an entity in 1998, it must include that entity's 1997 revenues in items 5(a) and 5(b)(i). It must also include that entity's most recent year's revenues in Item 5(b)(iii) and/or Item 5(c).

**Item 5(a)**-*Dollar revenues by industry*. Provide aggregate 6-digit NAICS industry data for 1997.

**Item 5(b)(i)**-*Dollar revenues by manufactured product*. Provide the following information on the aggregate operations for the person filing notification for 1997 for each 10-digit NAICS product of the person in NAICS Sectors 31-33 (manufacturing industries).

**NOTE:** Where the *1997 Numerical List* denotes footnote 1 at the end of a specific Subsector, refer to Appendices A, and then B for detail collected in a specified Current Industrial Report. You must provide 10-digit NAICS product codes and descriptions listed in Appendix B.

**Item 5(b)(ii)**-*Products added or deleted*. Within NAICS Sectors 31-33 (manufacturing industries), identify each product of the person filing notification added or deleted subsequent to 1997, indicate the year of addition or deletion, and state total dollar revenues in the most recent year for each product that has been added. Products may be identified either by 10-digit NAICS product code or in the manner ordinarily used by the person filing notification.

Do not include products added since 1997 by reason of mergers or acquisitions of entities occurring since 1997. Dollar revenues derived from such products should be included in response to Item 5(b)(i). However, if an entity acquired since 1997 by the person filing notification (and now included within the person) itself has added any products since 1997, these products and the dollar revenues derived therefrom should be listed here. Products deleted by reason of dispositions of assets constituting less than substantially all of the assets of an entity since 1997 should also be listed here.

**Item 5(b)(iii)**-*Dollar revenues by manufactured product class*. Provide the following information concerning the aggregate operations of the person filing notification for the most recent year for each 7-digit NAICS product class within NAICS Sectors 31-33 (manufacturing industries) in which the person engaged. If such data have not been compiled for the most recent year, estimates of dollar revenues by 7-digit NAICS product class may be provided if a statement describing the method of estimation is furnished.

**Item 5(c)**-*Dollar revenues by non-manufacturing industry*. Provide the following information concerning the aggregate operations of the person filing notification for the most recent year for each 6-digit NAICS industry code in NAICS Sectors other than 31-33 (manufacturing industries) in which the person engaged. If such data have not been compiled for the most recent year, estimates of dollar revenues by 6-digit NAICS industry code may be provided if a statement describing the method of estimation is furnished. Industries for which the dollar revenues totaled less than one million dollars in the most recent year may be omitted.

**NOTE:** *This million dollar minimum is applicable only to Item 5(c).*

## CORPORATIONS AND UNICORPORATED ENTITIES AT THE TIME OF FORMATION

**Item 5(d)**-Supply the following information only if the acquisition is the formation of corporation pursuant to § 801.40 or the formation of an unincorporated entity pursuant to § 801.50

**Item 5(d)(i)**-List the name and mailing address of the new corporation or unincorporated entity.

**Item 5(d)(ii)(A)**-List contributions that each person forming the new corporation or unincorporated entity has agreed to make, specifying when each contribution is to be made and the value of the contribution as agreed by the contributors.

**Item 5(d)(ii)(B)**-Describe any contracts or agreements the new corporation or unincorporated entity will obtain assets or capital from sources other than the persons forming it.

**Item 5(d)(ii)(C)**-Specify whether and in what amount the persons forming the new corporation or unincorporated entity have agreed to guarantee its credit or obligations.

**Item 5(d)(ii)(D)**-Describe fully the consideration which each person forming the new corporation or unincorporated entity will receive in exchange for its contribution(s).

**Item 5(d)(iii)**-Describe generally the business in which the new corporation or unincorporated entity will engage, including location of headquarters and principal plants, warehouses, retail establishments or other places of business, its principal types of products or activities, and the geographic areas in which it will do business.

**Item 5(d)(iv)**-Identify each 6-digit NAICS industry code in which the new corporation or unincorporated entity will derive dollar revenues. If the new corporation or unincorporated entity will be engaged in manufacturing also specify each 7-digit NAICS product class in which it will derive dollar revenues.

## ITEM 6

This item need not be completed by a person filing notification only as an acquired person if only assets are to be acquired. Persons filing notification may respond to Items 6(a), 6(b), or 6(c) by referencing a "document attachment" furnished with this Form if the information so referenced is a complete response and is up-to-date and accurate. Indicate for each Item the specific page(s) of the document that are responsive to that Item.

**Item 6(a)**-*Entities within the person filing notification*. List the name and headquarters mailing address of each entity included within the person filing notification. Entities with total assets of less than $10 million may be omitted.

**Item 6(b)**-*Shareholders of person filing notification*. For each entity (including the ultimate parent entity) included within the person filing notification the voting securities of which are held (see § 801.1(c)) by one or more other persons, list the issuer and class of voting securities, the name and headquarters mailing address of each other person which holds five percent or more of the outstanding voting securities of the class and the number and percentage held by that person. Holders need not be listed for entities with total assets of less than $10 million.

**Item 6(c)**-Holdings of person filing notification. If the person filing notification holds voting securities of any issuer not included within the person filing notification, list the issuer and class, the number and percentage held, and (optionally) the entity within the person filing notification which holds the securities. Holdings of less than five percent of the outstanding voting securities of any issuers, and holding of issuers with total assets of less than $10 million may be omitted.

**ITEM 7**

**Item 7**-*NAICS codeoverlaps*. If, to the knowledge or belief of the person filing notification, the person filing notification derived dollar revenues in the most recent year from operations in industries within any 6-digit NAICS industry code in which any other person that is a party to the acquisition also derived dollar revenues in the most recent year (or in which the new corporation or unincorporated entity will derive dollar revenues), then for each such 6-digit NAICS industry code:

**Item 7(a)**-supply the 6-digit NAICS industry code and description for the industry;

**Item 7(b)**-list the name of each person which is a party to the acquisition which also derived dollar revenues in the 6-digit industry (note: In the formation of a new corporation or unincorporated entity report only overlaps between the person filing notification and the new corporation or unincorporated entity);

**Item 7(c)**-*Geographic market information*:

**Item 7(c)(i)**-for each 6-digit NAICS industry code within NAICS Sectors 31-33 (manufacturing industries) listed in Item 7(a) above, list the states or, if desired, portions thereof in which, to the knowledge or belief of the person filing notification, the products in that 6-digit NAICS code produced by the person filing notification are sold without a significant change in their form, whether they are sold by the person filing notification or by others to whom such products have been sold or resold;

**Item 7(c)(ii)**- for each 6-digit NAICS industry code within NAICS Sectors or Subsectors 11 (agriculture, forestry, fishing and hunting); 21 (mining); 22 (utilities); 23 (construction); 48-49 (transportation and warehousing); 511(publishing industries); 513 (broadcasting and telecommunications); and 71 (arts, entertainment and recreation) listed in item 7(a) above, list the states or, if desired, portions thereof in which the person filing notification conducts such operations;

**Item 7(c)(iii)**-for each 6-digit NAICS industry code within NAICS Sector 42 (wholesale trade) listed in Item 7(a) above, list the states or, if desired, portions thereof in which the customers of the person filing notification are located;

**Item 7(c)(iv)**-for each 6-digit NAICS industry code within NAICS Sectors or Subsectors 44-45 (retail trade); 512 (motion picture and sound recording industries); 521 (monetary authorities-central bank); 522 (credit intermediation and related activities); 532 (rental and leasing services); 62 (health care and social assistance); 72 (accommodations and food services); 811 (repair and maintenance); and 812 (personal and laundry services) listed in Item 7(a) above, provide the address, **arranged by state, county and city or town,** of each establishment from which dollar revenues were derived in the most recent year by the person filing notification;

**Item 7(c)(v)**- for each 6-digit NAICS industry code within NAICS Subsectors 514 (information services and data processing services); 523 (securities, commodity contracts and other financial investments and related activities); 525 (funds, trusts and other financial vehicles); 531 (real estate); 533 (lessors of nonfinancial intangible assets, except copyright works); 54 (professional, scientific and technical services); 55 (management of companies and enterprises); 56 (administrative and support and waste management and remediation services); 61 (educational services); 813 (religious, grantmaking, civic, professional, and similar organizations); and NAICS Industry Group 5242 (insurance agencies and brokerages, third party administration of insurance and pension funds, claims adjusting, and other insurance related activities) listed in Item 7(a) above, list the states or, if desired, portions thereof in which establishments were located from which the person filing notification derived revenues in the most recent year; and

**Item 7(c)(vi)**-for each 6-digit NAICS industry code within NAICS Industry Group 5241 (insurance carriers) listed in Item 7(a) above, list the state(s) in which the person filing notification is licensed to write insurance.

**NOTE**: Except in the case of those NAICS major industries in the Sectors and Subsectors mentioned in Item 7(c)(iv) above, the person filing notification may respond with the word "national" if business is conducted in all 50 states.

**ITEM 8**

**Item 8**-*Previous acquisitions* (to be completed by acquiring persons). Determine each 6-digit NAICS industry code listed in Item 7(a) above, in which the person filing notification derived dollar revenues of $1 million or more in the most recent year and in which either the acquired issuer derived revenues of $1 million or more in the recent year (or, in which, in the case of the formation of a new corporation or unincorporated entity, the new corporation or unincorporated entity reasonably can be expected to derive revenues of $1 million or more), or revenues of $1 million or more in the most recent year were attributable to the acquired assets. For each such 6-digit NAICS industry code, list all acquisitions made by the person filing notification in the five years prior to the date of filing of entities deriving dollar revenues in that 6-digit NAICS industry code. List only acquisitions of 50 percent or more of the voting securities of an issuer which had annual net sales or total assets greater than $10 million in the year prior to the acquisition, and any acquisitions of assets valued at or above the statutory size-of-transaction test at the time of their acquisition.

For each such acquisition, supply:

(a) the name of the entity acquired;

(b) the headquarters address of the entity prior to the acquisition;

(c) whether securities or assets were acquired;

(d) the consummation date of the acquisition; and

(e) the 6-digit (NAICS code) industries by (number and description) identified above in which the acquired entity derived dollar revenues.

**CERTIFICATION- (See § 803.6.)**

TRANSACTION NUMBER ASSIGNED ☐☐☐☐☐☐☐☐

**16 C.F.R. Part 803 - Appendix**
**NOTIFICATION AND REPORT FORM FOR CERTAIN MERGERS AND ACQUISITIONS**

Approved by OMB
3084-0005
Expires 05/31/04

THE INFORMATION REQUIRED TO BE SUPPLIED ON THESE ANSWER SHEETS IS SPECIFIED IN THE INSTRUCTIONS

↓ Attach the Affidavit required by § 803.5 to this page.

FEE INFORMATION

AMOUNT PAID $_____

In cases where your filing fee would be higher if based on acquisition price or where the acquisition price is undetermined to the extent that it may straddle a filing fee threshold, attach an explanation of how you determined the appropriate fee *(acquiring persons only)*.

Attachment Number _____

TAXPAYER IDENTIFICATION NUMBER _____
or SOCIAL SECURITY NUMBER of payer _____
*(acquiring person (and payer if different from acquiring person))*

CHECK ATTACHED ☐ MONEY ORDER ATTACHED ☐

WIRE TRANSFER ☐ CONFIRMATION NO._____

FROM: NAME OF INSTITUTION _____

NAME OF PAYER (if different from PERSON FILING) _____

IS THIS A CORRECTIVE FILING? ☐ YES ☐ NO

IS THIS ACQUISITION SUBJECT TO FOREIGN FILING REQUIREMENTS? ☐ YES ☐ NO
If YES, list jurisdictions: *(voluntary)* _____

IS THIS ACQUISITION A CASH TENDER OFFER? ☐ YES ☐ NO | BANKRUPTCY? ☐ YES ☐ NO

DO YOU REQUEST EARLY TERMINATION OF THE WAITING PERIOD? *(Grants of early termination are published in the Federal Register AND on the FTC web site www.ftc.gov)*
☐ YES ☐ NO

**ITEM 1 – PERSON FILING**

1(a) NAME and
HEADQUARTERS ADDRESS
of PERSON FILING

1(b) PERSON FILING NOTIFICATION IS
☐ an acquiring person ☐ an acquired person ☐ both

1(c) PUT AN "X" IN THE APPROPRIATE BOX TO DESCRIBE PERSON FILING NOTIFICATION
☐ Corporation ☐ Partnership ☐ Other *(Specify)*: _____

1(d) DATA FURNISHED BY
☐ calendar year ☐ fiscal year *(specify period )* _____ (month/year) to _____ (month/year)

THIS FORM IS REQUIRED BY LAW and must be filed separately by each person which, by reason of a merger, consolidation or acquisition, is subject to §7A of the Clayton Act, 15 U.S.C. §18a, as added by Section 201 of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, Pub. L. No. 94-435, 90 Stat. 1390, and rules promulgated thereunder (hereinafter referred to as "the rules" or by section number). The statute and rules are set forth in the *Federal Register* at 43 FR 33450; the rules may also be found at 16 CFR Parts 801-03. Failure to file this **Notification and Report Form**, and to observe the required waiting period before consummating the acquisition in accordance with the applicable provisions of 15 U.S.C. §18a and the rules, subjects any "person," as defined in the rules, or any individuals responsible for noncompliance, to liability for a penalty of not more than $11,000 for each day during which such person is in violation of 15 U.S.C. §18a.

All information and documentary material filed in or with this Form is confidential. It is exempt from disclosure under the Freedom of Information Act, and may be made public only in an administrative or judicial proceeding, or disclosed to Congress or to a duly authorized committee or subcommittee of Congress.

**Filing** - Complete and return *two* copies (with one original affidavit and certification and one set of documentary attachments) of this Notification and Report Form to: Premerger Notification Office, Bureau of Competition, Room 303, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. *Three* copies (with one set of documentary attachments) should be sent to: Director of Operations and Merger Enforcement, Antitrust Division, Department of Justice, Patrick Henry Building, 601 D Street, N.W., Room #10013, Washington, D.C. 20530. (For FEDEX airbills to the Department of Justice, do not use the 20530 zip code; use zip code 20004.)

DISCLOSURE NOTICE - Public reporting burden for this report is estimated to vary from 8 to 160 hours per response, with an average of 39 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this report, including suggestions for reducing this burden to:

Premerger Notification Office,
H-303
Federal Trade Commission
Washington, DC 20580

Office of Information and
Regulatory Affairs,
Office of Management and Budget
Washington, DC 20503

Under the Paperwork Reduction Act, as amended, 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. That number is 3084-0005, which also appears in the upper right-hand corner of the first page of this form.

| NAME OF PERSON FILING NOTIFICATION | DATE |
|---|---|

1(e) PUT AN X IN THE APPROPRIATE BOX AND GIVE THE NAME AND ADDRESS OF ENTITY FILING NOTIFICATION (if other than ultimate parent entity)

☐ NA ☐ This report is being filed on behalf of a foreign person pursuant to § 803.4. ☐ This report is being filed on behalf of the ultimate parent entity by another entity within the same person authorized by it to file pursuant to § 803.2(a).

| NAME OF ENTITY FILING NOTIFICATION | ADDRESS |
|---|---|
| | |

1(f) NAME AND ADDRESS OF ENTITY MAKING ACQUISITION OR WHOSE ASSETS OR VOTING SECURITIES ARE BEING ACQUIRED IF DIFFERENT FROM THE ULTIMATE PARENT ENTITY IDENTIFIED IN ITEM 1(a)

PERCENT OF VOTING SECURITIES HELD BY EACH ENTITY IDENTIFIED IN ITEM 1(a)

1(g) IDENTIFICATION OF PERSON TO CONTACT REGARDING THIS REPORT

| | |
|---|---|
| NAME OF CONTACT PERSON | |
| TITLE | |
| FIRM NAME | |
| BUSINESS ADDRESS | |
| TELEPHONE NUMBER | |
| FAX NUMBER | |
| E-MAIL ADDRESS | |

(h) IDENTIFICATION OF AN INDIVIDUAL LOCATED IN THE UNITED STATES DESIGNATED FOR THE LIMITED PURPOSE OF RECEIVING NOTICE OF ISSUANCE OF A REQUEST FOR ADDITIONAL INFORMATION OR DOCUMENTS. (See § 803.20(b)(2)(iii))

| | |
|---|---|
| NAME OF CONTACT PERSON | |
| TITLE | |
| FIRM NAME | |
| BUSINESS ADDRESS | |
| TELEPHONE NUMBER | |
| FAX NUMBER | |
| E-MAIL ADDRESS | |

**ITEM 2**

| 2(a) LIST NAMES OF ULTIMATE PARENT ENTITIES OF ALL ACQUIRING PERSONS | LIST NAMES OF ULTIMATE PARENT ENTITIES OF ALL ACQUIRED PERSONS |
|---|---|
| | |

2(b) THIS ACQUISITION IS *(put an X in all the boxes that apply)*

- ☐ an acquisition of assets
- ☐ a merger (see § 801.2)
- ☐ an acquisition subject to § 801.2(e)
- ☐ a formation of a joint venture of other corporation (see § 801.40)
- ☐ an acquisition subject to § 801.30 (*specify type*)
- ☐ other (*specify*) _____
- ☐ a consolidation (see § 801.2)
- ☐ an acquisition of voting securities
- ☐ a secondary acquisition
- ☐ an acquisition subject to § 801.31

2(c) INDICATE THE HIGHEST NOTIFICATION THRESHOLD IN § 801.1(h) FOR WHICH THIS FORM IS BEING FILED *(acquiring person only in an acquisition of voting securities)*

☐ $50 million ☐ $100 million ☐ $500 million ☐ 25% (see Instructions) ☐ 50%

| 2(d)(i) VALUE OF VOTING SECURITIES TO BE HELD AS A RESULT OF THE ACQUISITION | (ii) PERCENTAGE OF VOTING SECURITIES | (iii) VALUE OF ASSETS TO BE HELD AS A RESULT OF THE ACQUISITION | (iv) AGGREGATE TOTAL VALUE |
|---|---|---|---|
| $ | % | $ | $ |

| NAME OF PERSON FILING NOTIFICATION | DATE |
|---|---|
| | |

2(e) If aggregate total value in 2(d)(iv) is based in whole or in part on a fair market valuation pursuant to § 801.10(c)(3), identify the person or persons responsible for making the valuation *(acquiring persons only)*.

**ITEM 3**

3(a) DESCRIPTION OF ACQUISITION

| NAME OF PERSON FILING NOTIFICATION | DATE |
|---|---|
| | |

3(b)(i) ASSETS TO BE ACQUIRED (to be completed only for asset acquisitions)

3(b)(ii) ASSETS HELD BY ACQUIRING PERSON

3(c) VOTING SECURITIES TO BE ACQUIRED

3(c)(i) LIST AND DESCRIPTION OF VOTING SECURITIES AND LIST OF NON-VOTING SECURITIES:

3(c)(ii) TOTAL NUMBER OF SHARES OF EACH CLASS OF SECURITY:

3(c)(iii) TOTAL NUMBER OF SHARES OF EACH CLASS OF SECURITY BEING ACQUIRED:

| NAME OF PERSON FILING NOTIFICATION | DATE |
|---|---|
| | |

3(c)(iv) IDENTITY OF PERSONS ACQUIRING SECURITIES:

3(c)(v) DOLLAR VALUE OF SECURITIES IN EACH CLASS BEING ACQUIRED:

3(c)(vi) TOTAL NUMBER OF EACH CLASS OF SECURITIES TO BE HELD AS A RESULT OF THE ACQUISITION:

3(d) SUBMIT A COPY OF THE MOST RECENT VERSION OF CONTRACT OR AGREEMENT (or letter of intent to merge or acquire)

DO NOT ATTACH THIS DOCUMENT TO THIS PAGE ATTACHMENT OR REFERENCE NUMBER OF CONTRACT OR AGREEMENT _____

| NAME OF PERSON FILING NOTIFICATION | DATE |
|---|---|
| | |

**ITEM 4** PERSONS FILING NOTIFICATION MAY PROVIDE BELOW AN OPTIONAL INDEX OF DOCUMENTS REQUIRED TO BE SUBMITTED BY ITEM 4 (See Item by Item instructions). THESE DOCUMENTS SHOULD NOT BE ATTACHED TO THIS PAGE.

| 4(a) DOCUMENTS FILED WITH THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION | ATTACHMENT OR REFERENCE NUMBER |
|---|---|
| | |

| 4(b) ANNUAL REPORTS, ANNUAL AUDIT REPORTS, AND REGULARLY PREPARED BALANCE SHEETS | ATTACHMENT OR REFERENCE NUMBER |
|---|---|
| | |

| 4(c) STUDIES, SURVEYS, ANALYSES, AND REPORTS | ATTACHMENT OR REFERENCE NUMBER |
|---|---|
| | |

| NAME OF PERSON FILING NOTIFICATION | DATE |
|---|---|
| | |

**ITEM 5** (See "References" listed in the General Instructions to the Form. Refer to the *North American Industry Classification System-United States, 1997* (*1997 NAICS Manual*) for the 6-digit (NAICS) industry codes. Refer to the *1997 Numerical List of Manufactured and Mineral Products* (EC97M31R-NL) for the 7-digit product class codes and the 10-digit product codes. Report revenues for the 7-digit product class codes and 10-digit product codes using the codes in the columns labeled "Product code." For further information on NAICS-based codes visit the www.census.gov web site.)

5(a) DOLLAR REVENUES BY INDUSTRY

| 6-DIGIT INDUSTRY CODE | DESCRIPTION | 1997 TOTAL DOLLAR REVENUES |
|---|---|---|
| | | |

| NAME OF PERSON FILING NOTIFICATION | DATE |
|---|---|
| | |

ITEM 5(b)(i) DOLLAR REVENUES BY MANUFACTURED PRODUCTS

| 10-DIGIT PRODUCT CODE | DESCRIPTION | 1997 TOTAL DOLLAR REVENUES |
|---|---|---|
| | | |

| NAME OF PERSON FILING NOTIFICATION | DATE |
|---|---|
| | |

ITEM 5(b)(ii) PRODUCTS ADDED OR DELETED

| DESCRIPTION (10-DIGIT PRODUCT CODE) | ADD | DELETE | YEAR OF CHANGE | TOTAL DOLLAR REVENUES |
|---|---|---|---|---|
| | | | | |

ITEM 5(b)(iii) DOLLAR REVENUES BY MANUFACTURED PRODUCT CLASS

| 7-DIGIT PRODUCT CLASS | DESCRIPTION | YEAR<br>\|_____\|<br>TOTAL DOLLAR REVENUES |
|---|---|---|
| | (Item 5(b)(iii) continued on page 10) | |

| NAME OF PERSON FILING NOTIFICATION | DATE |
|---|---|
| | |

ITEM 5(b)(iii) DOLLAR REVENUES BY MANUFACTURED PRODUCT CLASS - CONTINUED

| 7-DIGIT PRODUCT CLASS | DESCRIPTION | YEAR \|_____\| TOTAL DOLLAR REVENUES |
|---|---|---|
| | | |

ITEM 5(c) DOLLAR REVENUES BY NON-MANUFACTURING INDUSTRY

| 6-DIGIT INDUSTRY CODE | DESCRIPTION | YEAR \|_____\| TOTAL DOLLAR REVENUES |
|---|---|---|
| | | |

| NAME OF PERSON FILING NOTIFICATION | DATE |
|---|---|
| | |

5(d) COMPLETE ONLY IF ACQUISITION IS IN THE FORMATION OF A NEW CORPORATION OR UNICORPORATED ENTITY

5(d)(i) NAME AND ADDRESS OF THE NEW CORPORATION OR UNICORPORATED ENTITY

5(d)(ii)

(A) CONTRIBUTIONS THAT EACH PERSON FORMING THE NEW CORPORATION OR UNICORPORATED ENTITY HAS AGREED TO MAKE

(B) DESCRIPTION OF ANY CONTRACTS OR AGREEMENTS

(C) DESCRIPTION OF ANY CREDIT GUARANTEES OR OBLIGATIONS

(D) DESCRIPTION OF CONSIDERATION WHICH EACH PERSON FORMING THE NEW CORPORATION OR UNICORPORATED ENTITY WILL RECEIVE

5(d)(iii) DESCRIPTION OF THE BUSINESS IN WHICH THE NEW CORPORATION OR UNICORPORATED ENTITY WILL ENGAGE

5(d)(iv) SOURCE OF DOLLAR REVENUES BY 6-DIGIT INDUSTRY CODE (non-manufacturing) AND BY 7-DIGIT PRODUCT CLASS (manufacturing)

| NAME OF PERSON FILING NOTIFICATION | DATE |
|---|---|
| | |

**ITEM 6**

6(a) ENTITIES WITHIN PERSON FILING NOTIFICATION

6(b) SHAREHOLDERS OF PERSON FILING NOTIFICATION

| NAME OF PERSON FILING NOTIFICATION | DATE |
|---|---|
| | |

6(c) HOLDINGS OF PERSON FILING NOTIFICATION

**ITEM 7** NAICS CODE OVERLAPS

7(a) 6-DIGIT NAICS CODE AND DESCRIPTION

7(b) NAME OF EACH PERSON WHICH ALSO DERIVED DOLLAR REVENUES

| NAME OF PERSON FILING NOTIFICATION | DATE |
|---|---|
| | |

7(c) GEOGRAPHIC MARKET INFORMATION

**ITEM 8** PRIOR ACQUISITIONS (to be completed by acquiring person only)

| NAME OF PERSON FILING NOTIFICATION | DATE |
|---|---|

## CERTIFICATION

This **NOTIFICATION AND REPORT FORM,** together with any and all appendices and attachments thereto, was prepared and assembled under my supervision in accordance with instructions issued by the Federal Trade Commission. Subject to the recognition that, where so indicated, reasonable estimates have been made because books and records do not provide the required data, the information is, to the best of my knowledge, true, correct, and complete in accordance with the statute and rules.

| NAME (Please print or type) | TITLE |
|---|---|
| SIGNATURE | DATE |

Subscribed and sworn to before me at the
City of _____, State of _____

this _____day of _____, the year _____

Signature _____

My Commission expires _____

[SEAL]

By direction of the Commission.

**Donald S. Clark,**

*Secretary.*

[FR Doc. 04–7537 Filed 4–7–04; 8:45 am]

**BILLING CODE 6750–01–C**

Federal Register

Thursday,
April 8, 2004

# Part III

# Department of Education

## Privacy Act of 1974; System of Records—RSA–911 Case Service Report; Notice

## DEPARTMENT OF EDUCATION

### Privacy Act of 1974; System of Records—RSA–911 Case Service Report

**AGENCY:** Office of Special Education and Rehabilitative Services, Department of Education.

**ACTION:** Notice of a new system of records.

**SUMMARY:** In accordance with the Privacy Act of 1974, as amended (Privacy Act), the Office of Special Education and Rehabilitative Services in the U.S. Department of Education (Department), publishes this notice of a new system of records entitled the RSA–911 Case Service Report. The RSA–911 Case Service Report is an annual report of demographic and caseload information, including financial information, related to all individuals who have exited the State Vocational Rehabilitation Services program (VR program).

**DATES:** The Department seeks comments on the new system of records described in this notice, in accordance with the requirements of the Privacy Act. We must receive your comments on or before May 10, 2004.

The Department filed a report describing the new system of records covered by this notice with the Chair of the Senate Committee on Governmental Affairs, the Chair of the House Committee on Government Reform, and the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on April 2, 2004. This new system of records will become effective at the later date of—(1) The expiration of the 40-day period for OMB review on May 12, 2004, or (2) May 10, 2004, unless the system of records needs to be changed as a result of public comment or OMB review.

**ADDRESSES:** Address all comments about this new system of records to Hugh Berry, Office of Policy and Planning, Office of the Assistant Secretary, Office of Special Education and Rehabilitative Services, U.S. Department of Education, 400 Maryland Avenue, SW., room 3131, Mary E. Switzer Building, Washington, DC 20202–2524. If you prefer to send your comments through the Internet, use the following address: *comments@ed.gov.*

You must include the term "RSA–911 Case Service Report'' in the subject line of the electronic message.

During and after the comment period, you may inspect all public comments about this notice in room 3131, Mary E. Switzer Building, 330 C Street, SW., Washington, DC, between the hours of 9 a.m. and 5:30 p.m., eastern time, Monday through Friday of each week except Federal holidays.

### Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record

On request, we will supply an appropriate aid, such as a reader or print magnifier, to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this notice. If you want to schedule an appointment for this type of aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

**FOR FURTHER INFORMATION CONTACT:** Hugh Berry. Telephone: (202) 205–8121. If you use a telecommunications device for the deaf (TDD), you may call the Federal Information 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 contact person listed in the preceding paragraph.

**SUPPLEMENTARY INFORMATION:**

### Introduction

The Privacy Act (5 U.S.C. 552a(e)(4)) requires the Department to publish in the **Federal Register** this notice of a new system of records maintained by the Department. The Department's regulations implementing the Privacy Act are contained in the Code of Federal Regulations (CFR) in 34 CFR part 5b.

The Privacy Act applies to a record about an individual that contains individually identifiable information that is retrieved by a unique identifier associated with the individual, such as a name or social security number. The information about each individual is called a "record,'' and the system, whether manual or computer-based, is called a "system of records.'' The Privacy Act requires each agency to publish a notice of a system of records in the **Federal Register** and to prepare a report to OMB whenever the agency publishes a new or altered system of records. Each agency is also required to send copies of the report to the Chair of the Senate Committee on Governmental Affairs and the Chair of the House Committee on Government Reform.

### Electronic Access to This Document

You may view this document, as well as other Department documents 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 version of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html.*

Dated: April 2, 2004.

**Troy R. Justesen,**

*Acting Deputy Assistant Secretary for Special Education and Rehabilitative Services.*

For the reasons discussed in the preamble, the Office of Special Education and Rehabilitative Services of the U.S. Department of Education publishes a notice of a new system of records to read as follows:

**18–16–02**

**SYSTEM NAME:**

RSA–911 Case Service Report.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION(S):**

Office of Policy and Planning, Office of the Assistant Secretary, Office of Special Education and Rehabilitative Services, U.S. Department of Education, 330 C Street, SW., Mary E. Switzer Building, room 3131, Washington, DC 20202–2524.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

The RSA–911 Case Service Report database includes information on all persons exiting the State Vocational Rehabilitation Services program (VR program) during each fiscal year.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

This system consists of records relating to individuals who have exited the VR program, including, but not limited to—the individual's social security number, disability characteristics, services and training, health insurance, employment outcomes, and earnings.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Sections 13(b) and 101(a)(10) of the Rehabilitation Act of 1973, as amended (29 U.S.C. 712(b) and 721(a)(10)).

**PURPOSE(S):**

This system of records is maintained for program research and evaluation purposes.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

The U.S. Department of Education (Department) may disclose information contained in a record in this system of records under the routine uses listed in this system of records without the consent of the individual if the disclosure is compatible with the purposes for which the record was collected. The Department may make these disclosures on a case-by-case basis or, if the Department has complied with the computer matching requirements of the Computer Matching and Privacy Protection Act of 1988, under a computer matching agreement.

(1) *Freedom of Information Act (FOIA) Advice Disclosure.* The Department may disclose records to the Department of Justice (DOJ) and the Office of Management and Budget (OMB) if the Department seeks advice regarding whether records maintained in the system of records must be released under the FOIA and the Privacy Act of 1974, as amended (Privacy Act).

(2) *Disclosure to the DOJ.* The Department may disclose records to the DOJ to the extent necessary for obtaining DOJ advice on any matter relevant to an audit, inspection, or other inquiry related to the program covered by this system.

(3) *Contract Disclosure.* If the Department contracts with an entity for the purposes of performing any function that requires disclosure of records in this system to employees of the contractor, the Department may disclose the records to those employees. Before entering into such a contract, the Department shall require the contractor to maintain Privacy Act safeguards as required under 5 U.S.C. 552a(m) with respect to the records in the system.

(4) *Litigation and Alternative Dispute Resolution (ADR) Disclosures.*

(a) *Introduction.* In the event that one of the following parties is involved in litigation or ADR, or has an interest in litigation or ADR, the Department may disclose certain records to the parties described in paragraphs (b), (c), and (d) of this routine use under the conditions specified in those paragraphs:

(i) The Department, or any of its components; or

(ii) Any Department employee in his or her official capacity; or

(iii) Any Department employee in his or her individual capacity if the DOJ agrees or has been requested to provide or to arrange for representation of the employee;

(iv) Any Department employee in his or her individual capacity if the Department has agreed to represent the employee; or

(v) The United States if the Department determines that the litigation is likely to affect the Department or any of its components.

(a) *Disclosure to the DOJ.* If the Department determines that disclosure of certain records to the DOJ is relevant and necessary to litigation or ADR and is compatible with the purpose for which the records were collected, the Department may disclose those records as a routine use to the DOJ.

(b) *Adjudicative Disclosures.* If the Department determines that disclosure of certain records to an adjudicative body before which the Department is authorized to appear or to an individual or an entity designated by the Department or otherwise empowered to resolve or mediate disputes is relevant and necessary to the litigation or ADR, the Department may disclose those records as a routine use to the adjudicative body, individual, or entity.

(c) *Parties, Counsels, Representatives, and Witnesses.*

If the Department determines that disclosure of certain records to a party, counsel, representative, or witness is relevant and necessary to the litigation or ADR, the Department may disclose those records as a routine use to the party, counsel, representative, or witness.

(5) *Research Disclosure.* The Department may disclose records to a researcher if an appropriate official of the Department determines that the individual or organization to which the disclosure would be made is qualified to carry out specific research related to functions or purposes of this system of records. The official may disclose records from this system of records to that researcher solely for the purpose of carrying out that research related to the functions or purposes of this system of records. The researcher shall be required to maintain Privacy Act safeguards with respect to the disclosed records.

(6) *Congressional Member Disclosure.* The Department may disclose information to a Member of Congress from the record of an individual in response to an inquiry from the Member made at the written request of that individual. The Member's right to the information is no greater than the right of the individual who requested it.

(7) *Enforcement Disclosure.* In the event that information in this system of records indicates, either on its face or in connection with other information, a violation or potential violation of any applicable statute, regulations, or order of a competent authority, the Department may disclose the relevant records to the appropriate agency, whether foreign, Federal, State, tribal, or local, charged with the responsibility of investigating or prosecuting that violation or charged with enforcing or implementing the statute, Executive order, rule, regulations, or order issued pursuant thereto.

(8) *Disclosure for Use By Other Law Enforcement Agencies.* The Department may disclose information to any Federal, State, tribal, local, or foreign agency or other public authority responsible for enforcing, investigating, or prosecuting violations of administrative, civil, or criminal law or regulations if that information is relevant to any enforcement, regulatory, investigative, or prosecutorial responsibility within the receiving entity's jurisdiction.

(9) *Disclosure to Other Federal Agencies, Including the Social Security Administration and the Department of Veterans Affairs.* The Department may disclose records to other Federal agencies, including the Social Security Administration and the Department of Veterans Affairs, for program research and evaluation purposes.

(10) *Disclosure to the Veterans' Disability Benefits Commission.* The Department may disclose records to the Veterans' Disability Benefits Commission if requested to do so by this commission in order to carry out the provisions of Title XV of Pub. L. 108–136, the National Defense Authorization Act for Fiscal Year 2004.

**DISCLOSURES TO CONSUMER REPORTING AGENCIES:**

Not applicable to this system of records.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISCLOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

The Office of Special Education and Rehabilitative Services (OSERS) maintains all data on a computer mainframe and CD–ROMs. Printed reports containing sensitive data produced from this system are maintained within the locked filing cabinets within the access-restricted Basic State Grants Branch within OSERS Headquarters.

**RETRIEVABILITY:**

This system will be accessible only to employees of OSERS. Each record in

this system can be retrieved by any of the categories of information listed under the **CATEGORIES OF RECORDS IN THE SYSTEM** section in this notice.

**SAFEGUARDS:**

Access to this system will require a unique user identification as well as a password to enter the system. Users will be required to change their passwords periodically, and they will not be allowed to repeat old passwords. Any individual attempting to log on who fails is locked out of the system after three attempts. Access after that time requires intervention by the system manager.

The computer system employed by the Department offers a high degree of resistance to tampering and circumvention. This security system limits data access to Department and contract staff on a "need to know'' basis and controls individual users' ability to access and alter records within the system.

The location of the server includes safeguards and firewalls, including the physical security of the server room. In addition, the server is located in a secure room, with limited access only through a special pass. Further, all physical access to the site where the server is maintained is controlled and monitored by security personnel who check each individual entering the building for his or her employee or visitor badge.

All printed reports containing sensitive data produced from this system are immediately used for data clearing procedures and then shredded or placed into a confidential security file. The files are maintained within the locked filing cabinets within the access-restricted Basic State Grants Branch within OSERS Headquarters. In addition to these controls, computers are not left on and unattended when users access the database, and sensitive information is placed out of sight if visitors are present.

Shared output does not contain sensitive information. Aggregated data cannot be used to identify individuals. For individual-level data that are shared with researchers, all identifying information is removed from the file before the data are shared.

In addition, the following guidelines and procedures have been implemented for protecting sensitive data and resources in this system:

- Backup CDs are properly labeled "For Official Use Only—Property of the OSERS Basic State Grants Branch.''
- Electronic data (*e.g.*, copies of the database on CDs with identifying information and edit reports with identifying information) are stored in the locked file cabinets in the OSERS Basic State Grants Branch. Management, operational, and technical controls for ensuring the safety of confidential information are detailed within the Case Services System Security Plan.

**RETENTION AND DISPOSAL:**

Records in this system will be retained in accordance with the National Archives and Records Administration (NARA) General Records Schedule 20, Item 1.c, which provides disposal authorization for electronic files and hard-copy printouts created to monitor system usage. Records will be deleted or destroyed when the agency determines they are no longer needed for administrative, legal, audit, or other operational purposes.

**SYSTEM MANAGER AND ADDRESS:**

RSA–911 Case Service Report System Manager, Rehabilitation Services Administration, Office of Special Education and Rehabilitative Services, U.S. Department of Education, 400 Maryland Avenue, SW., room 3226, Mary E. Switzer Building, Washington, DC 20202–2524.

**NOTIFICATION PROCEDURE:**

If you wish to determine whether a record exists about you in the system of records, provide the system manager with your name, address, and social security number. Your request for notification must also meet the requirements of the regulations in 34 CFR 5b.5, including proof of identity. You may also present your request in person or make your request in writing to the system manager at the above address.

**RECORD ACCESS PROCEDURES:**

Request to access a record must also reasonably specify the record contents sought and otherwise meet the requirements of the regulations in 34 CFR 5b.5, including proof of identity.

**CONTESTING RECORD PROCEDURES:**

If you wish to change the content of a record in this system of records, you must contact the system manager at the above address and follow the steps outlined in the **NOTIFICATION PROCEDURE** section of this notice. Requests to amend a record must also reasonably identify the record, specify the information being contested, provide in writing your reasons for requesting the change, and otherwise meet the regulations in 34 CFR 5b.7.

**RECORD SOURCE CATEGORIES:**

Records in this system are obtained from State vocational rehabilitation agencies pursuant to Federal reporting requirements. These agencies collect data from individuals with disabilities who exit their programs.

**SYSTEM EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

[FR Doc. 04–7894 Filed 4–7–04; 8:45 am]

**BILLING CODE 4000–01–P**

Federal Register

Thursday,
April 8, 2004

# Part IV

# Department of Health and Human Services

## Food and Drug Administration

**21 CFR Parts 206, 250, 314, 600, and 601**
**Supplements and Other Changes to an Approved Application; Final Rule**
**Guidance for Industry on Changes to an Approved NDA or ANDA; Availability; Notice**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 206, 250, 314, 600, and 601**

**[Docket No. 1999N–0193]**

**RIN 0910–AB61**

## Supplements and Other Changes to an Approved Application

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending its regulations on supplements and other changes to an approved application to implement the manufacturing changes provision of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). The final rule requires manufacturers to assess the effects of manufacturing changes on the identity, strength, quality, purity, and potency of a drug or biological product as those factors relate to the safety or effectiveness of the product. The final rule sets forth requirements for changes requiring supplement submission and approval before the distribution of the product made using the change, changes requiring supplement submission at least 30 days prior to the distribution of the product, changes requiring supplement submission at the time of distribution, and changes to be described in an annual report.

**DATES:** This rule is effective June 22, 2004.

**FOR FURTHER INFORMATION CONTACT:** David J. Cummings, Center for Drug Evaluation and Research (HFD–357), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5187, or Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373.

**SUPPLEMENTARY INFORMATION:**

### I. Background

Section 116 of the Modernization Act (Public Law 105–115) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 506A (21 U.S.C. 356a). That section describes requirements and procedures for making and reporting manufacturing changes to approved new drug and abbreviated new drug applications, to new and abbreviated animal drug applications, and to license applications for biological products under section 351 of the Public Health Service (PHS) Act (the PHS act). Section 506A of the act revises current procedures for approving manufacturing changes. Major manufacturing changes, as defined in section 506A of the act, are of a type determined by the Secretary of Health and Human Services (the Secretary) to have a substantial potential to adversely affect the identity, strength, quality, purity, and potency as they may relate to the safety and effectiveness of a drug. Such changes require prior approval of a supplemental application. Section 506A of the act also states that the Secretary may require submission of a supplemental application for drugs made with manufacturing changes that are not major and may establish categories of manufacturing changes for which a supplemental application is required. In such a case, the applicant may begin distribution of a drug 30 days after FDA has received a supplemental application unless the agency notifies the applicant within the 30-day period that prior approval of the application is required. Under the statute, FDA may also designate a category of manufacturing changes that permit the applicant to begin distributing a drug made with such changes upon receipt by the agency of a supplemental application for the change. Finally, FDA may also authorize applicants to distribute drugs manufactured with a change without submitting a supplemental application. The law provides that FDA may establish categories of manufacturing changes that may be made without submitting a supplemental application.

*A. Development of the Regulation*

In the **Federal Register** of June 28, 1999 (64 FR 34608), FDA published a proposed rule to implement section 506A of the act for human new drug applications (NDAs) and abbreviated new drug applications (ANDAs), as well as for licensed biological products (the June 1999 proposal). In that same issue of the **Federal Register** (64 FR 34660), FDA announced the availability of a draft guidance for industry entitled "Changes to an Approved NDA or ANDA.'' This guidance was intended to assist applicants in determining how they should report changes to an approved NDA or ANDA under section 506A of the act as well as under the proposed revisions to the human drug regulations pertaining to supplements and other changes to an approved application. In the **Federal Register** of November 23, 1999 (64 FR 65716), FDA announced the availability of a guidance to assist applicants in determining how they should report changes to an approved NDA or ANDA under section 506A of the act, pending finalization of the June 1999 proposal. FDA has revised the guidance to conform to this final rule and is announcing the availability of the guidance elsewhere in this issue of the **Federal Register**.

*B. A Risk-Based Approach*

The publication of this final rule is an important step in the process of adopting a risk-based approach to the regulation of pharmaceuticals. In the 1990s, FDA sponsored research at the University of Maryland and other universities on the types of chemistry and manufacturing changes to immediate release solid oral drug products that could affect drug performance (i.e., identity, strength, quality, purity, and potency) and, therefore, safety and effectiveness. Using that research, FDA's Center for Drug Evaluation and Research (CDER) began to develop a risk-based approach to the implementation of manufacturing changes. The approach provided for a continued high level of scrutiny by FDA of changes that were most likely to affect the performance of a drug and decreased scrutiny of changes that were not likely to affect the performance of a drug.

The risk-based approach was first explained in a series of guidance documents (the Scale-up and Postapproval Changes (SUPAC) guidances) that reduced the regulatory burden of obtaining FDA authorization to make certain changes. The work continued in regulations issued by the Center for Biologics Evaluation and Research (CBER) in 1997 (21 CFR 601.12). In November 1997, this risk-based approach was codified in section 116 of the Modernization Act.

This final rule implements section 116 of the Modernization Act by incorporating the statutory standards for characterizing proposed changes as having substantial, moderate, or minimal potential to adversely affect the identity, strength, quality, purity, and potency of a drug as they may relate to its safety and effectiveness and determining submission requirements based on the potential risks associated with the changes. For changes with a substantial potential to affect the designated characteristics of a drug, FDA must review and approve a supplement that contains information showing that the proposed change will not adversely affect the drug's characteristics (i.e., information developed by the holder of the application to validate the effect of the proposed change) before distribution of the product made using the change.

It was anticipated when section 116 of the Modernization Act was written that the science of manufacturing would evolve over time and affect whether changes would be considered major or nonmajor. To accommodate future technological advancements, section 116 of the Modernization Act and this final implementing regulation both provide that FDA may, by regulation or guidance, change the designation of a particular category of change from major to nonmajor or vice versa. This concept of an evolving risk-based approach to manufacturing changes also is consistent with the agency's Good Manufacturing Practices Initiative ("Pharmaceutical cGMPs for the 21st Century,'' *www.fda.gov/cder/gmp/index.htm*). The goals of that initiative, launched in August 2002, include:

- Ensuring that state-of-the-art pharmaceutical science is utilized in the regulatory review and inspection policies;
- Encouraging the adoption of new technological advances in high quality and efficient manufacturing by the pharmaceutical industry;
- Assessing the applicable current good manufacturing practice (CGMP) requirements relative to the best quality management practices;
- Strengthening public health protection by implementing risk-based approaches that focus both industry and FDA attention on critical areas for improving product safety and quality; and
- Enhancing the consistency and coordination of FDA's drug quality oversight activities.

Specifically, one of the efforts of the CGMP initiative is to facilitate continuous improvement and innovation in manufacturing by allowing manufacturers to make certain types of changes in their processes without prior FDA approval. This rule, in keeping with that initiative, provides for a mechanism of continuous improvement through the guidance process (21 CFR 10.115) that may provide for less burdensome documentation of certain changes as manufacturing processes and pharmaceutical science develop.

## II. Highlights of Revisions to the Proposed Rule

### *A. Definitions*

FDA has revised the proposed definition of "specification'' by changing the phrase "other components including container closure systems and in-process materials'' to "components, in-process materials, container closure systems, and other materials used in the production of a drug substance or drug product.'' FDA made this change for consistency with other regulations. FDA proposed a definition for the term "validate the effects of the change.'' In the final rule, the agency has changed the word "validate'' to "assess'' and provides a definition for the term "assess the effects of the change.''

### *B. Changes to an Approved Application*

The proposal required that the holder of an approved application validate the effects of manufacturing changes on the identity, strength, quality, purity, and potency of the drug as these factors may relate to the safety or effectiveness of the drug. FDA has revised this provision to require that the holder of an approved application assess the effects of manufacturing changes. FDA has deleted the phrase "on the identity, strength, quality, purity, and potency of the drug product as these factors may relate to the safety or effectiveness of the drug product'' because this information is already included in the definition of the term "assess the effects of the change.''

Previously, § 314.70(c) (21 CFR 314.70(c)) stated that the applicant who submits a changes-being-effected supplement to FDA must promptly revise all promotional labeling and advertising to make it consistent with any change in the labeling. The proposal retained this provision and FDA stated in the preamble that the requirement would apply equally to all labeling changes. FDA has revised this provision to limit the requirement to those labeling changes submitted in supplemental applications and not to those in annual reports.

The proposal required the applicant to include in a cover letter a list of all changes contained in the supplement or annual report. FDA has clarified that the requirement to include the list of changes in a cover letter applies only to changes contained in a supplement; the information is already submitted in an annual report.

### *C. Changes Requiring Supplement Submission and Approval Prior to Distribution of the Product Made Using the Change (Major Changes)*

FDA has limited the requirement to include only those changes to a drug product container closure system that involve changes in the type or composition of a packaging component. FDA intends to provide additional guidance on container closure systems changes that will be considered moderate changes or changes that can be reported in an annual report.

FDA proposed to require that a reference list of relevant standard operating procedures (SOPs) be contained in all supplements submitted under this section. FDA has revised this provision to specify that a reference list of relevant SOPs must be submitted for changes to a natural product, a recombinant deoxyribonucleic acid (DNA)-derived protein/polypeptide product, or a complex or conjugate of a drug substance with a monoclonal antibody, and for changes to the sterilization process and test methodologies related to sterilization process validation.

### *D. Changes Requiring Supplement Submission at Least 30 Days Prior to Distribution of the Drug Product Made Using the Change (Moderate Changes)*

FDA has revised the June 1999 proposal to clarify that the requirement to submit 12 copies of finished product labeling applies to supplements for changes that may be implemented 30 days after FDA receives the supplement.

FDA has clarified that the changes in the container closure system submitted in supplements under these moderate changes provisions do not include the changes described under the provisions requiring prior approval or the changes submitted in an annual report.

FDA has revised the changes solely affecting a natural protein product, a recombinant DNA-derived protein/polypeptide product, or a complex or conjugate of a drug with a monoclonal antibody to specify the use of "different equipment'' instead of "new or different equipment'' for changes in production scale, and equipment of "a different design'' instead of "similar but not identical design and operating principle'' for the replacement of equipment.

FDA is also adding to the moderate changes provisions a change in the relaxation of an acceptance criterion or deletion of a test to comply with an official compendium that is consistent with FDA statutory and regulatory requirements. FDA is not requiring that a prior approval supplement be submitted for this type of change because the change has been reviewed by the United States Pharmacopeia (USP), and FDA and the public have had an opportunity to review, in general, the change through the USP process. However, because FDA will not have reviewed such a change in the context of each individual application affected by the change, a changes-being-effected-in-30-days supplement will still be required.

FDA has revised the proposal to clarify that the applicant may not

distribute the drug product until the supplement for a change under this provision has been amended to provide missing information that has been requested by FDA.

*E. Changes That May Be Implemented When FDA Receives a Supplement (Moderate Changes)*

FDA has clarified that labeling changes that normally require a prior approval supplement may, at the agency's request, be implemented when FDA receives a supplement.

*F. Changes To Be Described in the Next Annual Report*

FDA has revised the June 1999 proposal to state that any change made to comply with an official compendium that is consistent with FDA statutory and regulatory requirements may be submitted in the next annual report, except a change involving the relaxation of an acceptance criterion or deletion of a test to comply with an official compendium.

FDA has revised the June 1999 proposal to clarify that the majority of changes concerning replacement of equipment with equipment of the same design and operating principles may be submitted in an annual report. However, there are certain equipment changes identified in this rule that require submission in a changes-being-effected-in-30-days supplement or a changes-being-effected supplement.

FDA has revised the June 1999 proposal to clarify that certain changes made to the container closure systems for sterile drug products may be submitted in annual reports, as may certain changes for nonsterile drug product container closure systems. The changes are those based on a showing of equivalency under an approved or official compendium protocol.

FDA has revised the June 1999 proposal to clarify that an extension of an expiration dating period that can be reported in an annual report can be based on production batches instead of full production batches. FDA considers a production batch to be one made at production scale using production equipment in a production facility as specified in the application. Production scale does not necessarily mean the largest batch size produced, but a batch of a size or within a batch size range that has been approved in the application.

FDA has deleted the requirement that an annual report contain a list of all products involved in the changes. FDA has also clarified that an annual report must include the date each change was implemented instead of the date each change was made. FDA considers "the date each change was implemented'' to be the date that the condition established in the approved application is changed, not when the product made with the change is distributed. FDA has also revised the June 1999 proposal to clarify when validation protocols and SOPs must be included in an annual report submission.

*G. Other Information*

FDA has revised the June 1999 proposal to clarify that a protocol must be submitted as a prior approval supplement if the protocol was not already included in an approved application or when changing an approved protocol. In the June 1999 proposal, FDA used the terms "drug,'' "drug product,'' "drug substance,'' and "product.'' The agency has standardized the terminology throughout the final rule and used the terms "drug product,'' "drug substance,'' and/or "product'' as appropriate. In addition, the agency has made minor edits to the final rule in response to former President Clinton's June 1, 1998, memo on plain language in Government writing.

## III. Responses to Comments on the June 1999 Proposal

FDA received comments on most aspects of the June 1999 proposal from more than 30 pharmaceutical companies, pharmaceutical industry associations, and other interested persons. The comments and the agency's responses follow.

*A. General Comments*

(Comment 1) Many comments said the June 1999 proposal does not meet the intent of Congress when establishing section 506A of the act. The comments said that Congress expected the following: (1) Significant changes in FDA's past practices on manufacturing changes; (2) substantial improvement in the management of technical supplements for manufacturing changes; (3) regulatory relief without compromising quality, safety, or efficacy of drugs; (4) appropriate action on the marketing of regulated products in a manner that does not unduly impede innovation or product availability; (5) reduction in reporting and regulatory requirements; and (6) a small number of major manufacturing changes that require prior approval, but that most changes would require a less burdensome means of reporting than has been required in the past. Several comments said the June 1999 proposal generates new requirements for making regulatory submissions, adds new categories for making those submissions, and increases the documentation burden on industry. One comment also noted that the SUPAC guidances[1] would not fulfill the Congressional intent because they were published before the Modernization Act.

FDA believes that these regulations are consistent with the intent of Congress and that the regulatory requirements and reporting categories are consistent with section 506A of the act. Section 506A of the act provides FDA with considerable flexibility to determine the information and filing mechanism required for the agency to assess the effect of manufacturing changes in the safety and effectiveness of the product. There is a corresponding need to retain such flexibility in the proposed regulations implementing section 506A of the act to ensure that the least burdensome means for reporting changes are available. FDA believes that such flexibility will allow it to be responsive to increasing knowledge of and experience with certain types of changes and help ensure the efficacy and safety of the products involved. For example, a change that may currently be considered to have a substantial potential to have an adverse effect on the safety or effectiveness of the product may, at a later date, based on new information or advances in technology, be determined to have a lesser potential to have such an adverse effect. Conversely, a change originally considered to have a minimal or moderate potential to have an adverse effect on the safety or effectiveness of the product may later, as a result of new information, be found to have an increased, substantial potential to adversely effect the product.

The agency believes it can more readily respond to knowledge gained from manufacturing experience, further research and data collection, and advances in technology by issuing regulations that set out broad, general categories of manufacturing changes and by using guidance documents to provide FDA's current thinking on the specific changes that fall into those general categories. The regulations provide for a new approach to regulating postapproval manufacturing changes. The approach is based on the potential for a change to adversely affect the identity, strength, quality, purity, or potency of drug products as these factors relate to the safety and effectiveness of the product. The

[1] As explained in the June 1999 proposal, FDA developed the SUPAC guidances to ease preapproval requirements by categorizing certain manufacturing changes according to whether they had a minor, moderate, or major potential to affect product quality and performance.

regulations and companion guidance "Changes to an Approved NDA or ANDA'' will provide significant regulatory relief by allowing postapproval manufacturing changes to be implemented more rapidly, while still ensuring the identity, strength, quality, purity, and potency of drug products.

The regulation reduces the overall number of supplements requiring FDA approval prior to product distribution. In addition, many changes that are currently reported in supplements would be reported in annual reports. The regulation will not increase the number of annual reports but will allow applicants to include in an annual report information currently required to be reported to the agency in a supplemental application. The number of manufacturing changes currently reported in supplements that will be reported in annual reports is approximately 1,283.

For example, under the previous regulations, all manufacturing site changes for drug products required prior approval. Now only a few types of drug product manufacturing site changes must be submitted in a prior approval supplement. The majority can be submitted in a changes-being-effected-in-30-days supplement or in an annual report. Moreover, FDA further reduced many reporting requirements from the levels recommended in previous FDA guidances. For example, the SUPAC guidances recommended notification in an annual report when moving production operations between buildings at the same manufacturing site. Now, generally no notification is required for such changes affecting drug products that were covered under the following SUPAC guidances: (1) "Immediate-Release Solid Oral Dosage Forms: Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation'' (SUPAC–IR); (2) "Modified Release Solid Oral Dosage Forms: Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation'' (SUPAC–MR); and (3) "Nonsterile Semisolid Dosage Forms: Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls, In Vitro Release Testing, and In Vivo Bioequivalence'' (SUPAC–SS).

FDA believes that the approach to postapproval changes embodied in the SUPAC guidances is consistent with section 506A of the act. However, certain aspects of these documents need to be updated to be consistent with specific requirements included in the act. For example, the new reporting category for changes-being-effected-in-30-days supplements needs to be incorporated. FDA intends to update these guidances in the near future.

(Comment 2) Several comments said that FDA should adopt a "decision tree'' or "key questions'' approach in implementing section 506A of the act. The comments contend that this approach would allow a new approach to manufacturing changes that bases the regulatory reporting requirements on the results of scientific comparison of pre- and post-change material rather than allowing the reporting category to be determined by the potential for a change to have an adverse effect. The decision tree would focus on answering the key questions rather than exhaustive categorization of potential types of changes. One comment provided examples of decision trees for consideration.

FDA agrees that decision trees are a viable approach to postapproval manufacturing changes. However, a decision tree must consider the potential for a change to have an adverse effect to be consistent with section 506A of the act. The act bases the reporting category for a change on the potential for that change to have an adverse effect, not on the outcome of assessment studies. In some cases, based on the potential for an adverse effect, the act would require FDA to review a change prior to distribution of the drug product with the change, even if the applicant concludes that its studies and data demonstrate that the change has no significant adverse effect. FDA must evaluate whether the studies performed by the applicant were sufficient to assess the effect of the change and whether the data support the applicant's claim that the change has not adversely affected the identity, strength, quality, purity, and potency of the drug product as they may relate to the safety or effectiveness of a drug product. For example, an applicant may decide to develop an in vivo/in vitro correlation (IVIVC) for an extended release oral dosage form (see CDER's guidance entitled "Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In vitro/In vivo Correlations'' (September 1997)). If an IVIVC is established, the dissolution test will be used by the applicant as a surrogate for in vivo bioequivalence when it is necessary to document bioequivalence for postapproval changes. Establishing an IVIVC has a significant potential to affect the identity, strength, quality, purity, and potency of the drug product as they may relate to safety and effectiveness of the drug product, and requires a prior approval supplement. The applicant, based on its evaluation of the data, may believe that an IVIVC has been established but the agency, after evaluation of the applicant's data, may not concur. If the applicant decided that a prior approval supplement was not necessary based on its conclusions that an IVIVC has been established and implemented the change without waiting for the agency's concurrence, a drug product that is not bioequivalent could be distributed to the public.

FDA regulates a wide range of products, and a decision tree should address the fact that the potential for adverse effect will vary depending on factors such as the dosage form and route of administration. For example, in general, packaging changes that involve parenteral drug products are viewed by FDA to have a higher potential to have an adverse effect on the quality of the drug product as it relates to the safety and efficacy of the drug product than a packaging change for a solid oral dosage form product. Leachables from the packaging into parenteral drug products are more likely to occur than for a solid oral dosage form, and if leaching occurs, there is a higher potential for adverse reactions because of the route of administration. A safety determination by FDA must be made before the change is implemented. An applicant wishing to rely on a decision tree can submit the decision tree using an appropriate mechanism, such as submission of a comparability protocol containing a decision tree, and FDA will evaluate the decision tree for consistency with section 506A of the act.

(Comment 3) Another comment said that the proposal consisted of heightened reporting requirements for changes in packaging materials for sterile liquid dosage forms.

Previously, under § 314.70(b), changes in packaging for sterile liquid dosage forms routinely required prior approval by FDA before they could be implemented. The final rule, at § 314.70(b)(2)(iii), still emphasizes the importance, from the safety perspective, of ensuring the sterility of drug products by requiring that changes that may affect drug product sterility assurance be reported in a prior approval supplement. However, the guidance "Changes to an Approved NDA or ANDA,'' announced elsewhere in this issue of the **Federal Register**, includes certain changes in the packaging of these products that can be implemented by means other than prior approval supplements. This action has reduced, rather than heightened, the regulatory

burden relating to the packaging of sterile liquid dosage forms. FDA has included these changes in the guidance because, as stated in the proposal, the agency believes it can more readily respond to knowledge gained from manufacturing experience, further research and data collection, and advances in technology by issuing regulations that set out broad, general categories of manufacturing changes and by using guidance documents to provide FDA's current thinking on the specific changes that fall into those general categories (64 FR 34608 at 34610). Section 506A of the act explicitly provides FDA the authority to use guidance documents to determine the type of changes that do or do not have a substantial potential to adversely affect the safety or effectiveness of the drug product. As discussed previously in this document, the use of guidance documents will allow FDA to more easily and quickly modify and update important information. Guidance documents will be developed according to the procedures set out in FDA's good guidance practices (see the **Federal Register** of September 19, 2000 (65 FR 56468), and 21 CFR 10.115).

(Comment 4) Another comment requested that FDA specifically address in the final rule and/or guidance or in separate guidance how a change in the device aspect of a drug-device combination product is to be reported in applications. The comment said that when establishing rules for reporting changes in packaging and packaging components, FDA should not simply apply the rules for changes to drugs and biologics to the device-like aspects of combination products. Rather, the comment said, FDA should consider how the equivalent change is managed for the analogous medical device and apply that approach.

CDER and CBER work cooperatively with the Center for Devices and Radiological Health (CDRH) in the review of drug-device combinations. Determinations as to which regulations apply to a given combination product are product and application specific. Sponsors of combination products should consult with the Center that provided the approval of their application and with the Office of Combination Products to determine what requirements are applicable to the changes they wish to make to their product.

(Comment 5) Several comments said that the proposal put an overwhelming emphasis on postapproval changes for drug products and little on drug substances. The comments identified the following concerns: (1) The proposal is written entirely from the perspective of NDA and ANDA applicants and includes nothing for Drug Master File (DMF) holders; (2) a reporting classification system depending on the potential of a change to have an impact may usually work in the drug product area but is less apt to work for the drug substance, where the actual change may only be gauged by the data obtained when the change is made; and (3) the processes used in drug product and drug substance manufacturing differ greatly, making it difficult to determine how the changes outlined for drug products apply to drug substances. Several comments said that a separate document addressing changes relating to drug substances should be prepared.

The regulations emphasize changes in drug products and are written for NDA and ANDA applicants because the regulations describe the procedures for notifying FDA about changes in conditions established in an approved drug product application. Changes in a drug substance are only one of many types of changes that may occur in a drug product application. FDA has provided specific recommendations on drug substance changes in the guidance entitled "Changes to an Approved NDA or ANDA.'' In the **Federal Register** of February 16, 2001 (66 FR 10699), the agency announced a guidance that focuses specifically on postapproval manufacturing changes for certain drug substances entitled "BACPAC I: Intermediates in Drug Substance Synthesis, Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation'' (the BACPAC I guidance). FDA believes that the BACPAC I guidance addresses the concerns expressed in the comments.

(Comment 6) Several comments reiterated comments previously provided to the agency on the guidances entitled "BACPAC I'' and "Changes to an Approved NDA or ANDA,'' and asked FDA to consider these comments in finalizing the proposed regulation.

FDA has considered and addressed these resubmitted comments in this document to the extent that they were applicable to the proposed regulation.

(Comment 7) Another comment said that FDA should provide for realistic and workable filing mechanisms and requirements with regard to changes in the manufacturing of drug substances where the information is included in DMFs.

The regulations and companion guidance entitled "Changes to an Approved NDA or ANDA'' provide recommendations on reporting changes in the conditions established in an approved application, including changes in drug substance covered by DMFs. Issues relating to DMFs and how these are used in the application review process are outside the scope of this rulemaking.

(Comment 8) One comment stated that the rule should clearly address how changes in the manufacture of pharmaceutical packaging and pharmaceutical packaging components are to be handled. The comment said that the current regulation and the proposal and guidance address this issue incompletely, and frequently packaging and packaging component manufacturers are left to try to interpret the regulation as it applies to packaging.

FDA has clarified the requirements for packaging components in the final regulations as a result of the public comments and has included information on this topic in the guidance "Changes to an Approved NDA or ANDA.''

(Comment 9) Several comments said that the use of broad and vague terms (e.g., any change, may impact) should be minimized. The comments said that such terms lend themselves to different interpretations, are likely to cause confusion and inconsistent application, and are likely to result in more burdensome reporting requirements for changes that would be more appropriately categorized as moderate and/or minor changes. One comment said that FDA should revise these terms, and suggested adding the modifier "significant'' or "significantly'' in several instances to sharpen the intended meaning. The comment said that since the term "significant'' is itself undefined, it suggests that, in this context, "significant'' means "likely to adversely affect the identity, strength, quality, purity or potency of the related product.''

FDA agrees that the use of broad and vague terms should be minimized and has clarified the regulation, as appropriate, in response to comments received on the use of such terms as "any change'' and "may impact,'' and those comments suggesting adding the term "significant.''

(Comment 10) One comment asked whether the final regulations will contain references to appropriate guidance documents.

The final regulations do not reference specific guidance documents. FDA continues to update and develop guidances to address particular regulatory and scientific issues, and any references included in a regulation may quickly become outdated. Guidances that provide FDA's current thinking on specific topics can be located on the Internet at *http://www.fda.gov/cder/*

*guidance/index.htm* and *http://www.fda.gov/cber/guidelines.htm*.

(Comment 11) One comment said that although the proposal applies only to human drugs and biologics, the Center for Veterinary Medicine (CVM) may be preparing a similar proposal and may be compelled to apply most if not all of the principles described in the proposed rule. The comment said that the animal drug industry is very pleased with the successful 1996 CVM initiative, "Alternate Administrative Process for the Implementation and Submission of Supplemental Chemistry, Manufacturing and Control Changes (AAP).'' The comment said that its support of the Modernization Act was given based on the legal interpretation that the Modernization Act did not preclude the continuation of the AAP program. The comment said that the AAP program succinctly provides a process for determining minor supplemental chemistry, manufacturing, and control changes that are reported on a biennial basis. The comment continues to strongly support the concepts embodied in the AAP and is concerned that implementation of the proposed rule would be more burdensome, on both FDA and industry, than the AAP. The comment said that CVM and Animal Health Institute (AHI) member companies have had 3 years of successful implementation of this program and believe that the proposed rule, if applied to animal drugs, would be a major step backwards.

Comments relating to the AAP are outside the scope of this rulemaking and should be directed to the proposed rule for veterinary drug products entitled "Supplements and Other Changes to Approved New Animal Drug Applications'' (published in the **Federal Register** of October 1, 1999 (64 FR 53281)) (the October 1999 proposal).

*B. Definitions*

FDA proposed to amend the definitions sections of the regulations on applications for FDA approval to market a new drug (§ 314.3 (21 CFR 314.3)) and a biological product (§ 600.3 (21 CFR 600.3)) by adding definitions for "specification'' and "validate the effects of the change.'' Proposed §§ 314.3(b) and 600.3(hh) defined "specification'' as the quality standard (i.e., tests, analytical procedures, and acceptance criteria) provided in an approved application to confirm the quality of drug substances, drug products, intermediates, raw materials, reagents, and other components including container closure systems, and in-process materials. The term "acceptance criteria'' refers to numerical limits, ranges, or other criteria for the tests described.

FDA has revised the proposed definition of specification to make the use of the term "component'' consistent with the definition of "component'' at § 210.3 (21 CFR 210.3). FDA has revised the definition as follows:

*Specification* means the quality standard (i.e., tests, analytical procedures, and acceptance criteria) provided in an approved application to confirm the quality of drug substances, drug products, intermediates, raw materials, reagents, components, in-process materials, container closure systems, and other materials used in the production of a drug substance or drug product. For the purpose of this definition, *acceptance criteria* means numerical limits, ranges, or other criteria for the tests described.

FDA has made the same changes to proposed § 600.3(hh) (new § 600.3(jj)) and clarified the definition of specification for biological products by replacing the phrase "drug substances, drug products'' with "products.'' The term "products'' is defined in § 600.3(g).

(Comment 12) Several comments stated that "intermediates, raw materials, reagents, and other components including container closure systems, and in-process materials'' should be deleted from the definition of specification, and changes for these materials should be handled separately from the final rule and final guidance. The comments said that the definition is not consistent with the International Conference on Harmonisation (ICH) guidance on specifications entitled "Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances'' (ICH Q6A), which includes only drug substance and drug product. The comments said that to include items beyond the drug substance and drug product represents a level of complexity that would be better dealt with in guidances that can adequately evaluate the significance of changes to specific items.

FDA declines to revise the definition as requested. Section 505 of the act (21 U.S.C. 355) requires that a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of a drug be provided in an application. The regulations at § 314.50(d)(1) (21 CFR 314.50(d)(1)) require that an application include specifications as are necessary to ensure the identity, strength, quality, purity, and potency of the drug substance and drug product. Moreover, the regulation at § 314.50(d)(1)(ii)(a) specifically requires that specifications be provided for each component. It identifies specifications for container closures systems as an example of a specification needed to ensure the identity, strength, quality, purity, and potency of the drug product. For biologics, an applicant must submit a full description of manufacturing methods (§ 601.2 (21 CFR 601.2)). Intermediates, raw materials, reagents, container closure systems, in-process materials and other materials that are used in the manufacture of drug substances, drug products, and biologics are considered part of the manufacturing method and can have a direct effect on the identity, strength, quality, purity, and potency of the drug substance, drug product, or biologic. While the extent of a specification (e.g., number or type of tests, strictness of acceptance criteria) for these materials may vary depending on their use in a given manufacturing process, FDA has required specifications for these materials to be included in applications as part of the description of the manufacturing method and will continue to do so.

The ICH Q6A guidance and the ICH guidance on specifications entitled "Test Procedures and Acceptance Criteria for Biotechnology/Biological Products'' (ICH Q6B) are limited in scope. For example, ICH Q6A specifically excludes fermentation products. Interpreting the limitations of the ICH guidances to mean that specifications are not required for fermentation products or other materials outside the scope of ICH Q6A or ICH Q6B would be incorrect.

FDA requires specifications for intermediates, raw materials, reagents, container closure systems, in-process materials, and other materials used in the manufacturing process to be included in the application and, therefore, has included these materials in the definition of specification. Any changes in a specification, except editorial, must be reported to FDA and applicants need guidance on how to implement these changes. FDA declines deferring recommendations on these changes to a later guidance and has provided guidance on the recommended reporting categories for changes in specifications in FDA's guidances entitled "Changes to an Approved NDA or ANDA'' and "Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products'' (July 1997).

(Comment 13) One comment said that the term "specifications and test procedures'' was used in part 314 (21 CFR part 314) in the past, but the proposal replaced this with the term "specification,'' which is intended to mean both tests and specifications. The comment said that using one word to represent several things is confusing

and recommended retaining the previous terminology.

FDA declines to revise the use of the term "specification'' as requested. In the past, "specification'' as used in part 314 meant numerical limits, ranges, or other criteria for a test. In developing the ICH Q6A and ICH Q6B guidances, FDA agreed to define specification differently. A specification, as defined in ICH Q6A and ICH Q6B, includes tests, analytical procedures, and acceptance criteria. FDA has used the ICH Q6A and ICH Q6B terminology in this rule to promote consistency with the ICH documents.

(Comment 14) One comment identified various types of specification changes and recommended how these should be categorized and reported.

FDA declines to expand the discussion of specification changes in the regulation. As stated in the June 1999 proposal, the agency believes it can more readily respond to knowledge gained from manufacturing experience, further research and data collection, and advances in technology by issuing regulations that set out broad, general categories of manufacturing changes and by using guidance documents to provide FDA's current thinking on the specific changes that fall into those general categories (64 FR 34608 at 34610). FDA has provided recommendations on specific changes in specifications in FDA's guidances entitled "Changes to an Approved NDA or ANDA'' and "Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products.''

Proposed §§ 314.3(b) and 600.3(ii) defined "validate the effects of the change'' as an assessment of the effect of a manufacturing change on the identity, strength, quality, purity, or potency of a drug as these factors relate to the safety or effectiveness of the drug.

(Comment 15) Many comments recommended that FDA replace the terms validate or validation with assess or assessment. Several comments stated that although FDA used the terms consistently with Congress's use of the terms in section 506A of the act, they believe that the term "validate'' is likely to cause confusion because this term has long been associated with and has specific meaning under FDA's CGMP regulation.

FDA agrees and has revised the definition as requested by replacing "validate'' with "assess.'' In addition, as a result of comments requesting that the use of the terms drug, drug product, drug substance, and product be standardized, FDA has clarified the definition in § 314.3(b) by replacing the term "drug'' with "drug product.'' FDA has clarified the definition in proposed § 600.3(ii) (new § 600.3(kk)) by replacing the term "drug'' with "product.'' The terms drug product and products are defined at §§ 314.3(b) and 600.3(g), respectively. FDA, on its own initiative, has also revised the phrase "purity, or potency'' to "purity, and potency'' and the phrase "as these factors relate'' to "as these factors may relate'' to be consistent with section 506A(b) of the act, and the phrase "to assess the effect'' to "to evaluate the effects'' for clarity. FDA notes that while the effect of a manufacturing change on the identity, strength, quality, purity and potency of a drug or biological product is to be assessed, this assessment could involve testing of materials directly affected by a change (e.g., drug substance) in addition to or instead of drug or biological product testing.

(Comment 16) Several comments recommended that unambiguous definitions of substantial, moderate, and minimal potential for adverse effects be added to the regulation, and one comment recommended that examples be added for clarification. One comment asked that a definition of natural product be added.

FDA declines to revise the regulation as requested. The regulations apply to many types of changes for a broad spectrum of products. The meaning of substantial, moderate, and minimal potential for adverse effects is most easily illustrated through the use of examples. FDA has decided to use guidance documents to provide specific examples of changes that are considered to have substantial, moderate, and minimal potential to have adverse effect rather than enumerate them in the regulation. FDA has provided many examples of types of changes in FDA's guidances entitled "Changes to an Approved NDA or ANDA'' and "Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products.'' In addition, FDA has provided an explanation of the term "natural products'' in the guidance on "Changes to an Approved NDA or ANDA.''

(Comment 17) Concerning the regulations on the content and format of an application in § 314.50, one comment noted that § 314.50(d)(1)(i) and (d)(i)(ii) includes the following statement for drug substance and drug product: "Reference to the current edition of the USP/NF [National Formulary] may satisfy the relevant requirements in the paragraph.'' The comment said it appeared that this statement was being deleted and contended that it should be retained in the regulations.

FDA is clarifying that this sentence has not been deleted from § 314.50(d)(1)(i) or (d)(1)(ii). As stated in the June 1999 proposal, FDA is revising the first two sentences of these paragraphs.

*C. Changes to an Approved Application*

Proposed § 314.70(a)(1) set forth general requirements under which an applicant must notify FDA about each change in each condition established in an approved application beyond the variations already provided for in the application. The notice is required to describe the change fully. Depending on the type of change, the applicant must notify FDA about the change in a supplement under § 314.70(b) or (c) or by inclusion of the information in an annual report under § 314.70(d).

(Comment 18) One comment said that the statements "an applicant must notify FDA about each change in each condition established in an approved application beyond the variations already provided for in the application'' and that "the notice is required to describe the change fully'' should be clarified because it could be overly burdensome from the standpoint that some changes, for example, changes made to batch records submitted as part of the application, may not require reporting under § 314.70.

FDA declines to revise the regulation as requested and notes that the agency does not expect to be informed about nonsubstantive editorial changes in information included in an application. Nonsubstantive editorial changes include such changes as corrections of spelling or typographical errors or reformatting of documents (e.g., batch records, specification sheets).

Proposed §§ 314.70(a)(2) and 601.12(a)(2) (21 CFR 601.12(a)(2)) required the holder of an approved application to validate the effects of manufacturing changes on the identity, strength, quality, purity, or potency of a drug as these factors may relate to the safety or effectiveness of the drug before distributing a drug made with a manufacturing change.

(Comment 19) A few comments said that the proposal would increase the reporting burden despite the specific provision in the Modernization Act for having assessment data at the time of submission of manufacturing change supplements. The comment said that the Modernization Act specifies that a drug made with a manufacturing change may be distributed only after completing studies that assess the effects of the change. The comment said

that the legislative intent of the Modernization Act is that if appropriate studies comparing pre- and postchange material are performed and no evidence of an adverse effect is found, then a reduced reporting category for the evaluated changes is appropriate. The comment reasoned that a given proposed manufacturing change can indeed have substantial potential for adverse effects at its inception because little might be known about the impacts of the change. However, by the time actual material has been made with the change and assessment studies have been successfully completed, most or all of the potential impacts of the change have been eliminated. The comment said that the assessment information should permit a reduced reporting requirement.

FDA disagrees with these comments. Section 506A(c)(2) of the act states that a major manufacturing change is "a change that is determined by the Secretary to have substantial *potential* to adversely affect the identity, strength, quality, purity, or potency of the drug as they may relate to the safety or effectiveness of a drug'' (emphasis added). The act bases the reporting category for a change on the potential for that change to have an adverse effect, not on the outcome of the assessment studies. The comment implies that the only changes that would be reported in a prior approval supplement are those where the applicant's studies to assess the effects of the change demonstrate that there is in fact an adverse effect on the identity, strength, quality, purity, or potency of the drug as they may relate to the safety or effectiveness of a drug product. FDA does not believe that this was the intent of Congress. Some manufacturing changes have an adverse effect on the identity, strength, quality, purity, or potency of the drug product. In many cases, the applicant chooses not to implement these manufacturing changes, but sometimes the applicant wishes to do so. If an assessment indicates that a change has adversely affected the identity, strength, quality, purity, or potency of the drug product, the change must be submitted in a prior approval supplement, regardless of the recommended reporting category for the change. For example, a process change recommended for a changes-being-effected-in-30-days supplement could cause the formation of a new degradant that requires qualification and/or identification. The applicant may believe that there are no safety concerns relating to the new degradant. Even so, the applicant must submit this change in a prior approval supplement with appropriate information to support the continued safety and effectiveness of the product. During the review of the prior approval supplement, FDA will assess the impact of any adverse effect on the drug product as this change may relate to the safety or effectiveness of the drug product.

FDA also received comments requesting that the term "assess'' be used instead of "validate.'' FDA has made this change in §§ 314.70(a)(2) and 601.12(a)(2), where appropriate. In § 314.70(a)(2), FDA, on its own initiative, has deleted the phrase "on the identity, strength, quality, purity, and potency of the drug product as these factors may relate to the safety or effectiveness of the drug product'' because "assess the effects of the change,'' as defined in § 314.3(b), includes this phrase.

Proposed §§ 314.70(a)(3) and 601.12(a)(3) stated that notwithstanding the supplement submission requirements, an applicant must make a manufacturing change in accordance with a regulation or guidance that provides for a less burdensome notification of the change.

(Comment 20) Several comments noted that they were pleased that the provision that a change can be made "in accordance with a regulation or guidance that provides for a less burdensome notification of the change'' was proposed because it permits less burdensome reporting mechanisms for changes.

FDA acknowledges these comments and has retained this provision in the final rule.

Proposed §§ 314.70(a)(4) and 601.12(a)(4) stated that the applicant must promptly revise all promotional labeling and advertising to make it consistent with any labeling change implemented in accordance with this section.

(Comment 21) Several comments said that the previous provisions in § 314.70 limited the requirement to promptly revise all promotional labeling and advertising to those changes that were to be filed in a changes-being-effected supplement, and that this requirement is not necessary for the type of labeling changes that would be filed in an annual report. The comments suggested that this requirement be limited to those labeling changes that would be filed in supplemental applications.

The agency agrees with the comments and has revised § 314.70(a)(4) to require applicants to revise promotional labeling and advertising to make it consistent with labeling changes implemented in accordance with § 314.70(b) and (c). In addition, § 601.12(a)(4) requires applicants to revise promotional labeling and advertising to make it consistent with labeling changes implemented in accordance with § 601.12(f)(1) and (f)(2).

Proposed § 314.70(a)(5) stated that, except for a supplement providing for a change in the labeling, the applicant must include in each supplemental application providing for a change under paragraph (b) or (c) a statement certifying that a field copy of the supplement has been provided to the applicant's home FDA district office.

(Comment 22) A few comments requested that FDA clarify whether the field copy that is to be sent to the applicant's "home FDA district office'' should be the FDA office where the change is being made or the FDA office in the district of the company's corporate headquarters from where the submission documents are sent. The comments also said that if the field copy should be sent to the office where the change is being made, FDA should clarify what FDA office(s) serve for changes made internationally. The comment said that the clarification will help to ensure that the appropriate documents get to the correct FDA district office.

Mailing information for field copies is provided in § 314.440(a)(4). Currently, FDA recommends that the "applicant's home FDA district office'' referred to in § 314.440(a)(4) be the district office where the applicant's headquarters is located. FDA has clarified this provision by cross-referencing § 314.440(a)(4). Section 314.440(a)(4) also provides mailing information for international applicants. FDA, on its own initiative, has also clarified the provision by adding "amendments to supplements.'' A field copy of an amendment to a supplement, which is submitted by an applicant to incorporate additional or corrected information into their original supplement, is currently required under § 314.440(a)(4).

Proposed §§ 314.70(a)(6) and 601.12(a)(5) added a requirement that a list of all changes contained in the supplement or annual report must be included in the cover letter for the supplement or annual report.

(Comment 23) Many comments agreed that a list of changes should be included in the cover letter for a supplement. However, the comments disagreed that a list of all changes contained in the annual report should be included in a cover letter. The comments said that including a list in a cover letter to an annual report is overburdensome because cover letters are not required for annual reports, only a Form FDA 2252, and a list of changes is already provided

in a section of an annual report. Several comments said that an applicant should have the option of providing the list in a location other than the cover letter, such as at the beginning of the supplement.

FDA agrees with the requests to permit the list of changes to be provided in the summary section of the annual report and has revised §§ 314.70(a)(6) and 601.12(a)(5) to require changes to be listed in the cover letter only for supplemental applications.

An annual report is required to contain a brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product (§ 314.81(b)(2)(i)). FDA's guidance for industry entitled "Format and Content for the CMC Section of an Annual Report'' (September 1994) states, regarding the summary of new information, that the firm should include in the annual report "a brief summary of all changes made to the application during the reporting period including changes made in accordance with approved supplements under 21 CFR 314.70(b) and * * * supplements under 21 CFR 314.70(c)* * *.'' Supplements are not required to have a summary section (§ 314.50(c)).

FDA is requiring that a list of changes be provided in both supplemental applications and annual reports. FDA proposed this requirement as a means to more efficiently locate and identify changes in what are often documents of substantial length. The list will also allow FDA to quickly assess whether the appropriate reporting category was used. To achieve these objectives, it is essential that the list be in a consistent location for each type of submission.

(Comment 24) Several comments were concerned that the list of changes, if included in a cover letter, would not be considered confidential information.

The standards for disclosing specific information from a cover letter or application do not differ depending on where this information is provided. Information that is exempted from disclosure (e.g., trade secret or confidential commercial information) is not disclosed whether it is in a cover letter or an application (see also §§ 314.430 and 601.51 (21 CFR 601.51)).

(Comment 25) One comment requested that the phrase "list of all changes'' be revised to "a brief summary of major changes.''

FDA declines to revise the regulation as suggested. Each change, including moderate and minor changes, should be listed. FDA notes that the description of the listed change should be in sufficient detail to allow the agency to quickly determine whether the appropriate reporting category for the change has been used. For example, describing a change as "a change in the drug product specification'' does not provide sufficient detail. A description such as "deletion of the friability test and associated acceptance criteria and analytical procedure from the drug product specification'' would allow FDA to quickly assess whether the appropriate reporting category was used. The detailed information about each change and the information developed to assess the effects of the change would be provided in the supplement or elsewhere in the annual report.

(Comment 26) Several comments suggested changes in Form FDA 2252 that accompanies an annual report.

FDA declines to revise Form FDA 2252 because it is not within the scope of this regulation.

*D. Changes Requiring Supplement Submission and Approval Prior to Distribution of the Product Made Using the Change (Major Changes)*

Proposed § 314.70(b)(1) required that a supplement requiring prior approval must be submitted for any change in the product, production process, quality controls, equipment, or facilities that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as these factors may relate to the safety or effectiveness of the product.

(Comment 27) Many comments asked whether a prior approval supplement would be required even if the applicant has demonstrated that the change has no significant adverse affect.

Section 506A(c)(2) of the act states that a major manufacturing change is "a change that is determined by the Secretary to have substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as they may relate to the safety or effectiveness of a drug.'' The act bases the reporting category for a change on the potential for that change to have an adverse effect, not on the outcome of the assessment studies. FDA would expect a prior approval supplement to be submitted for a change that has substantial potential to adversely affect the identity, strength, quality, purity, or potency of a drug product even if the applicant concludes that their studies and data demonstrate that the change has no adverse effect. Prior to distribution of the drug product made with the change, FDA must evaluate whether the studies performed by the applicant were sufficient to assess the effect of the change and that the data support the applicant's claim that the change has not adversely affected the identity, strength, quality, purity, or potency of the drug product as they may relate to the safety or effectiveness of a drug product.

(Comment 28) One comment said that section 506A of the act identifies major changes as formulation, specification, or those requiring studies in accordance with part 320 (21 CFR part 320) to demonstrate the equivalence of the drug product to the drug product as manufactured without the change or to the reference listed drug. The comment said that FDA has proposed prior approval supplements for changes that are clearly outside of these three major change categories. Another comment said it appears that FDA has overutilized section 506A(c)(2)(C) of the act.

FDA disagrees that it has overutilized this part of the act. In addition to the three major changes identified previously in this document, section 506A(c)(2)(C) of the act states that a major change "is another type of change determined by the Secretary by regulation or guidance to have a substantial potential to adversely affect the safety or effectiveness of the drug.'' In previous regulations, many manufacturing changes required prior approval supplements. FDA has used this provision of the act to identify a limited number of changes that it considers to have a substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as they may relate to the safety or effectiveness of a drug. The regulation reduces the overall number of supplements requiring FDA approval prior to product distribution. In addition, many changes that are currently reported in supplements will be able to be reported in annual reports. The regulation will not increase the number of annual reports but will allow applicants to include in an annual report information currently required to be reported to the agency in a supplemental application. Moreover, FDA further reduced many reporting requirements from the levels recommended in previous FDA guidances.

Proposed § 314.70(b)(2)(i) provided that, except as provided in § 314.70(c) and (d), prior approval is required for changes in the qualitative or quantitative formulation of the drug, including inactive ingredients, or in the specifications provided in the approved application.

(Comment 29) A few comments recommended that proposed

§ 314.70(b)(2)(i) be revised to better reflect section 506A(c)(2)(A) of the act which allows exceptions to the requirement to obtain prior approval before changing the qualitative or quantitative formulation of the drug. One comment recommended the provision be revised to state: "Except as provided in paragraphs (c) and (d) of this section or exempted by regulation or guidance * * *."

FDA declines to revise the regulation as requested. Section 506A(c)(2)(A) of the act states that a prior approval supplement is required when a change "is made in the qualitative or quantitative formulation of the drug involved or the specifications in the approved application or license * * * (unless exempted by the Secretary by regulation or guidance * * *)." Proposed § 314.70 is consistent with the provisions of the act. Exemptions by regulation are provided in § 314.70(c) or (d). This language is already included in § 314.70(b)(2)(i). In addition, FDA may use guidance documents to provide for a less burdensome notification of a specific change. This exemption is included in § 314.70(a)(3) and applies to § 314.70(b)(2)(i) as well as the other changes listed in § 314.70.

(Comment 30) Several comments noted that the SUPAC guidances allowed for some changes in qualitative or quantitative formulation of the drug product to be filed in changes-being-effected supplements or annual reports. One comment said that the regulations should follow the standards in the SUPAC guidances.

FDA has not incorporated the qualitative and quantitative formulation change information from the SUPAC guidances in the regulation because, as stated in the proposal, the agency's approach is to issue regulations that set out broad, general categories of manufacturing changes and use guidance documents to provide FDA's current thinking on the specific changes included in those categories.

(Comment 31) Several comments said that changes in specification to comply with an official compendium should not require prior approval supplements.

FDA is not requiring prior approval supplements for specification changes made to comply with an official compendium. A complete discussion of this issue is provided under section III.F of this document, "Changes To Be Described in the Next Annual Report," in response to comments on § 314.70(d)(2)(i).

(Comment 32) One comment recommended the proposed language be revised to limit specification changes to those for drug substance or drug product.

FDA considers a specification to be a quality standard (i.e., tests, analytical procedures, and acceptance criteria) provided in an approved application to confirm the quality of drug substances, drug products, intermediates, raw materials, reagents, components, in-process materials, container closure systems, or other materials used in the production of a drug substance or drug product. Therefore, FDA declines to revise the proposal as suggested.

Proposed § 314.70(b)(2)(ii) required prior approval for changes requiring completion of studies in accordance with part 320 to demonstrate the equivalence of the drug to the drug as manufactured without the change or to the reference listed drug.

(Comment 33) One comment said that reference to part 320 suggests that bioequivalence must be addressed for "a change in the manufacturing process * * *." The comment said that this will lead to significant interpretation issues. The comment said that a selective subset of major manufacturing changes that truly have "substantial potential" should be specified here. Another comment said that when the product is a true solution, changes to the manufacturing process (not formulation) are highly unlikely to change the formulation and additional clinical (bioequivalence) studies should not always be required.

FDA declines to revise the proposal based on these comments. The requirements for when a study is needed to demonstrate the equivalence of a drug product made with the proposed change to a drug product made without the change or to the reference listed drug are provided in part 320. Part 314 is not intended to supplement, supersede, or clarify these requirements. Section 314.70(b)(2)(ii) specifies only that if such a study is required under part 320 to support a postapproval change, the postapproval change must be submitted using a prior approval supplement. Changes that require a study under part 320 are considered major changes that have a significant potential to affect the identity, strength, quality, purity, or potency of the product as it relates to the safety or effectiveness of a product, and FDA would need to review such studies before a product made with the change is placed into distribution.

Proposed § 314.70(b)(2)(iii) required prior approval for changes that may affect product sterility assurance, such as changes in product or component sterilization method(s) or an addition, deletion, or substitution of steps in an aseptic processing operation.

(Comment 34) Many comments stated that the proposed language was too broad and should be modified to state "changes that may significantly affect product sterility assurance" or "changes that significantly affect product sterility assurance". One comment said that the term "may affect" is not appropriate because any change may affect one or more attributes of a sterile drug.

Sterility of drug products or drug substances is a fundamental and essential quality attribute of these drugs and is a critical aspect of the safety assessment. The manufacture of a sterile drug is an exacting, difficult, and highly controlled series of processes, especially in the case of aseptically processed drugs. The concept of significance or "significantly affect" implies that a measurement of an attribute, such as sterility, can be made. However, no test is sensitive enough to detect unacceptable sterility assurance levels (i.e., the probability of a nonsterile unit). For example, a batch of drug product tested using the standard drug product sterility test described in the USP/NF will fail the sterility test only when at least 14 percent of the batch is contaminated (95 percent confidence level). This sterility assurance level is unacceptable. The probability of nonsterile units for terminally sterilized and aseptically processed drugs is normally expected by FDA to be less than 0.0001 percent and 0.1 percent, respectively. FDA ensures the safety of sterile drugs by assessing the efficacy of a given sterilization process for a specific drug and by ensuring that the facilities producing sterile drugs comply with CGMPs. The assessment of the efficacy of a sterilization process includes review of multiple protocols and scientific experiments designed to demonstrate that the sterilization process and associated control procedures can reproducibly deliver a sterile product. The data derived from the experiments and control procedures allow certain conclusions to be drawn about the probability of nonsterile units. A properly validated sterilization process will provide the sterility assurance level required by FDA to ensure the safety of sterile drugs. Because of the lack of adequate test procedures for assessing sterility and the complexity in evaluating the process validation and controls information to determine the level of sterility assurance that a given process provides for a specific drug, FDA has used the term "may affect" and declines to revise the proposal as suggested.

(Comment 35) Many comments stated that the proposed language should be clarified to state "changes that may adversely affect product sterility assurance * * *'' or "changes that may reduce (or decrease) product sterility assurance * * *''.

New § 314.70(b)(1) already identifies that the changes that should be submitted in prior approval supplements are those that have a substantial potential to have an "adverse effect.'' FDA declines to revise proposed § 314.70(b)(2)(iii) as requested because the addition of the term "adversely'' is redundant. FDA emphasizes that the assessment of whether a change may adversely affect sterility assurance is a complex and multidimensional analysis. For example, a change to a more stringent terminal sterilization process, while in theory providing a lower probability of nonsterile units, may damage the container closure system so that sterility of individual units could not be maintained.

(Comment 36) Several comments said that the proposed language is too restrictive because it indicates that all changes to sterile products should be submitted in prior approval supplements. The comments said that this contradicts what is in the guidance entitled "Changes to an Approved NDA or ANDA,'' which identifies some changes that do not have to be filed in prior approval supplements. One comment identified specific examples of manufacturing changes for sterile products and said that these should not be considered major changes.

FDA considers changes that may affect the sterility assurance level of a drug to have significant potential to affect the safety of the drug. Therefore, FDA has identified this change as one that requires prior approval. As stated in the June 1999 proposal, this rulemaking sets out broad, general categories of manufacturing changes, and the agency uses guidance documents to provide FDA's current thinking on the specific changes included in those categories. Under § 314.70(a)(3), an applicant must notify FDA of a manufacturing change in accordance with either a regulation or a guidance that addresses the same issues as the regulation but that provides for a less burdensome notification of the change than the regulation (for example, by submission of a supplement that does not require approval prior to distribution of the product). For example, in the guidance entitled "Changes to an Approved NDA or ANDA,'' FDA has identified less burdensome reporting categories for certain changes that it believes have less potential to affect sterility assurance and consequently the safety of the drug.

(Comment 37) A few comments said that this provision increases the regulatory burden with respect to sterile products. The comments said that only fundamental changes to sterile processing require prior approval.

FDA disagrees with this comment. Under the previous regulations at § 314.70, manufacturing site, processing, and packaging changes for sterile drugs almost always required a prior approval supplement (previous § 314.70(b)(1)(iv), (b)(1)(v), (b)(2)(iv), (b)(2)(v), and (b)(2)(vi)). Under § 314.70(c) and (d), certain changes related to sterile drugs may be submitted in changes-being-effected supplements or annual reports (for example, § 314.70(d)(2)(i) and (iii)). In the guidance entitled "Changes to an Approved NDA or ANDA,'' FDA has identified many changes related to sterile drugs that may now be submitted in changes-being-effected supplements or annual reports.

Proposed § 314.70(b)(2)(iv) required prior approval for changes in the synthesis or manufacture of the drug substance that may affect the impurity profile and/or the physical, chemical, or biological properties of the drug substance.

(Comment 38) One comment said that the proposal should be revised to state "Changes in the route of synthesis or * * *.'' Changes such as an additional recrystallization step (using the same solvents, and so forth) should be considered for changes-being-effected status.

FDA declines to revise the proposal as suggested. Changes in the synthesis, including the route of synthesis, may have an effect on the impurity profile and/or the physical, chemical, or biological properties of the drug substance. For example, a change in a solvent used in the crystallization step may affect the impurity profile and physical properties of the drug substance even though this change would not be considered a change in the "route of synthesis.''

(Comment 39) Several comments stated that the proposed language should be clarified to state "changes that may adversely affect the impurity profile * * *'' because changes that improve the quality of the drug substance should not require a prior approval supplement.

New § 314.70(b)(1) states that the changes that should be submitted in prior approval supplements are those that have a substantial potential to have an "adverse effect.'' FDA declines to revise the provision as requested because the addition of the term "adversely'' is redundant.

(Comment 40) One comment suggested that FDA change "may affect the impurity profile of the drug product'' to "are likely to affect the impurity profile of the drug product.'' The comment said that many factors could affect the impurity profile, and this stringent reporting requirement should be reserved for factors that are likely to produce a change.

FDA believes the phrase "may affect'' is appropriate because the decision on whether a change should be considered a major, moderate, or minor change is based on the potential for the change to adversely affect the identity, strength, quality, purity, or potency of the drug as they may relate to the safety or effectiveness of a drug product. FDA considers a change that "may affect the impurity profile and/or the physical, chemical, or biological properties of the drug substance'' to be a change that has a substantial potential to result in an adverse effect and declines to delete "may.''

(Comment 41) One comment said that inserting the clause "beyond those studied in the pre-clinical studies and requiring a change in the approved specifications'' after impurity profile would add clarity. The comment said that according to the ICH guidance entitled "Impurities in New Drug Substances'' (ICH Q3A), impurities below a certain threshold would not necessarily require registration.

The process of qualifying impurities and determining if a postchange impurity profile for a drug substance is equivalent or better than the impurity profile of the prechange material is a complex issue. FDA does not believe it is possible to clarify the regulations to adequately address the many different types of human drugs it regulates. For example, not all drug approvals require preclinical studies. FDA declines to revise the proposal as suggested. FDA published the BACPAC I guidance to provide recommendations on how to evaluate changes in impurity profiles.

(Comment 42) Several comments said that the proposed regulations were not consistent with the BACPAC I guidance. Several comments said that the proposal was much more restrictive than what was included in the BACPAC I guidance. One comment said that changes in drug substance synthesis route, which occur prior to the formation of key intermediates, should not be regarded as major changes, since the potential to impact the quality, strength, identity, and purity of the final product is low.

FDA declines to revise the regulations as requested. The BACPAC I guidance is an example of a guidance that permits certain specific changes that fall under the general category of a change that "may affect the impurity profile and/or the physical, chemical, or biological properties of the drug substance'' to be reported using a less burdensome method of notification. Under § 314.70(a)(3), an applicant must notify FDA of a manufacturing change in accordance with either a regulation or a guidance that addresses the same issues as the regulation but that provides for a less burdensome notification of the change than the regulation (for example, by submission of a supplement that does not require approval prior to distribution of the product).

Proposed § 314.70(b)(2)(v) required prior approval for changes in labeling, except those described in § 314.70(c)(6)(iii), (d)(2)(ix), or (d)(2)(x).

On its own initiative, FDA has revised § 314.70(b)(2)(v) to add: "If applicable, any change to a Medication Guide required under part 208 of this chapter, except for changes in the information specified in § 208.20(b)(8)(iii) and (b)(8)(iv) of this chapter.'' This provision, which was previously in § 314.70(b)(3)(ii), was inadvertently omitted from the proposed rule.

(Comment 43) Many comments said that FDA should clarify "labeling'' to indicate "drug product labeling'' because drug substance labeling changes need not be submitted.

FDA declines to revise the regulations as requested. The term "labeling'' in § 314.70 is consistent with "labeling'' as used in part 201 (21 CFR part 201). Part 201 applies to the labeling of drugs and/or drug products.

Proposed § 314.70(b)(2)(vi) required prior approval for changes in a container closure system that controls drug delivery or that may affect the impurity profile of the drug product.

(Comment 44) Several comments requested that the proposed language be clarified to state "changes that may adversely affect the impurity profile * * *'' or "changes that adversely affect the impurity profile ***.''

FDA declines to revise the provision because the addition of the term "adversely'' is redundant. New § 314.70(b)(1) already states that the changes that should be filed in prior approval supplements are those that have a substantial potential to have an "adverse effect.'' FDA believes the phrase "may affect'' is appropriate because the decision on whether a change should be considered a major, moderate, or minor change is based on the potential for the change to adversely affect the identity, strength, quality, purity, or potency of the drug as they may relate to the safety or effectiveness of a drug product. FDA considers a change that "may affect the impurity profile of the drug product'' to be a change that has a substantial potential to result in an adverse effect and declines to delete "may.''

(Comment 45) One comment requested clarification of what is meant by "controls drug delivery,'' such as quantity dispensed, machine calibration, and volume of fill.

For some drug products, the container closure system itself, rather than a person, regulates the amount of drug product that is administered to a patient. These container closure systems are considered to "control drug delivery.'' For example, a patient that uses a metered dose inhalation product as instructed cannot control the amount of drug product the container closure system delivers or verify that the appropriate amount has been administered. Where a drug product container closure system controls drug delivery, FDA requires information to be submitted to support that the container closure system can accurately and repeatedly deliver the required amount of drug product. The design and operation of these container closure systems is critical to ensure that the patient receives the correct dose. A drug product may not be safe or effective if a patient receives too much or too little of the drug product. Changes in these systems are considered to have a substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as they may relate to the safety or effectiveness of a drug product. Container closure systems for drug products where a person controls the amount of drug product administered and/or which allow for verification that the appropriate amount has been administered (e.g., number of tablets, milliliters of liquid) are not considered container closure systems that "control drug delivery.''

(Comment 46) Another comment asked whether this section specifically refers to the final packaged product only.

Changes in "a container closure system that controls drug delivery'' applies only to the marketed drug product container closure system, and the language has been revised in the final rule to clarify this. Changes that "may affect the impurity profile of the drug product'' applies to any type of container closure system.

(Comment 47) One comment noted an apparent conflict between § 314.70(b)(2)(vi), which says that a "change in a container closure system that * * * may affect the impurity profile of the drug product'' should be submitted in a prior approval supplement and § 314.70(c)(2)(i), which says that "a change in the container closure system that does not affect the quality of the final drug product'' should be submitted in a changes-being-effected-in-30-days supplement. The comment said that this would allow for inconsistent and overly conservative interpretations of what might fall into this latter category.

FDA agrees that clarification of the wording in these two provisions of the regulations is needed. FDA has particular concerns about changes in the type (e.g., glass to high density polyethylene (HDPE), HDPE to polyvinyl chloride, vial to syringe) or composition (e.g., one HDPE resin to another HDPE resin) of packaging components because these changes may affect the impurity profile of the drug product. These concerns are compounded by the fact that, in most cases, the packaging component manufacturer considers the manufacturing process confidential information and discloses it only to FDA. Therefore, an applicant does not have knowledge of all potential impurities that a different type or composition of a packaging component may introduce into a product. Depending on the dosage form affected and its route of administration, FDA may have to evaluate the safety of changes in the type or composition of a packaging component. Because of the safety concerns relating to new impurities from a packaging component with this type of change, FDA considers such changes to have a substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as they may relate to the safety or effectiveness of a drug product. FDA has revised § 314.70(b)(2)(vi) to limit the requirement to situations involving changes in the type or composition of a packaging component. FDA considers a deletion or addition of a packaging component to fall within the meaning of a change in the type of packaging component. FDA may, through regulations or guidance, identify certain dosage forms and/or routes of administration where there is a lower potential for adverse effect and allow changes in type or composition of a packaging component in these situations to be reported in changes-being-effected supplements or annual reports.

For consistency with the proposal, FDA has revised § 314.50(d)(1)(ii)(*a*) to

change "containers and closure systems'' to "container closure systems.''

Proposed § 314.70(b)(2)(vii) required prior approval for changes solely affecting a natural product, a recombinant DNA-derived protein/polypeptide product, or a complex or conjugate of a drug with a monoclonal antibody for the following:

(1) Changes in the virus or adventitious agent removal or inactivation method(s); (2) changes in the source material or cell line; and (3) establishment of a new master cell bank or seed.

(Comment 48) Several comments requested that FDA delete the reference to "natural products,'' while others requested that FDA provide a definition for natural products. A few comments asked whether fermentation-based products are considered natural products.

FDA declines to delete natural products from this provision. The changes identified in this provision are considered to be major changes and apply equally to a natural product, a recombinant DNA-derived protein/polypeptide, or a complex or conjugate of a drug substance with a monoclonal antibody. FDA has provided a definition of natural product in the guidance entitled "Changes to an Approved NDA or ANDA'' but declines to provide the definition in the regulation because advancements in technology may require that the definition be revised. FDA has defined natural product in the guidance to mean "materials (e.g., drug substance, excipients) that are derived from plants, animals, or microorganisms. The specific recommendations for natural products are not applicable to inorganic compounds (e.g., salts, minerals).'' Fermentation based products are considered natural products.

(Comment 49) A few comments said that this provision increases the regulatory burden with respect to natural products. One comment said that there was no need to distinguish a natural product, a recombinant DNA-derived protein/polypeptide, or a complex or conjugate of a drug substance with a monoclonal antibody from other products.

FDA disagrees with these comments. Under the previous regulations at § 314.70, many manufacturing process changes for drug substances and drug products, including those for a natural product, a recombinant DNA-derived protein/polypeptide, or a complex or conjugate of a drug substance with a monoclonal antibody, required a prior approval supplement (previous § 314.70(b)(1)(iv) and (b)(2)(v)). FDA has reduced the reporting category for many manufacturing process changes relating to these products by allowing them to be reported in changes-being-effected supplements or annual reports. However, the three changes specified in this provision, which are unique to these specific types of drugs, are considered to have a substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug product as they may relate to the safety or effectiveness of a drug product. Virus or adventitious agent removal or inactivation processes are the means by which FDA ensures that adventitious agents such as porcine parovirus, if present, are removed. Failure to remove such adventitious agents has a significant potential to adversely affect public safety. Changes in source material or cell line and establishment of a new master cell bank or seed have a substantial potential to affect the quality of a drug substance. For example, a change in source material (e.g., species, geographic region of harvesting) could result in different impurities or contaminants (e.g., pesticides) than were previously seen or a change in potency.

Proposed § 314.70(b)(3) stated that the applicant must obtain approval of a supplement from FDA before distributing a product using a change and specified the information to be included in the supplement.

(Comment 50) A few comments requested adding "as appropriate'' as follows: "Except for submissions under paragraph (e) of this section, the following shall be contained in the supplement, as appropriate.'' The comments said that not all listed material is relevant for every submission.

FDA declines to revise the provision as requested. FDA expects that the information specified in § 314.70(b)(3)(i) through (b)(3)(v) will be needed for almost all supplemental applications. FDA believes that the addition of "as appropriate'' may incorrectly give the impression that this information is not routinely needed and would result in supplemental applications being submitted with insufficient information. FDA may specify in a guidance that information required in § 314.70(b)(3)(i) through (b)(3)(v) is not needed for a particular change. However, in the absence of such a recommendation, FDA would expect § 314.70(b)(3)(i) through (b)(3)(v) to be addressed in each supplemental application. The information in § 314.70(b)(3)(vi) and (b)(3)(vii) is needed only in certain situations, and this is clearly indicated.

Proposed § 314.70(b)(3)(vi) stated that for a natural product, a recombinant DNA-derived protein/polypeptide product, or a complex or conjugate of a drug with a monoclonal antibody, relevant validation protocols must be provided in addition to the requirements in § 314.70(b)(3)(iv) and (b)(3)(v).

(Comment 51) One comment said that the requirement that relevant validation protocols be provided is overly restrictive and burdensome. The comment suggested that this statement be rephrased to state "validation protocols may be requested by the FDA.'' Another comment recommended that this section be deleted because there is no need for different requirements for these products. The comment said that this information (relevant validation protocols) is available for review onsite. The comment said that if FDA disagrees and feels that special requirements are warranted, the comment recommended these specific details be more appropriately captured in the guidance instead.

Unless otherwise specified by FDA, validation protocols and data need not be filed in the application. For most products, FDA does not require the submission of validation protocols and data. However, for a natural product, a recombinant DNA-derived protein/polypeptide, or a complex or conjugate of a drug substance with a monoclonal antibody, FDA does require the submission of validation protocols for certain critical manufacturing processes unique to these drug substances and drug products. For example, FDA would expect the validation protocol for the virus or adventitious agent removal or inactivation process to be submitted in an application. FDA currently requires this type of information to be submitted in an application and believes it is necessary; therefore, FDA declines to revise the regulation as suggested.

Proposed § 314.70(b)(3)(vii) stated that for sterilization process and test methodologies, relevant validation protocols must be provided in addition to the requirements in § 314.70(b)(3)(iv) and (b)(3)(v).

(Comment 52) One comment said that the inclusion of validation protocols for sterilization assurance is new. The comment also said that submitting all validation data is different from data summaries previously requested and provided for microbiological consults.

FDA disagrees with this comment. The information on sterility assurance FDA expects an applicant to provide in an application and the format of the data are described in the guidance

entitled "Submission of Documentation of Sterilization Process Validation in Applications for Human and Veterinary Drug Products.'' The provisions of § 314.70(b)(3)(vii) are consistent with current FDA policy.

(Comment 53) One comment said that clarification is needed that the test methodologies and validation protocols referred to in this section are for the sterilization process only.

FDA agrees and has replaced "test methodologies'' with "test methodologies related to sterilization process validation'' in new § 314.70(b)(3)(vii).

Proposed § 314.70(b)(3)(viii) stated that a reference list of relevant SOPs, when applicable, must be contained in the supplement.

(Comment 54) Many comments recommended that reference to SOPs be deleted. Several of these comments said that it was unclear what value a reference list of SOPs provides in the division review process and that SOPs are generally considered a CGMP issue. One comment said that reference to appropriate SOPs is currently required only as it pertains to sterilization processes and biologic products. The comment also contended that inclusion of a reference list of SOPs in the submission for any type of change is not necessary. Several comments said that "when applicable'' was too vague and one comment recommended that the provision be revised to state "A reference list of relevant standard operating procedures (SOPs) for aseptic processing operations.''

An applicant is required to submit a "full description of controls used for the manufacture, processing, and packing of a drug'' (section 505 of the act). This information may be submitted in different forms, including SOPs. In most cases, SOPs do not include information relevant to the NDA or ANDA review, but rather information relevant to determining an applicant's compliance with CGMPs. However, in the case of a natural product, a recombinant DNA-derived protein/polypeptide, a complex or conjugate of a drug substance with a monoclonal antibody, or a sterilization process, information contained in SOPs is often relevant to the review of certain aspects of an application. FDA has deleted proposed § 314.70(b)(3)(viii) and revised § 314.70(b)(3)(vi) and (b)(3)(vii) to limit the need for information on SOPs in these situations. The agency clarifies that information regarding SOPs is needed in some cases. FDA wishes to emphasize that while the information is needed for the application review, it is not always necessary to submit the actual SOP as long as the required information is provided in sufficient detail as part of the application.

On its own initiative, FDA has revised § 314.70(b)(3)(iv) by replacing the phrase "evaluate the effect of the change * * * (validating the effects of the change)'' with "assess the effects of the change'' because the term is defined at § 314.3(b). In the introductory text of § 314.70(b)(3), FDA replaced the phrase "the following shall'' with "the following information must'' to add clarity.

Proposed §§ 314.70(b)(4) and 601.12(b)(4) provided that an applicant may request an expedited review of a supplement if a delay in making the change would impose an extraordinary hardship or for public health reasons.

(Comment 55) One comment said that a complete definition of expedited review from FDA's "Manual of Policies and Procedures'' (MAPPs) should be incorporated in the regulation. One comment said FDA should consider adding mandatory vendor-imposed changes (without sufficient reaction time) to the list of "not reasonably foreseen'' events.

FDA has published two MAPPs on expedited review—MAPP 5420.1 entitled "Requests for Expedited Review of Supplements to Approved ANDAs and AADAs'' and MAPP 5410.3 entitled "Requests for Expedited Review of NDA Chemistry Supplements.'' These MAPPs contain criteria that FDA uses in granting expedited review based on public health need, extraordinary hardship on the applicant, or agency need. FDA declines to add this detailed information on internal FDA procedures to the regulation but encourages applicants to review these MAPPs to see how FDA would assess a request for an expedited review. The MAPPs already include "abrupt discontinuation of supply of active ingredient, packaging material, or container closure'' as an example of an extraordinary hardship that was not reasonably foreseen. An applicant is required to submit sufficient documentation to support a need for an expedited review. In the case of an abrupt discontinuation of supply, FDA will require information to support that the discontinuation was abrupt such as when the supplier informed the applicant of the discontinuation of supply, the amount of supplies available in-house and from the supplier, and the date the supplies are expected to run out. FDA emphasizes that inadequate planning on the part of an applicant is not a reason for FDA to expedite the review of a supplement based on extraordinary hardship.

(Comment 56) A few comments requested that FDA provide feedback to the sponsor on acceptance or refusal of an "expedited review'' request within 30 days.

FDA's MAPPs 5240.1 and 5310.3 describe procedures for processing expedited review requests. All requests for expedited review are reviewed promptly, usually within 30 days of receipt. If the review division denies the request, the applicant will be contacted. FDA declines to specify that it will contact applicants to advise them that their expedited review request has been granted or that the decision will be made within 30 days. However, applicants can contact the review division at any time about the status of their request.

*E. Changes Requiring Supplement Submission at Least 30 Days Prior to Distribution of the Drug Product Made Using the Change (Moderate Changes)*

Proposed § 314.70(c)(1) required that a supplement be submitted for any change in the product, production process, quality controls, equipment, or facilities that has a moderate potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as these factors may relate to the safety or effectiveness of the product. If the change concerns labeling, 12 copies of the final printed labeling must be included.

(Comment 57) One comment said that in the preamble to the final rule, FDA should further clarify the criteria to be used to distinguish between changes-being-effected supplements that can be implemented immediately and those where distribution cannot occur until 30 days after FDA receives the supplement.

The decision by FDA as to whether a moderate change should be classified as one that can be implemented by an applicant when FDA receives a supplement or one requiring supplement submission at least 30 days prior to distribution of the drug product made using the change depends on many factors. Some of these factors include the need for FDA to verify compliance status, dosage form, route of administration, or whether, based on FDA's experience, a particular type of change is usually complete and provides the proper information. It is not possible to provide a general list of factors considered because different factors are considered by FDA for each type of change.

(Comment 58) A few comments requested changes in the format of this section. One comment said that supplements for changes being effected in 30 days as well as changes being

effected immediately are defined as "moderate changes.'' The comment asked whether there can be different verbiage for these two categories to allow differentiation. Another comment suggested that the two types of changes-being-effected supplements should be separated into different paragraphs under this section.

FDA declines to revise the regulations as requested. FDA believes that the format and terms are adequate and will not be unclear when individuals become more familiar with the regulations and the guidance.

(Comment 59) One comment said it recognizes that the supplements for changes being effected in 30 days is a statutory classification. The comment said that, unfortunately, the provision does not provide material advantage over a changes-being-effected supplement for either the agency or the industry, especially for new chemical entities (NCEs). The comment said that, instead, the provision adds a 30-day wait period that does not currently exist for NCEs. The comment said that, from FDA's point of view, the reviewer will be spending twice the amount of time on the same application, first for an administrative review for the completeness of the information and later to actually review the application. The comment said that from industry's point of view, the 30-day wait period does not necessarily provide increased assurance of an approval action. The comment suggested that any change that can be the subject of a changes-being-effected-in-30-days supplement could just as easily be reclassified as a changes-being-effected supplement. The comment said that this would save time for both FDA and industry.

FDA declines to revise the regulation as requested. The changes-being-effected-in-30-days provision allows certain changes previously requiring prior approval to be implemented rapidly, thus reducing the percentage of supplements requiring prior approval. FDA recognizes that the public health can be adequately protected without requiring approval of certain manufacturing changes prior to distribution of the product made with the change. FDA continues to believe that it is important that such changes be documented and validated so there is a mechanism for assessing the consequences of the changes and that the agency approve such changes. Ready access to information regarding such changes through submission of a supplement 30 days before distribution of the product would protect against the distribution of unsafe or ineffective products while speeding the availability of improved products. The provision is intended to benefit the public health because it permits FDA to stop or delay a product from being distributed to the public when the product is made with a major change (i.e., one with a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as these factors may relate to the safety or effectiveness of the product) that is improperly categorized as a moderate change. The provision also permits the agency to act when information necessary to demonstrate that the change has not adversely affected product quality is not provided.

(Comment 60) Several comments recommended inserting "only'' in the last sentence to read: "If the change concerns only labeling, include 12 copies of final printed label.'' One comment said that there are changes that have minor impacts on labeling (for example, signature changes) that, if implemented as stated, would result in an increased regulatory burden to provide finished product labeling prior to change implementation.

FDA declines to revise the regulation as requested because changes-being-effected supplements (within 30 days and immediately) that include both manufacturing changes and labeling changes must also include 12 copies of the final printed labeling, if appropriate. However, FDA has clarified that the only labeling changes that require submission of 12 copies of finished product labeling at the time of supplement submission are those classified as a moderate change. Changes-being-effected manufacturing supplements that result in labeling changes that are classified as minor under § 314.70(d) do not have to include copies of final printed labeling. The final printed labeling for these minor labeling changes can be submitted in the next annual report in accordance with § 314.81(b)(2)(iii).

FDA has clarified § 314.70(c)(1) to explain when final printed labeling must be submitted by revising the last sentence to read "If the supplement provides for a labeling change under paragraph (c)(6)(iii) of this section, 12 copies of the final printed labeling must be included.''

(Comment 61) One comment said that FDA should delete the requirement to provide 12 copies of the final printed labeling with a changes-being-effected labeling supplement. The comment said that although the specified changes may be submitted in a changes-being-effected supplement, at times they may not be implemented until after the submission. The comment said that to print final labeling specifically for the changes-being-effected supplement is unnecessarily expensive and complicates the normal labeling printing process. The comment said that an alternative would be to submit a typed copy of the labeling and submit the final printed labeling in the annual report.

FDA declines to revise the regulation as requested. Moderate labeling changes, which are those that have a moderate potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as these factors may relate to the safety or effectiveness of the product, can be implemented immediately without FDA's prior approval. In FDA's experience, errors that occurred when draft labeling was converted to final printed labeling have made the final printed labeling unacceptable. Also, FDA reviews not only the content of labeling for accuracy but also the format (e.g., layout, size of print) for clarity. A typed copy of the labeling does not always accurately reflect the format of the final printed labeling. The labeling should be available for review at the time of submission whether or not the applicant intends to implement the change immediately upon FDA receipt of the supplement.

(Comment 62) One comment stated that current § 314.70(c)(3) permits a different facility to be used for the production of the drug substance under certain conditions. The comment said that the proposal does not include this provision, and that FDA intends to provide recommendations concerning this in certain guidance documents. The comment said that this provision of current § 314.70 should be retained in the revised regulation because the industry is familiar with the provision and has used it for years.

FDA declines to revise the proposal as requested. As stated in the proposal, the agency's approach is to issue regulations that set out broad, general categories of manufacturing changes and use guidance documents to provide FDA's current thinking on the specific changes included in those categories. FDA has provided recommendations on changes in manufacturing sites in FDA's guidance entitled "Changes to an Approved NDA or ANDA.''

Proposed § 314.70(c)(2)(i) stated that changes requiring supplement submission at least 30 days prior to distribution of the drug product made using the change (moderate changes) includes the following change: A change in the container closure system that does not affect the quality of the final drug product.

(Comment 63) Many comments recommended that the requirement should be changed to include "significant change'' and/or "adversely affect,'' so that the regulation would read: "A significant change in the container closure system that does not adversely affect the quality of the final drug product.''

FDA declines to revise the provision as requested. New § 314.70(c)(1) already states that the changes that should be filed in changes-being-effected supplements are those that have a moderate potential to have an "adverse effect.'' Adding the word "adversely'' to this provision is redundant. Adding the term "significant'' is also inappropriate because any change, whether big or small, should not adversely affect the quality of the final drug product. Some manufacturing changes have an adverse effect on the identity, strength, quality, purity, or potency of the drug product. In many cases, the applicant chooses not to implement these manufacturing changes, but sometimes the applicant wishes to do so. If an assessment indicates that a change has adversely affected the identity, strength, quality, purity, or potency of the drug product, the change should be submitted in a prior approval supplement, regardless of the recommended reporting category for the change. For example, a process change recommended for a changes-being-effected-in-30-days supplement could cause the formation of a new degradant that requires qualification and/or identification. The applicant may believe that there are no safety concerns relating to the new degradant. Even so, the applicant should submit this change in a prior approval supplement with appropriate information to support the continued safety and effectiveness of the product. During the review of the prior approval supplement, FDA will assess the impact of any adverse effect on the drug product as this change may relate to the safety or effectiveness of the drug product.

(Comment 64) One comment noted an apparent conflict between proposed § 314.70(b)(2)(vi), which stated that a "change in a container closure system that * * * may affect the impurity profile of the drug product'' should be filed in a prior approval supplement, and proposed § 314.70(c)(2)(i), which stated that "a change in the container closure system that does not affect the quality of the final drug product'' should be filed in a changes-being-effected-in-30-days supplement. The comment said that this would allow for inconsistent and overly conservative interpretations of what might fall under § 314.70(b)(2)(vi).

FDA agrees and has clarified the wording in these two provisions. Changes to proposed § 314.70(b)(2)(vi) were discussed previously under section III.C of this document. For consistency, § 314.70(c)(2)(i) was revised to exclude changes that would be included under § 314.70(b) and (d).

FDA emphasizes that the container closure system and packaging component changes identified in § 314.70(b) must be filed in a prior approval supplement even if an applicant concludes that the quality of the drug product has not been adversely affected. The provision has also been revised to standardize terminology, as requested, by changing "final drug product'' to "drug product.''

Proposed § 314.70(c)(2)(ii) stated that changes requiring supplement submission at least 30 days prior to distribution of the drug product made using the change (moderate changes) included the following change: Changes solely affecting a natural protein product, a recombinant DNA-derived protein/polypeptide product or a complex or conjugate of a drug with a monoclonal antibody, including the following: (1) An increase or decrease in production scale during finishing steps that involves new or different equipment; and (2) replacement of equipment with that of similar, but not identical, design and operating principle that does not affect the process methodology or process operating parameters.

(Comment 65) Several comments said that having special requirements for this category of products represents additional regulatory reporting requirements beyond current practice. A few comments recommended that this section be deleted. One comment said that these products should not be regulated differently than the traditional products. The comment said that if FDA disagrees and feels that this requirement is warranted, the specific details be captured in the guidance instead.

FDA declines to revise the regulation as requested. There are specific issues and concerns relating to the production of proteins that are not routinely associated with other classes of drugs; therefore, FDA has specified certain requirements for proteins. Proteins are susceptible to denaturation. Denaturation can be caused by changes in sheer force as a result of scale and/or equipment changes. Also, proteins differentially adsorb to surfaces. The identity, strength, quality, purity, or potency of the product could be affected by changes in scale or equipment because of these characteristics.

(Comment 66) A few comments requested that FDA clarify whether this section applies to drug products or drug substance.

FDA agrees and has clarified the proposed language, which is intended to apply to both drug substance and drug product.

(Comment 67) A few comments recommended that FDA delete reference to "natural protein products.'' The comments also requested clarification as to whether the definition natural products includes fermentation products.

FDA declines to revise the regulation as requested. Issues about scale and equipment and concerns associated with proteins are the same whether the protein is derived from a natural source or by other means, such as DNA technology. The definition of natural products was discussed in comment number 48 of this document. Natural proteins are a subset of natural products.

(Comment 68) One comment said that this section applies to both an increase and decrease in batch size involving new equipment. The comment asked whether new equipment includes replacement equipment.

FDA agrees and has clarified the proposed language. The phrase "new or different equipment'' has been replaced by the phrase "different equipment.'' Different equipment can include new models, changes in capacity, construction materials (e.g., glass-lined tanks to stainless steel), equipment design, and/or equipment operating principles. If a scale change involves replacing equipment with equipment that is identical in all critical aspects (e.g., same model and capacity, same construction materials), this is a type of change that could be reported in an annual report. For the same reasons, FDA is revising § 601.12(c)(2)(ii) to delete the word "new.''

(Comment 69) A few comments requested clarification of "finishing steps.''

FDA declines to revise the regulations to provide clarification of the term "finishing steps.'' In general, finishing steps are considered those steps in the manufacturing process where the stability, or the property and performance, of a protein product is less likely to be affected by changes in scale or equipment. The steps in a manufacturing process that would be considered finishing steps depend on the manufacturing process and the specific protein being manufactured. A particular manufacturing step may be

considered a finishing step for one product but not for another. An applicant is encouraged to discuss with FDA which steps would be considered finishing steps for a particular product and process. This discussion should occur as early in the process as possible, including during investigational new drug (IND) meetings.

(Comment 70) A few comments requested clarification of the difference between equipment that is "similar but not identical,'' proposed as a changes-being-effected-in-30-days supplement, and the SUPAC terminology of equipment of the "same design and operating principle,'' which is already defined in the SUPAC guidances and the June 1999 proposal as an annual report change. The comment said that the difference is not readily apparent and may lead to varying interpretations of regulatory submission requirements. The comments said that for equipment changes that are of different operating principle and design, FDA should consider the major change category, and for equipment changes that are of the same operating principle but different design, FDA should consider the moderate change category.

FDA agrees and has clarified the requirement by replacing the phrase "of similar, but not identical, design and operating principle that'' with the phrase "that of a different design that.'' Equipment of a different design may or may not have a different operating principle.

(Comment 71) One comment suggested inserting the word "adversely'' before "affect'' to read: "Replacement of equipment with that of similar, but not identical, design and operating principle that does not adversely affect the process methodology or process operating parameters.'' The comment said that replacement of equipment that does not adversely affect the process methodology or operating parameters and/or positively affects process methodology or operating parameters should be reported as a minor change.

FDA declines to revise the provision as requested. New § 314.70(c)(1) already states that the changes that should be filed in changes-being-effected supplements are those that have a moderate potential to have an "adverse effect.'' Adding the word "adversely'' to this provision is redundant.

Proposed § 314.70(c)(4) stated that pending approval of the supplement by FDA, except as provided in paragraph (c)(6), distribution of the product made using the change may begin not less than 30 days after receipt of the supplement by FDA. The information listed in § 314.70(b)(3)(i) through (b)(3)(viii) must be contained in the supplement.

(Comment 72) One comment said that the last sentence in § 314.70(c)(4) should be revised to read: "The information listed in paragraphs (b)(3)(i) through (b)(3)(vii) * * *'' because currently CGMP validation information, including a reference to appropriate SOPs, is required to be submitted in applications only as it pertains to sterilization processes.

FDA has revised § 314.70(c)(4) to make it consistent with the changes made in § 314.70(b)(3) to address the concerns raised by the comment (see discussion in comment numbers 50 through 54 in section III.C of this document) and also to clarify the term "product.''

(Comment 73) One comment said that a time line and dispute resolution process needs to be defined by regulation or guidance in case of disputes regarding the type of information needed to support a change.

FDA does not believe it is necessary to revise proposed § 314.70 to address this issue. Actions by reviewers or other Center officials may be appealed through the appeals mechanism already in place in each Center to the Center Director and, ultimately, to the Commissioner of Food and Drugs. Dispute resolution procedures are detailed in 21 CFR 10.75 and 21 CFR 312.48, and §§ 314.103 and 601.12(h). FDA has also provided additional information in guidance documents. In the **Federal Register** of March 7, 2000 (65 FR 12019), FDA issued a guidance entitled "Formal Dispute Resolution; Appeals Above the Division Level.'' The guidance describes the mechanism for resolution of procedural (including administrative) and scientific disputes in CDER and CBER.

Proposed § 314.70(c)(5) stated that the applicant must not distribute the product made using the change if, within 30 days following FDA's receipt of the supplement, FDA informs the applicant that either: (1) The change requires approval prior to distribution of the product in accordance with paragraph (b); or (2) any of the information required under § 314.70(c)(4) is missing. The applicant must not distribute the product made using the change until FDA determines that compliance is achieved.

(Comment 74) One comment said that if FDA determines within 30 days of receipt of the supplement that the change is properly submitted but the required information is incomplete, the applicant would be required to supply the missing information and wait until FDA determines that the supplement is in compliance before distributing the product. The comment contended that as long as the firm submits the data requested by FDA, it should be able to go to market and not wait until FDA determines that the supplement is "in compliance,'' which could take months since FDA is not now bound by the 30-day requirement.

FDA agrees and has clarified the requirement based on this comment. FDA has revised § 314.70(c)(5) to provide that, in the case of missing information, the applicant must not distribute the drug product until the supplement has been amended to provide the missing information.

(Comment 75) One comment asked, when additional information is provided, whether FDA's determination of compliance with the requirements of this section is equivalent to an approval of the supplement.

FDA has revised this section, and this comment is no longer applicable. However, FDA clarifies that it sends a formal letter to an applicant stating that a particular supplement is approved and that no other communication from FDA should be construed as an approval.

Proposed § 314.70(c)(7) stated that if the agency disapproves the supplemental application, it may order the manufacturer to cease distribution of the drug products made with the manufacturing change.

(Comment 76) A few comments recommended that FDA replace this requirement with the following: "If FDA later determines that the supplemental application is not immediately approvable, the agency will work with the applicant to resolve all issues and to assure the continued availability of the drug.'' Another comment recommended that this requirement be limited to only those cases where an adverse effect on safety or efficacy can be demonstrated. One comment said that although this is the language contained in section 506A(d)(3)(B)(iii) of the act, it is a reversal of long-time FDA policy of allowing firms to respond to deficiencies and get the supplement approved without interfering with distribution. The comment said that FDA should continue its long-standing policy.

FDA declines to revise the provision as requested. The regulation is consistent with section 506A(d)(3)(B)(iii) of the act. There may be some instances where FDA determines, after the drug product made using the change has been distributed, that the information submitted in the supplement fails to adequately demonstrate the continued safety and

effectiveness of the drug product. In such cases, FDA will make all possible efforts to resolve problems with the applicant concerning the supplement submission without requiring the removal of the drug product from the marketplace. In cases where FDA determines that there may be a danger to public health due to continued marketing of the drug product or when FDA determines that the issues may not otherwise be resolved, the agency may require that the applicant cease distribution of the drug product made using the change or that the product be removed from distribution pending resolution of the issues related to the change.

(Comment 77) One comment said that if FDA disapproves a changes-being-effected-in-30-days supplement, the sponsor should be notified within 30 days of this submission as stated in § 314.70(c)(5)(ii).

FDA declines to revise the regulation based on this comment. FDA intends during the 30-day period to focus its review on determining whether the applicant reported the change using the appropriate mechanism and, if so, whether any of the required information is missing. FDA intends to perform the substantive review of the submission as expeditiously as possible, but this is unlikely to occur within 30 days of receipt of the supplement.

*F. Changes For Which Distribution of the Drug Product Involved May Commence When FDA Receives a Supplement (Moderate Changes)*

Proposed § 314.70(c)(6) stated that FDA may designate a category of changes for which the holder of an approved application making such a change may begin distribution of the drug upon receipt by FDA of a supplemental application for the change. These changes include, under § 314.70(c)(6)(i), an addition to a specification or changes in the methods or controls to provide increased assurance that the drug will have the characteristics of identity, strength, quality, purity, or potency that it purports or is represented to possess.

(Comment 78) Several comments recommended that an addition to a specification or change in the methods or controls to provide increased assurance that the drug will have the characteristics of identity, strength, quality, purity, or potency that it purports or is represented to possess should be considered to have a minimal potential to have an adverse effect and should be allowed to be filed in the annual report.

FDA declines to revise the regulation as requested. FDA has identified certain specific changes that provide increased assurance that may be submitted in an annual report, such as the tightening of an acceptance criterion. However, this is a general provision and the assessment of whether or not a change provides "increased assurance'' is subjective and must be supported by studies and data, as appropriate. FDA must have the opportunity to concur with an applicant's assessment that a change provides "increased assurance'' in a timely manner. Reporting of such changes in an annual report would not afford FDA this opportunity because a change may be in effect for up to a year before FDA would have the opportunity to review the change. Changes that do not necessarily provide increased assurance may be a type of change that must be submitted in a changes-being-effected-in-30-days supplement or a supplement that requires approval prior to distribution of the product made using the change.

(Comment 79) One comment recommended that FDA change "addition to a specification or changes in the methods or controls'' to "addition to a specification or changes in the tests, analytical procedures, or acceptance criteria.''

FDA declines to revise the regulation as requested. The phrase "methods or controls'' is not used by FDA to mean tests, analytical procedures, or acceptance criteria. Methods and controls relate to the manufacturing process.

Proposed § 314.70(c)(6)(ii) included the following category: A change in the size and/or shape of a container for a nonsterile drug product, except for solid dosage forms, without a change in the labeled amount of product or from one container closure system to another.

(Comment 80) A few comments recommended adding "a sterile drug product, or a sterile drug substance'' to read "* * * container for a nonsterile drug product, except for solid dosage forms, a sterile drug product, or a sterile drug substance without a change.'' The comments said that changes in the size and shape of containers for sterile drug substances or sterile drug products have only moderate potential impact. The comments said that this is especially true when the nature of the size/shape changes are very minor, as is often the case when suppliers make minute adjustments in their packaging components.

FDA declines to revise the regulation as requested. As discussed in the comments for § 314.70(b)(2)(iii) in section III.C of this document, sterility of drug products or drug substances is a fundamental and essential quality attribute of these drugs and is a critical aspect of the safety assessment. Changes in the container closure system, even if minimal, may affect the sterility assurance of the drug product and are a major change. For sterile drug substances, the effect of changes in the size and/or shape of the container closure system is considered by FDA to be of lower risk because of the differences in procedures for sterilizing drug substances and drug products, but the risk is still higher than for nonsterile products. Therefore, FDA declines to specify in the regulations that these changes can be submitted in a changes-being-effected supplement. Additional information on changing container closure systems for sterile drug substances or drug products is included in the guidance "Changes to an Approved NDA or ANDA.''

(Comment 81) Several comments pertained to the phrase "without a change in the labeled amount of product.'' The comments said that proportional changes (i.e., ratio of the amount of drug product to size of container) are not expected to adversely affect the drug product, and one of these comments recommended that FDA should add "and a change in the labeled amount of product as long as the size of the container/closure system is changed proportionally.'' Other comments said that a corresponding change in fill quantity, along with a change in container size, is expected and readily acceptable and that it is illogical to assume that a change in the amount of product would present any greater risk than a change in container size.

FDA declines to revise the regulation as requested or with similar language included in § 314.70(d)(2)(iv). The phrase "labeled amount of product'' refers to the total quantity of drug product (e.g., milliliters, grams). FDA has included the phrase "without a change in the labeled amount of product'' because of the agency's concern about the proliferation of unit-of-use containers that may invite the misuse of drug products. A unit-of-use container is one that contains a specific quantity of a drug product and that is intended to be dispensed to the patient without further modification except for the addition of appropriate labeling. Although few in number, some drug products may cause life-threatening side effects, such as permanent liver damage, if used for longer periods of time than recommended in the labeling. Similarly, certain drugs must be used for a specific length of time (e.g., antibiotics) or the treatment may be ineffective. Unit-of-

use containers that contain a quantity of drug product that invite underuse or overuse of the product as recommended in the labeling may be a public health risk. FDA considers changes in the labeled amount of a nonsterile drug product in a unit-of-use container to have a moderate potential to adversely affect the safety and efficacy of the drug product and expects that these changes would normally be submitted in a changes-being-effected-in-30-days supplement under § 314.70(c)(2)(i). This would give FDA an opportunity to raise a concern about a package presentation prior to distribution of the product.

FDA's concern is less when the "labeled amount of product'' is changed in multiple-unit containers for nonsterile drug products. FDA considers this change to have the same level of risk as a change in the size and/or shape of the container. A multiple-unit container is a container that permits withdrawal of successive portions of the contents without changing the strength, quality, or purity of the remaining portion. This type of container is not for direct distribution to patients, but is used by health care practitioners who dispense the drug in smaller amounts in accordance with a physician's instructions. While FDA declines to revise the regulations to specify the distinction between unit-of-use and multiple-use containers because of the complexity of the issue, FDA will address this issue when revising the guidances "Changes to an Approved NDA or ANDA'' and "Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products.''

Proposed § 314.70(c)(6)(iii)(C) included as a moderate change a change in the labeling to add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the product.

(Comment 82) One comment said that FDA should replace the words "and administration'' in § 314.70(c)(6)(iii)(C) with the words "administration and storage.''

FDA declines to revise the regulation as requested. The addition or strengthening of a storage statement could reflect a change in the expected characteristics or quality of a drug product and would be a major change. Also, one of FDA's objectives is to have the same drug products stored similarly to avoid confusion in the marketplace. FDA would need to review the proposed change prior to implementation to determine if: (1) The change is appropriate, (2) any changes in product quality causing the labeling change significantly impact the safety or effectiveness of the drug, and (3) there are other issues that need to be addressed either on an individual company basis or globally.

Proposed § 314.70(c)(6)(iii)(E) included as a moderate change any other change specifically requested by FDA.

(Comment 83) One comment said that any changes made to the labeling that are specifically required by the FDA should be reportable in the annual report.

FDA declines to revise the June 1999 proposal as requested but has revised § 314.70(c)(6)(iii)(E) to provide clarification. As stated in the June 1999 proposal, FDA proposed adding this section to allow labeling changes that normally require prior approval to be submitted in a changes-being-effected supplement when FDA specifically requests the change. FDA has clarified § 314.70(c)(6)(iii)(E) as follows: "Any labeling change normally requiring a supplement submission and approval prior to distribution of the drug product that FDA specifically requests be submitted under this provision.'' FDA has also clarified § 601.12(f)(2)(i)(E) as follows: "Any labeling change normally requiring a supplement submission and approval prior to distribution of the product that FDA specifically requests be submitted under this provision.''

*G. Changes To Be Described in the Next Annual Report (Minor Changes)*

Proposed § 314.70(d)(1) required that changes in the product, production process, quality controls, equipment, or facilities that have a minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as these factors may relate to the safety or effectiveness of the product must be documented by the applicant in the next annual report in accordance with § 314.81(b)(2).

Proposed § 314.70(d)(2)(i) required the following change to be documented in the next annual report: Any change made to comply with an official compendium that is consistent with FDA requirements and provides increased assurance that the drug will have the characteristics of identity, strength, quality, purity, or potency that it purports or is represented to possess.

FDA received 18 comments on this provision. Fifteen comments requested that FDA change this requirement to read "Any change to comply with an official compendium;'' two comments requested that FDA change this requirement to read "Any change made to comply with an official compendium that is consistent with FDA requirements;'' and one comment did not provide a suggested revision.

FDA declines to revise the provision as requested in the comments but has revised the provision to provide further clarification. The basis for this decision is discussed below. The majority of the comments pertained to drugs regulated under, and the statutory requirements regarding official compendia included in, the act. Therefore, FDA has responded to the comments from this perspective. FDA has made corresponding changes to § 601.12(c) and (d) for biologics regulated under section 351 of the PHS Act.

(Comment 84) Many comments said that the proposal to require supplemental applications for some changes that are made to comply with an official compendium fails to recognize the legal status of the USP/NF under the act and undermines the authority of the USP/NF as official compendia and sources of standards. One comment stated that if a drug product meets compendial requirements, it is considered unadulterated under the act. Another comment stated that the USP is the responsible compendial body for regulatory specifications.

Under section 501(b) of the act (21 U.S.C. 351(b)), a drug that is recognized in an official compendium may be considered adulterated if its strength differs from, or its quality or purity fall below, the standards set in the compendium. Determinations of adulteration under this provision of the act must be made in accordance with the analytical procedures set in the compendium. When there is no analytical procedure prescribed in the compendium or the tests prescribed in the compendium are insufficient, the agency can follow the process outlined in the statute and issue a regulation to provide an appropriate analytical procedure. As stated in the act, no drug defined in an official compendium will be considered adulterated under section 501(b) of the act because its strength differs from, or its quality or purity fall below, the standards set in the compendium if the differences from the standard are stated in its label. Under section 502(g) of the act (21 U.S.C. 352), a drug that is recognized in an official compendium may be considered misbranded if the drug is not packaged and labeled as prescribed in the compendium.

The agency is aware of the legal status of the USP/NF under the act as a standard for determining whether a drug may be considered adulterated or misbranded. A compendial product that fails to comply with USP/NF standards

may be considered to be adulterated or misbranded under the act. However, a compendial product can still be considered adulterated or misbranded under other provisions of sections 501 or 502 of the act, even if it complies with USP/NF standards.

While the standards in the USP/NF are legally enforceable standards for determining whether a product is considered adulterated under section 501 of the act, these standards are not considered the complete regulatory specification. The agency is responsible for establishing regulatory specifications as part of the approval of an application. Under sections 505(b) and 505(j) of the act (21 U.S.C. 355(b) and 355(j)) , an application must include a full description of the methods used in and the facilities and controls used for, the manufacture, processing, and packing of the drug. If the specifications included in the description are considered inadequate to ensure and preserve the identity, strength, quality, purity, or potency of the drug, the agency will refuse to approve the application. Standards established by an official compendium may be inadequate for the purposes of approving an application under section 505 of the act. The USP acknowledges that:

> While one of the primary objectives of the Pharmacopeia is to assure the user of official articles of their identity, strength, quality, and purity, it is manifestly impossible to include in each monograph a test for every impurity, contaminant, or adulterant that might be present, including microbial contamination. These may arise from a change in the sources of the material or from a change in the processing, or may be introduced from extraneous sources. Tests suitable for detecting such occurrences, their presence of which is inconsistent with applicable good manufacturing practice or good pharmaceutical practice, should be employed in addition to the tests provided in the individual monograph. (USP 25, General Notices, page 7).

Similarly, while the labeling requirements in the USP/NF are legally enforceable standards for determining whether a product is misbranded under section 502 of the act, use of these standards alone does not ensure compliance with the act. The USP states "articles in this Pharmacopeia are subject to compliance with such labeling requirements as may be promulgated by governmental bodies in addition to the Pharmacopeial requirements set forth for the articles.'' (USP 25, General Notices, page 12).

Not all compendial standards or changes in existing compendial standards are: (1) Adequate to ensure and preserve the identity, strength, quality, purity, or potency of the drug or (2) consistent with other requirements of the act. For example, a deletion of an impurity test may result in an inadequate standard for ensuring the purity of the drug. Therefore, the agency does not believe that all changes made to comply with an official compendium are of a type that should be reported in an annual report.

(Comment 85) Many comments stated that the phrases "which are consistent with FDA requirements'' and "provides increased assurance that the drug will have the characteristics of identity, strength, quality, purity, or potency that it purports or is represented to possess'' are unclear. Several comments stated that "consistent with FDA requirements'' allows for individual review interpretations. Several comments said that deleting or widening a specification due to a change in the USP should be allowed in an annual report.

FDA concurs that the provisions regarding changes to comply with an official compendium should be clarified. Separate discussions of labeling, analytical procedures, and acceptance criteria and test changes follow, along with a discussion of the phrase "consistent with FDA requirements.''

*Labeling*: Under section 502(g) of the act, a drug recognized in an official compendium may be considered misbranded if the drug is not packaged and labeled as prescribed in the compendium. The method of packing may be modified with the consent of the agency. One comment stated that there would be confusion in the marketplace if compendial labeling changes were not instituted uniformly. The agency concurs that all labeling changes made to comply with an official compendium that are consistent with FDA requirements should be reported in an annual report. These changes have minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as these factors may relate to the safety and effectiveness of the product. Consistent labeling promotes the safe use of products and reduces confusion in the marketplace.

*Analytical procedures*: For compendial drugs, the determination of whether the drug is adulterated under section 501(b) of the act must be made in accordance with the analytical procedures set in the compendium except when no analytical procedure is prescribed in the compendium or the tests prescribed in the official compendium are insufficient. In these situations, the agency can follow the process outlined in the statute and issue a regulation to provide an appropriate analytical procedure. Because of the legal status of compendial analytical procedures in the act and other requirements relating to analytical procedures in the statute, the agency concurs that changes in analytical procedures to comply with an official compendium may be filed in an annual report, except for changes to comply with an official compendium that result in the deletion of a test or the relaxation of an acceptance criterion. The agency wishes to emphasize that under FDA's CGMPs, the suitability of all analytical procedures, including compendial procedures, must be verified under actual conditions of use. For example, an assay analytical procedure where degradation products, impurities, or excipients interfere with the analysis is not considered an acceptable analytical procedure. The use of unacceptable analytical procedures, even if specified in an official compendium, can be considered a violation of the act. The agency also wishes to emphasize that a change from an approved analytical procedure that is capable of quantifying impurities to a compendial analytical procedure that cannot quantify impurities is in essence a deletion of an impurities test. This change of procedure should not be reported in an annual report, but should be reported as any other request for deletion of an approved test.

*Tests and acceptance criteria*: Under sections 505(b) and 505(j) of the act, an application must include a full description of the methods used in and the facilities and controls used for, the manufacture, processing, and packing of the drug. If the specifications included in the description are considered inadequate to ensure and preserve the identity, strength, quality, purity, or potency of the drug, the agency will refuse to approve the application. As previously discussed in this document, the standards established by an official compendium may be inadequate for approving an application under section 505 of the act.

As part of the detailed application review process and in accordance with section 505 of the act, FDA requires that the application include tests and acceptance criteria that the agency believes are necessary to ensure and preserve the identity, strength, quality, purity, and potency of the product. The specifications included in the application are legally binding upon the applicant, and a product that fails to comply with the specifications included in the application can be considered an unapproved drug under section 505 of the act. Compendial standards are often

used in evaluating the specifications proposed in the application. However, compendial standards must often be supplemented with additional tests, such as a specific test for impurities, to ensure the identity, strength, quality, purity, and potency of the drug. Also, the tests and acceptance criteria in an application are often approved without benefit of a compendial standard for a drug because no compendial standard has been established. Situations could arise where, for example, FDA requires tests and acceptance criteria for specific impurities as part of approval of an application. These impurities are not specified in an existing monograph or are not included in a monograph published subsequent to the approval of the drug. If FDA allowed all changes to comply with an official compendium to be included in an annual report, the applicant could interpret this provision as allowing them to delete the tests which were required as a condition of approving the application.

A change to relax an acceptance criterion or delete a test is considered a major change. The agency needs to review a request for this type of change in the context of a particular NDA or ANDA to determine if the change will adversely affect the identity, strength, quality, purity, or potency of the product. Changes such as these, when requested solely at the initiative of the applicant, must be filed in a prior approval supplement. Reporting these changes in an annual report is not appropriate. However, when a change to relax an acceptance criterion or delete a test is made to comply with a change to an official compendium, the change is considered to have a moderate potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as these factors may relate to the safety and effectiveness of the product. The change is considered moderate because: (1) The change has been reviewed by an independent group that has the goal of promoting public health and (2) the agency has had the opportunity through the USP process of reviewing the proposed change in general, but not necessarily in the context of each individual application affected by the change. Based on these factors, the agency will require a changes-being-effected-in-30-days supplement for a change to relax an acceptance criterion or delete a test to comply with a change to an official compendium. A change made to comply with an official compendium that results in a tightening of an approved acceptance criterion or an addition of a test is considered a minor change and may be filed in an annual report.

(Comment 86) FDA proposed that changes to comply with an official compendium could be reported in an annual report only if they were consistent with FDA requirements. Several comments stated that "consistent with FDA requirements'' allows for individual review interpretations.

FDA declines to delete this phrasing but wishes to clarify that the term requirements means the requirements of the act or the applicable provisions in the Code of Federal Regulations (CFR). An annual report or changes-being-effected-in-30-days supplement should not be used to implement a change to comply with an official compendium when that change is not consistent with other FDA statutory or regulatory requirements. An example of this is a change to a compendial analytical procedure, when a different analytical procedure is specified in the regulations (e.g., 21 CFR part 610) because the use of the compendial analytical procedure is not consistent with FDA regulations. Another example of this is a change to a compendial analytical procedure that is proven not to be suitable under actual conditions of use because the use of such an analytical procedure, even if specified in an official compendium, is not consistent with CGMPs (21 CFR 211.194). If situations like this occur, applicants should contact the agency, inform them of the situation, and request advice.

For the reason discussed previously in this document, the agency is adding §§ 314.70(c)(2)(iii) and 601.12(c)(2)(iv) to require a changes-being-effected-in-30-days supplement for a relaxation of an acceptance criterion or deletion of a test to comply with an official compendium that is consistent with FDA statutory and regulatory requirements. The agency is revising § 314.70(d)(2)(i) as follows: "Any change made to comply with an official compendium, except a change described in paragraph (c)(2)(iii) of this section, that is consistent with FDA statutory and regulatory requirements.'' The agency is also revising § 601.12(d)(2)(i) as follows: "Any change made to comply with an official compendium, except a change described in paragraph (c)(2)(iv) of this section, that is consistent with FDA statutory and regulatory requirements.''

(Comment 87) Several comments stated that a drug must comply with the compendial quality standards or it may be considered adulterated or misbranded. The comments went on to say that when the USP makes a change and a company cannot comply until FDA approves the change, the marketed drug in the intervening period technically may be misbranded or adulterated if it fails to meet the changed compendial requirements.

The agency wishes to clarify as part of this final rule the circumstances under which a supplemental application must be submitted for changes to comply with an official compendium. A supplemental application must be submitted only when the change involves a relaxation of an acceptance criterion or deletion of a test. The standards for the drug will differ from the standards prescribed in the official compendium until the agency approves the change. However, under these circumstances, the drug as marketed will have tighter specifications or more testing will be performed than has been specified in the official compendium. Therefore, the drug will not fall below the standards set in the official compendium and would not be considered adulterated under section 501(b) of the act.

(Comment 88) One comment said that the proposed language implies that there may be separate and/or different requirements to fulfill USP and FDA criteria. Other comments said that the same product, from different applicants, should be held to the same standards.

As discussed previously in this document, while the specifications in an official compendium are legally enforceable standards under section 502(b) of the act for determining whether a product is considered adulterated, these standards may not be sufficient to ensure and preserve the identity, strength, quality, purity, and potency of the drug as required under section 505 of the act for approval to market a drug. Generally, FDA uses compendial standards in evaluating the specifications proposed in an application. However, compendial standards must often be supplemented with additional tests to ensure the identity, strength, quality, purity, or potency of the drug. Similarly, while the labeling requirements in USP/NF are legally enforceable standards for determining whether a product is misbranded under section 502(g) of the act, use of these standards alone does not ensure compliance with the act. The statutory requirements regarding compendial standards as well as other statutory requirements must be considered to ensure compliance with the act.

The requirements under sections 501(b) and 502(g) of the act for determining whether a product is adulterated or misbranded and of

section 505 of the act for approving an application are applied consistently to all products. Under sections 505(b) and 505(j) of the act, the specifications included in the application must be considered adequate to ensure and preserve the identity, strength, quality, purity, and potency of the drug or else the agency must refuse to approve the application. However, this does not mean that the specifications approved in different applications for the same drug are identical. For example, different analytical procedures may be approved as long as the analytical procedures are appropriate and valid. Another example is that where solvents are used, the agency routinely and consistently requests tests and acceptance criteria for residual solvents. However, because different manufacturers use different solvents, the tests and acceptance criteria will vary depending on the solvents used. In all cases, the approved specifications will have been determined by the agency to be adequate to ensure and preserve the identity, strength, quality, purity, and potency of the drug.

(Comment 89) Many comments stated that FDA is involved in the USP revision process and should use this process to resolve any differences between compendial requirements and FDA requirements and ensure that compendial changes do not compromise safety and efficacy. Once this is accomplished, all changes to comply with a compendial change should be submitted in an annual report.

The USP process for developing or changing a monograph, general notice, or general chapter is an open process. Anyone who is interested in a particular issue has the opportunity to comment. FDA participates in many USP activities, including joint committees and public forums, and has designated persons throughout the agency to act as liaisons to the USP.

FDA recognizes that public standards such as those instituted by the USP are beneficial. However, the USP is a nongovernmental organization that works independently from FDA, and FDA has no authority to stop USP from implementing a new or revised standard. FDA must ensure the identity, strength, quality, purity, and potency of drugs by requiring appropriate specifications. Compendial standards are not always sufficient to provide this assurance. Moreover, certain changes in a public standard, such as deletion of a test or relaxation of an acceptance criterion, cannot always be considered an improvement in the standard, nor is it always clear that the change will not lessen the assurance of the identity, strength, quality, purity, or potency of the products affected by the change. After review of a change such as these in the context of a specific NDA or ANDA, FDA may confirm that the change does not adversely affect the drug. However, allowing such a change to be documented in an annual report would not provide the opportunity for the agency to assess the effect of the change in a timely manner. FDA considers the provisions in the final rule necessary to ensure the safety and effectiveness of drugs.

(Comment 90) Several comments said that the proposed provision regarding changes to comply with an official compendium was inconsistent with the intent of the Modernization Act.

FDA disagrees with these comments. Section 506A of the act requires a change in the specifications in the approved application to be submitted in a supplemental application and approved by the agency prior to the applicant distributing the product affected by the change (section 506A(c)(2)(A) of the act). The act does not distinguish between changes in compendial and noncompendial specifications. The act allows the Secretary to exempt by regulation or guidance the requirement that changes in specifications may be submitted in prior approval supplements. However, the act also requires the agency to establish the reporting category for a change based on the potential for the change to adversely affect the identity, strength, quality, purity, and potency of the drug as they may relate to the safety and effectiveness of the drug. The agency believes the provisions in the final rule regarding changes to comply with changes in an official compendium are consistent with the intent of the Modernization Act.

(Comment 91) One comment also said that the proposal was not consistent with the initiatives under the National Partnership for Reinventing Government (REGO), the National Technology Transfer and Advancement Act (the NTTAA) of 1995 and the Paperwork Reduction Act of 1995 (the PRA).

FDA disagrees with this comment. The comment states that one of FDA's goals under REGO is a more efficient drug development process and review process that will lower the development costs and reduce by an average of 1 year the time required to bring important new drugs to the American people. This REGO goal relates to initiatives for drugs prior to approval by FDA and is not pertinent to this rule. However, one REGO initiative was to reduce the number of manufacturing changes that require agency preapproval for biological products and FDA revised its regulations to achieve this goal (see the **Federal Register** of January 29, 1996 (61 FR 2739), and July 24, 1997 (62 FR 39890)). FDA supports the REGO objective to transform FDA into a customer-oriented, results-driven organization and believes that the final rule, which reduces regulatory burden with respect to postapproval changes for both biological products and human drugs, achieves this objective.

The National Technology Transfer Act of 1995 (NTTAA) (Public Law 104–113, 15 U.S.C. 3701 (1996)) encourages the use of voluntary consensus standards by Federal agencies as a means to carry out policy objectives and puts into law the policies of OMB Circular A–119 (see the **Federal Register** of February 19, 1998 (63 FR 8546)). The standards set by USP/NF are not voluntary standards because the standards are recognized in sections 501 and 502 of the act for the purposes of determining if a compendial drug is adulterated or misbranded. Therefore, the NTTAA is not pertinent. FDA is authorized to cooperate with associations and scientific societies in the revision of the USP (21 U.S.C. 377). FDA is a committed participant in this endeavor and in developing other voluntary and nonvoluntary consensus standards.

The purposes of the PRA (44 U.S.C. 3501–3520) include minimizing paperwork for business resulting in collection of information for the government, ensuring the greatest public benefit from the information collected, and minimizing the cost to the government of the collection of information. Section 506A(b) of the act states that a drug made with a manufacturing change (whether a major manufacturing change or otherwise) may be distributed only if, before distribution of the drug as so made, the holder involved validates the effect of the change on the identity, strength, quality, purity, and potency of the drug as these factors may relate to the safety and effectiveness of the drug. Moreover, each supplemental application or annual report must contain such information as the Secretary determines to be appropriate and include the information developed by the applicant to validate the effects of the change (sections 506A(c)(1), (d)(2)(A), and (d)(3)(A) of the act). The information that will be submitted to support a change is independent of the reporting category for the change. FDA will require the same type of information to be submitted to support a change in a compendial specification regardless of whether the change is reported in a supplemental application or annual

report. There is no additional paperwork burden based solely on the designation of a reporting category for a particular change.

(Comment 92) Many comments said that requiring compendial changes to be reported in anything other than an annual report was an increase in regulatory burden over what has been done in the past. Several comments said that there has been no public discussion about any concerns with the previous policy to allow changes to comply with compendial changes to be filed in an annual report.

FDA recognizes that there has been confusion about the provision in previous § 314.70(d)(1) that allowed any change made to comply with an official compendium to be reported in an annual report. In the **Federal Register** of June 4, 1986 (51 FR 20310), FDA published a proposed rule to clarify and limit the types of compendial changes that could be made in an annual report. FDA was preparing to issue a final rule regarding this proposal when Congress initiated discussions about postapproval manufacturing changes. FDA delayed publishing the final rule and incorporated revisions regarding reporting of changes to comply with an official compendium into its proposed rule implementing section 506A of the act. The provisions in the final rule for changes made to comply with an official compendium might be viewed by some as an increase in burden over how FDA has been interpreting this regulation in the past. However, FDA believes that the provisions are necessary and consistent with the requirements of section 506A of the act to establish a reporting category for a change based on the potential for the change to adversely affect the identity, strength, quality, purity, or potency of the drug product as they may relate to the safety and effectiveness of the drug product. As explained previously, the information that will be submitted to support a change is independent of the reporting category for the change. FDA will require the same type of information to be submitted to support a change in a compendial specification regardless of whether the change is reported in a supplemental application or annual report. There is no additional paperwork burden based solely on the designation of a reporting category for a particular change.

(Comment 93) One comment stated that changes made to comply with changes in an official compendium should not have to include all the information needed for noncompendial products. The comment went on to say that a full description of the test methods and limits should not be necessary and that the company should not have to submit data demonstrating the suitability of a compendial change for the drug product if the compendial change is for a test method change or other change not specifically affecting the quality or the morphology of the material in question.

As previously discussed in this document, under section 506A of the act, each supplemental application or annual report must contain the information that the agency has determined to be appropriate and must include the information developed by the applicant to validate the effects of the change. Guidance on the information that should be submitted to support compendial and noncompendial analytical procedures is available from FDA.

Under proposed § 314.70(d)(2)(ii), the following change was to be documented in the next annual report: The deletion or reduction of an ingredient intended to affect only the color of the product.

(Comment 94) One comment recommended changing the requirement to read "the deletion, reduction or replacement with a color previously used in other CDER/CBER approved products.''

FDA declines to revise the regulation as requested. FDA believes that any recommendations it may make concerning notification in an annual report of changes involving replacement of colors are best handled in guidance documents so that the issues and conditions associated with such changes can be fully explained.

(Comment 95) One comment said that changes in formulation, regardless of the intended purpose of the ingredient, are more appropriately addressed in terms of percent change allowed at each level as delineated in the SUPAC guidances.

FDA agrees that the issues relating to changes in components and composition for specific dosage form drug products are better handled in guidance documents, where they can be discussed in detail, rather than in the regulations. FDA included this specific provision in the proposed regulations because this annual report change, with minor editing changes, has been in the regulation since 1985.

Under proposed § 314.70(d)(2)(iii), the following change was to be documented in the next annual report: Replacement of equipment with that of the same design and operating principles except for equipment used with a natural protein product, a recombinant DNA-derived protein/polypeptide product, or a complex or conjugate of a drug with a monoclonal antibody.

(Comment 96) Several comments suggested that FDA delete all words after "principles'' to read: "Replacement of equipment with that of the same design and operating principles.'' One comment said that it is reasonable to report in an annual report replacement with equipment of the same design and operating principles for these (i.e., protein) products.

FDA declines to revise the regulation as requested but has revised it to provide clarity. As discussed in section III.D of this document in response to comments on "Changes Requiring Supplement Submission at Least 30 Days Prior to Distribution of the Drug Product Made Using the Change (Moderate Change),'' changes to identical equipment used in the production of proteins could be reported in an annual report. However, a change to equipment of the same design and operating principle, but not identical equipment (e.g., capacity), is not considered a minor change for protein products.

FDA has revised § 314.70(d)(2)(iii) as follows: "Replacement of equipment with that of the same design and operating principles except those equipment changes described in paragraph (c) of this section.''

(Comment 97) One comment said the replacement of equipment of the same design and operating principles should not have to be reported. The comment said that for consistency with the existing SUPAC guidances, only a SUPAC subclass (i.e., design) change should be reported.

FDA declines to revise the regulation as requested. FDA's requirement to report changes in equipment of the same design and operating principle in an annual report is consistent with the existing SUPAC guidances. In the future, FDA may issue guidance lessening the reporting requirements in this area for specific cases. However, because of the diversity of drug products and manufacturing processes regulated, FDA is unable at this time to lower the requirements as suggested in the comments.

Under proposed §§ 314.70(d)(2)(iv) and 601.12(d)(2)(v), the following change was to be documented in the next annual report: A change in the size and/or shape of a container containing the same number of dosage units for a nonsterile solid dosage form, without a change from one container closure system to another.

(Comment 98) Several comments said that FDA should delete "containing the same number of dosage units.'' The comments said that proportional changes (i.e., ratio of the amount of drug

product to size of container) are not expected to adversely affect the drug product, that a corresponding change in fill quantity, along with a change in container size, is expected and readily acceptable, and that it is illogical to assume that a change in the amount of product would present any greater risk than a change in container size.

FDA declines to revise the regulation as requested. As discussed in the response to comment 81 of this document, FDA is concerned about the proliferation of unit-of-use containers that may invite the misuse of drug products.

Under proposed §§ 314.70(d)(2)(v) and 601.12(d)(2)(iv), the following change was to be documented in the next annual report: A change within the container closure system for a nonsterile drug product, based upon a showing of equivalency to the approved system under a protocol approved in the application or published in an official compendium.

(Comment 99) One comment said that the proposal, without further explanation, alters the reporting category applicable to changes within the container/closure system for sterile liquid drugs that are made based on a showing of equivalency to the approved system under a protocol approved in the application or published in an official compendium (for example, the USP). The comment said that under current § 314.70(d)(6), these changes are described in the annual report and do not require FDA prior approval. The comment said that FDA has not provided any rationale for its proposal to require a supplement to be filed in connection with any change within a packaging material for a sterile liquid drug, even in situations in which the change is based on a showing of equivalency to the approved system under a protocol approved in the application or published in an official compendium, and recommended that "nonsterile'' be deleted. The comment said that in the same way, it would be unduly burdensome to require FDA prior approval for a change within a container/closure system for a material based on a determination of equivalency made in accordance with a USP monograph that is specifically designed for that purpose. The comment said, for example, the USP chapter for "Polyethylene Terephthalate (PET) Bottles and Polyethylene Terephthalate G (PETG) Bottles'' provides standards and tests to characterize PET and PETG bottles "that are interchangeably suitable for packaging liquid oral dosage forms'' (USP 25, General Chapter <661> (2002 ed.)). The comment said that FDA is provided with the opportunity to review and comment on USP monographs before they are published in final form; thus, the requirement for an additional FDA prior review of a change made in accordance with USP monograph is unnecessary.

FDA declines to revise the regulation as requested. All container closure systems changes must be supported with data to demonstrate that various characteristics of the drug product and/or container closure system are unchanged or equivalent (e.g., physical, chemical). For a sterile drug product, however, data must also be provided to support that the sterility assurance level and the maintenance of sterility for the product has not been affected. Sterility of drug products is a fundamental and essential quality attribute of these drugs and is a critical aspect of the safety assessment. FDA would consider an assessment of the effects of a change in a container closure system for a sterile product to be inadequate if it did not include tests and data relating to sterility assurance and maintenance of sterility. FDA considers changes in the container closure system for sterile drug products to be changes that may affect the sterility assurance and/or maintenance of sterility of a drug and, therefore, may have significant potential to affect the safety of the drug. Therefore, FDA has identified this change as one that requires prior approval (see comment 34 of this document).

As stated in the June 1999 proposal, this rulemaking sets out broad, general categories of manufacturing changes, and the agency uses guidance documents to provide FDA's current thinking on the specific changes included in those categories. Through guidance, FDA may identify certain container closure system changes for sterile drug products that can be reported other than by submission of a prior approval supplement. Furthermore, an applicant could submit a comparability protocol that would allow it to implement postapproval changes in sterile container closure systems without a prior approval supplement. FDA notes that, as of 2002, no official compendia has finalized an equivalency protocol for container closure systems for sterile drug products. If such a protocol is published in the future, FDA will consider identifying in a guidance a reporting category other than a prior approval supplement for the compendial protocol if the protocol adequately addresses the appropriate scientific issues.

FDA specifically wishes to address the comment's implication that changes made under the USP monograph for "Polyethylene Terephthalate Bottles and Polyethylene Terephthalate G Bottles'' could be submitted in an annual report under this provision. As with any change and as required by the act, the applicant must assess the effects of the change on the identity, strength, quality, purity, and potency of the drug product as these factors may relate to the safety and effectiveness of the product. Moreover, USP <661> states that "the suitability of a specific PET or PETG bottle for use in the dispensing of a particular pharmaceutical liquid oral dosage form must be established by appropriate testing.'' Testing solely by the standards set in this general chapter would not usually be considered by FDA to be sufficient to assess the effects of the change because the interaction between a specific drug product and specific container and closure system should be assessed.

Under proposed §§ 314.70(d)(2)(vi) and 601.12(d)(2)(iii), the following change was to be documented in the next annual report: An extension of an expiration dating period based upon full shelf life data on full production batches obtained from a protocol approved in the application.

(Comment 100) Many comments recommended changes relating to the phrase "full production batches.'' A few comments recommended deleting the phrase because this requirement would unnecessarily increase regulatory burden, is unnecessarily restrictive, and/or because applicants should be allowed to use either pilot or production batches to extend an expiration date. One comment further said that pilot batches can be used to support the safety and efficacy of the product and for approval of an NDA expiration date; therefore, pilot batches should be allowed to support an extension of an expiration dating period. Another comment recommended that "full'' be replaced by "production-scale.'' The comment said that the word "full'' may cause confusion, where batch scale for a product may be varied. The comment said that "full'' could be interpreted as that only the largest size batch of an approved batch size range could be used to support an extension of an expiration dating period. One comment said that it should be clarified that the batch need not have been sold. One comment said that production lots should be defined in the "definitions'' section to include validation/scale-up batches manufactured by the representative production process within a ten-fold batch size for consistency with SUPAC/BACPAC.

FDA has revised §§ 314.70(d)(2)(vi) and 601.12(d)(2)(iii) by replacing the term "full production batch'' with "production batch.'' FDA declines to include a definition of production batch in the regulations. A definition is included in the ICH guidance entitled "Stability Testing of New Drug Substances and Drug Products.'' FDA considers a production batch to be one made at production scale using production equipment in a production facility as specified in the application. Production scale does not necessarily mean the largest batch size produced, but a batch of a size or within a batch size range that has been approved in the application. The batch need not have been sold, but should be one that is eligible to be sold (e.g., must pass its specification). In certain cases, FDA allows data from pilot batches to be used to support approval of an application. This is consistent with FDA's efforts to reduce the time it takes to bring new drugs to market. Often there are changes when moving from a pilot manufacturing process to a production process. Although these are usually minor in nature and not expected to affect the stability of the product, the definitive data to support an expiration date should be based on production batches; therefore, FDA declines to revise the regulation to include pilot batches. FDA would expect requests for an extension of an expiration dating period based on data from pilot batches to be submitted in a prior approval supplement.

Under proposed §§ 314.70(d)(2)(vii) and 601.12(d)(2)(vii), the following change is documented in the next annual report: "The addition, deletion, or revision of an alternate analytical procedure that provides the same or increased assurance of the identity, strength, quality, purity, or potency of the material being tested as the analytical procedure described in the approved application.'' FDA, on its own initiative, is clarifying these sections as follows: "The addition or revision of an alternative analytical procedure that provides the same or increased assurance of the identity, strength, quality, purity, or potency of the material being tested as the analytical procedure described in the approved application, or deletion of an alternative analytical procedure.''

Under proposed § 314.70(d)(2)(viii), the following change is to be documented in the next annual report: The addition by embossing, debossing, or engraving of a code imprint to a solid oral dosage form drug product other than a modified release dosage form, or a minor change in an existing code imprint.

(Comment 101) A few comments requested that FDA revise this provision to allow the addition of an ink imprint. One comment further said that under part 206 (21 CFR part 206) (Imprinting of Solid Oral Dosage Form Drug Products For Human Use), which has been in effect for over 5 years, all solid dosage forms are required to have imprints and that the requirement to imprint includes an ink code imprint. Another comment said it is not clear whether the provision includes ink printing, and a cross-reference to part 206 may also be helpful. One comment requested that wording should be added to allow for ink printing on modified dosage forms, as this should not impact drug release.

FDA declines to revise the regulation as requested and is clarifying that inks are not included in this provision. FDA believes that any recommendations on how to report the addition of inks is best handled in guidance documents so that the issues and conditions associated with such changes can be fully explained. For example, FDA would expect that any colors used in an ink imprint would have an acceptable status under FDA regulation (e.g., 21 CFR parts 73 and 74).

(Comment 102) One comment said that FDA should delete the word "minor'' from the phrase "minor change'' in the code imprint provision (proposed § 314.70(d)(2)(viii)).

FDA declines to revise the provision as requested. The term "minor'' has been included in this part of the regulation since 1985. Based on FDA's experience, this wording has not been found to be unclear, nor has it resulted in inconsistent implementation of such changes.

Under proposed § 314.70(d)(2)(x), the following change was to be documented in the next annual report: An editorial or similar minor change in labeling.

(Comment 103) A few comments requested that FDA provide in the regulations specific examples of editorial or similar minor changes in labeling.

FDA declines to provide specific examples in the regulations. As stated in the June 1999 proposal, the agency's approach is to issue regulations that set out broad, general categories of manufacturing changes and use guidance documents to provide FDA's current thinking on the specific changes included in those categories. FDA has provided recommendations on and examples of specific changes in specifications in FDA's guidances entitled "Changes to an Approved NDA or ANDA'' and "Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products.''

Proposed § 314.70(d)(3)(i) and (d)(3)(ii) required that, for changes described in the annual report, the applicant must submit a list of all products involved, a statement by the holder of the approved application that the effects of the change have been validated, and a full description of the manufacturing and controls changes, including the manufacturing site(s) or area(s) involved.

(Comment 104) Many comments recommended that the term "validated'' be replaced with "assessed'' or "assessed, as appropriate''. The comments' reasoning was similar to that discussed previously in similar comments for § 314.3(b) under section III.A of this document entitled "Definitions.''

FDA has replaced the term "validated'' with "assessed.'' However, FDA declines to add the term "as appropriate.'' Section 506A of the act requires an applicant to assess the effects of each change. FDA believes that the addition of "as appropriate'' may incorrectly give the impression that this information is not routinely needed and would result in changes being submitted with insufficient information.

(Comment 105) Concerning the phrase "a list of all products involved,'' one comment asked whether the same changes, proposed for multiple products, have to be included in this list, and whether FDA wants to be notified as to all of the products that are affected in all annual reports. The comment asked for clarification.

FDA has deleted the phrase "a list of all products involved.'' FDA does not expect the listing of cross references to drug products approved in other applications. FDA does expect the changes to be described fully (§ 314.70(d)(3)(ii)). If there are multiple products in an application (e.g., strengths), FDA would expect the description to identify which products in the application are affected by the change.

(Comment 106) One comment said including a statement that a change has been validated or assessed presents undue additional burden to the applicant. The comment said that assessment is guaranteed in the filing via provision of relevant supportive data and that restating this fact of compliance with regulatory requirements is redundant.

FDA disagrees that the requirement to include this statement is an undue

additional burden and declines to revise the regulation as requested.

(Comment 107) A few comments said that specifying details of exact "areas involved'' is inappropriate, since this information is not typically part of the NDA filing, but is subject to field inspection. The comment said it should not be provided in the annual report.

FDA disagrees that this information is only necessary for field inspections and declines to make the revision. This information may not be essential in all cases. However, it is necessary for many manufacturing site changes. For example, FDA requires the specific filling line/room for sterile products to be identified in the application.

Proposed § 314.70(d)(3)(iii) required that, for changes described in the annual report, the applicant must submit the date each change was made, a cross-reference to relevant validation protocols and/or SOPs, and relevant data from studies and tests performed to evaluate the effect of the change on the identity, strength, quality, purity, or potency of the product as these factors may relate to the safety or effectiveness of the product (validation).

(Comment 108) One comment recommended that § 314.70(d)(3)(iii) be deleted entirely because it represents additional reporting requirements that are not consistent with the act.

FDA declines to delete § 314.70(d)(3)(iii). Section 506A(d)(2)(A) of the act requires that an annual report contain such information as FDA determines to be appropriate and the information developed to assess the effects of the change. FDA is specifying the type of information it expects to be included in an annual report, and this action is consistent with the act.

(Comment 109) A few comments recommended that FDA should delete the phrase "the date each change was made.'' The comments included the following reasons for this recommendation: (1) Specifying an exact implementation date would present an undue burden on both manufacturing and regulatory affairs personnel, (2) the addition of this information to existing practice would result in increased regulatory burden, (3) the requirement is ambiguous as to whether the date is to be the date the product was made with the change or some other date such as the date the product made with the change was put into market distribution, and (4) the data represent information best suited for a field inspection. Some comments stated that the fact that an applicant has reported a change in an annual report covering a specified time period should be sufficient for agency review.

FDA declines to revise the regulation as requested. The date when a change is implemented is important to identify the production batches that may be affected by the change. This is important for various reasons, including allowing reviewers to compare data from different batches prepared at different times to determine if a change has affected product quality. FDA has required the date of implementation for changes reported in annual reports since 1985 under § 314.81(b)(2)(iv)(b) and does not believe that this provision can be construed as an undue or additional burden or the sole purview of a field inspection.

To maintain consistency with § 314.81(b)(2)(iv)(b), FDA has revised the phrase to read: "The date each change was implemented.'' FDA considers "the date each change was implemented'' to be the date that the condition established in the approved application is changed, not when the product made with the change is distributed.

(Comment 110) Many comments said that the phrase "a cross-reference to relevant validation protocols and/or SOP's'' should be deleted. The comments included the following reasons for this recommendation: (1) The addition of this information to existing practice would result in increased regulatory burden, (2) the requirement is ambiguous as validation protocols and/or SOPs are needed only in certain situations, and (3) the data represent information best suited for a field inspection.

FDA has revised this provision to clarify when a cross-reference to validation protocols and SOP's are needed. As discussed earlier in this document in response to similar comments on § 314.70(b)(3), validation protocols and data need not be submitted in the application, unless otherwise specified by FDA, but should be retained at the facility and be available for review by FDA at the agency's discretion. For most products, FDA does not require the submission of validation protocols and data. However, for a natural product, a recombinant DNA-derived protein/polypeptide, a complex or conjugate of a drug substance with a monoclonal antibody, or sterilization process, FDA does require the submission of validation protocols for certain critical manufacturing processes unique to these drug substances and drug products. In addition, an applicant is required to submit a "full description of controls used for, the manufacture, processing, and packing of a drug'' (section 505 of the act). This information may be submitted in different forms, including SOPs. In most cases, SOPs do not include information relevant to the NDA or ANDA review, but rather information relevant to determining an applicant's compliance with CGMPs. However, in the case of a natural product, a recombinant DNA-derived protein/polypeptide, a complex or conjugate of a drug substance with a monoclonal antibody, or a sterilization process, information contained in SOPs is often relevant to the review of certain aspects of an application.

(Comment 111) A few comments recommended that the term "validation'' be deleted. FDA also received comments requesting that the use of the terms drug, drug product, drug substance, and product be standardized.

FDA, on its own initiative, has divided proposed § 314.70(d)(3)(iii) into three paragraphs to provide clarity. FDA has clarified the information originally proposed in § 314.70(d)(3)(iii) by making changes consistent with § 314.70(b)(3)(vi) and (b)(3)(vii) and deleting the term "validation.'' On its own initiative, FDA is replacing the statement "evaluate the effect of the change on the identity, strength, quality, purity, or potency of the product as these factors may relate to the safety or effectiveness of the product (validation)'' with "assess the effects of the change'' because this phrase is defined in § 314.3(b).

*H. Protocols*

Proposed § 314.70(e) stated that an applicant may submit one or more protocols describing the specific tests and validation studies and acceptable limits to be achieved to demonstrate the lack of adverse effect for specified types of manufacturing changes on the identity, strength, quality, purity, or potency of the drug as these factors may relate to the safety or effectiveness of the drug. Such protocols, or changes to a protocol, would be submitted as a supplement requiring approval from FDA prior to distribution of a drug produced with the manufacturing change. The supplement, if approved, may subsequently justify a reduced reporting category because of the reduced risk of an adverse effect.

(Comment 112) Many comments recommended that protocols be submitted in changes-being-effected supplements. The reasons for this recommendation included: (1) The expected brevity of the review of the protocol, (2) the proposed change could be implemented and approved in the time it takes for approval and execution of the protocol, and (3) the ability to implement a protocol faster would bring

much needed regulatory relief. One comment said that mandatory limits on protocol review times should be established, otherwise there may be less of an incentive for applicants to adopt this procedure. Another comment said that requiring prior approval for these protocols may be construed as an increase in regulatory burden.

FDA declines to revise the regulation as requested. The time it takes FDA to review information is not a factor in determining how the change should be submitted. However, FDA does expect that it will take a substantial amount of time to review such a protocol. It is expected that applicants will use protocols to justify a reduced reporting category for a particular change. For example, applicants may request that they be allowed to implement a major change without prior approval by FDA. These protocols will in effect reduce regulatory oversight of the specified changes, and FDA considers this reduced oversight to have a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product. Therefore, these protocol submissions are classified as major changes.

Whether or not a proposed change could be implemented and approved in the time it takes for approval and execution of the protocol would be a factor in an applicant's decision to submit a protocol. However, increased efficiency could be achieved overall because a protocol can be used repeatedly for changes within the scope of the protocol. Also, fewer or no deficiencies are expected with a change implemented using a protocol, if properly executed, than with a change for which the specific tests, studies, and acceptance criterion were not discussed with the agency prior to the submission of the information.

FDA continually strives to reduce review times, including the time it takes to approve manufacturing changes. In addition, this rule reduces the overall regulatory burden by allowing many changes to be implemented without prior approval by FDA. As previously discussed in this document, FDA considers a protocol submission to be a major change. Therefore, FDA declines to allow these changes to be submitted in a changes-being-effected supplement to effect faster implementation. FDA also declines to establish mandatory limits on protocol review times. The timing of a review of a supplement for a protocol will be in accordance with current practice for reviewing supplements requiring FDA approval prior to implementation.

FDA does not agree that requiring prior approval for these protocols is an increase in regulatory burden. Where previously allowed by regulations, these changes were specified as requiring prior approval, and this rule just extends that option of submitting protocols for all human drugs. FDA emphasizes that the submission of a protocol is voluntary, and if an applicant decides that submission of a protocol is not beneficial, the applicant can make changes to an approved application by other means specified in the regulations.

(Comment 113) One comment said it would like to operate with the understanding that if a relevant protocol is subsequently published in an official compendium or FDA document, the less burdensome protocol may be applied.

FDA is unable to address this question in a general manner because of the complexity of the issues and the newness of comparability protocols for human drugs. A comparability protocol is an applicant and drug product specific document. Whether a comparability protocol could be superseded would depend on the product and changes covered by a comparability protocol.

(Comment 114) FDA received many comments requesting specific guidance on developing protocols. A few comments recommended that FDA issue a guidance document that includes specific examples of comparability protocols that are approvable. Another comment said that the comparability protocol guidance should contain a sufficient level of detail on testing requirements. One comment said it would welcome FDA's involvement in drafting "common'' comparability protocols, so that consistent requirements are imposed on all sponsors. The comment said that, alternatively, FDA guidance on comparability protocol format and content would be helpful.

In the **Federal Register** of February 25, 2003 (68 FR 8772), FDA published a draft guidance on comparability protocols. FDA wishes to advise applicants that while in certain cases FDA may be able to provide specific examples of acceptable protocols or "common'' comparability protocols, it is likely that these will be limited because a comparability protocol is an applicant- and drug product-specific document. Applicants will, in most cases, be responsible for developing their own protocols.

(Comment 115) One comment said that, in a manner similar to the procedure developed for disseminating bioequivalence guidance information, comparability protocols that have been reviewed and approved by the agency should be made available under the Freedom of Information Act. The comment said that this practice will help promote harmonization within the agency with respect to postapproval change and may provide interested parties with guidance on the agency's general submission requirements.

After FDA issues an approval letter, data and information in an application will be eligible for public disclosure to the extent permitted by the applicable statutes and agency regulations (see, for example, the Freedom of Information Act (5 U.S.C. 552), the Trade Secrets Act (18 U.S.C. 1905), 21 CFR part 20, and §§ 314.430 and 601.51).

(Comment 116) One comment recommended that FDA encourage the use of packaging equivalency protocols to reduce regulatory reporting burdens, expedite approval of manufacturing changes, and simplify reporting coordination for packaging manufacturers. The comment noted that submission of these protocols was sometimes discouraged by FDA in the past. The comment also suggested that such protocols may be submitted within Type III drug master files (DMFs) to expedite the implementation of manufacturing changes at the packaging and packaging component manufacturer level.

Protocols, including packaging equivalency protocols, may be submitted for FDA consideration. Under certain circumstances, such as changes affecting a large number of applications, FDA may review a protocol submitted to a Type III DMF that will be used to support changes affecting drug product applications. Information in a DMF is not approved or disapproved; therefore, any protocol submitted to a DMF cannot be approved (§ 314.420). Administrative issues relating to review of protocols in a DMF present some unique challenges, and a DMF holder should coordinate with the agency prior to submitting such a protocol.

(Comment 117) One comment requested that the words "validation studies'' be clarified. The comment asked whether this means "assessment studies'' to assess the impact of the change, or does it refer to CGMP validation studies. The comment said that if it refers to CGMP validation studies, it should only be applicable for sterility validation. A few comments requested that the provision be clarified to state that a protocol can be submitted in an original application.

FDA has clarified the provision by deleting the word "validation'' and indicating that a protocol may be submitted in an original application. Various types of studies, including validation studies, may be needed in a protocol. A comparability protocol can be submitted in an original application or after approval of the application in a supplement requiring approval from FDA prior to distribution of a drug product produced with the manufacturing change.

On its own initiative FDA has revised § 314.70(e) by replacing the phrase "acceptance limits'' with "acceptance criteria'' to promote consistency in the terminology used in the definition of specification and the phrase "purity, or potency'' with "purity, and potency'' for consistency with section 506A of the act.

*I. Implementation of the Final Rule and Guidance*

(Comment 118) Several comments urged FDA to withdraw the June 1999 proposal and guidance and develop new documents and permit an opportunity for comment. The comments encouraged FDA to work in collaboration with the industry and the public in crafting improved versions of these documents. The comments contended that the June 1999 proposal and guidance fail to realize the intent of Congress to relieve regulatory burden; that a substantial number of individual issues in the June 1999 proposed rule and guidance require revision; that there was a lack of industry and public involvement in drafting the documents; and, too short a time period was given for comments and subsequent revisions.

FDA declines to withdraw the June 1999 proposal and guidance. FDA's procedures for rulemaking are governed by the Administrative Procedure Act (5 U.S.C. 553) and set forth in FDA regulations at 21 CFR 10.40 and 10.80. Guidances are developed in accordance with the procedures set out in FDA's good guidance practices regulation (see the **Federal Register** of September 19, 2000 (65 FR 56468), and 21 CFR 10.115). As discussed previously in this document, the use of guidance documents will allow FDA to more easily and quickly modify and update important information. Moreover, section 506A of the act explicitly provides FDA the authority to use guidance documents to determine the type of changes that do or do not have a substantial potential to adversely affect the safety or effectiveness of the drug product. In the June 1999 proposal, FDA proposed to implement section 506A of the act for human NDAs and ANDAs and for licensed biological products. In that same issue of the **Federal Register**, FDA announced the availability of a draft guidance for industry entitled "Changes to an Approved NDA or ANDA'' to assist applicants in determining how they should report changes to an approved NDA or ANDA under section 506A of the act and under the proposed revisions to the human drug regulations pertaining to supplements and other changes to an approved application. FDA allowed for public participation in the development of the regulation and guidance consistent with FDA regulations and policy and to the extent practicable. The time period to provide public comment was consistent with FDA's regulations and statutory requirements. FDA also held a public meeting on August 19, 1999, to hear comments on the guidance and the proposed rule. In the **Federal Register** of November 23, 1999 (64 FR 65716), FDA announced the availability of a final guidance to assist applicants in determining how they should report changes to an approved NDA or ANDA under section 506A of the act (the November 1999 guidance). FDA has carefully considered the public comments and has revised the regulation and the guidance as appropriate. FDA believes that the final regulation and guidance provide for significant reduction in regulatory burden and therefore fulfill the intent of Congress.

(Comment 119) One comment recommended that FDA publish the final rule as soon as possible to minimize confusion during the transition period when section 506A of the act will govern changes.

FDA has carefully considered the public comments submitted on the June 1999 proposal and has issued a final rule as expeditiously as possible.

(Comment 120) One comment stated that the final rule should be implemented through a "phasing in'' of the regulation in order to educate industry and agency reviewers. The comment stated that the final promulgation and implementation of the proposed rule should be undertaken in conjunction with an industry-wide educational effort. The comment said that due to the cost and broad scope of the proposal, seminars or public workshops on the final rule would be of value and would allow for additional input from all affected parties. The comment stated that the impact of the proposed rule will affect regulatory practices and expectations of manufacturers, and by carrying out seminars, FDA could publicize and prepare all concerned for the new requirements. The comment also stated that the public seminars would serve to clarify regulatory expectations and interpretations.

FDA does not believe that phasing-in the regulation is necessary because section 506A has been in effect since November 20, 1999, but does intend to discuss the revised regulation and final guidance in public forums. FDA has already held public forums, such as the American Association of Pharmaceutical Scientists (AAPS)/FDA Workshop on Streamlining the CMC Regulatory Process for NDAs and ANDAs (June 11–13, 2002) to obtain feedback on postapproval changes. FDA will consider the information obtained from this workshop in any future updates of the guidance. FDA does not expect its reviewers to encounter many difficulties in the implementation of this regulation as FDA reviewers have been working with section 506A of the act since it became effective.

(Comment 121) Another comment said that FDA should issue a written explanation or hold a public meeting to discuss the impact of allowing the current statute to expire without a new rule being formally approved. The comment said that FDA should not allow the proposal to be implemented without adequate public comment and review simply because the statute may expire.

The statute has not expired, and FDA assumes that the comment refers to the expiration of § 314.70. Congress mandated that section 506A of the act "takes effect upon the effective date of regulations promulgated by the Secretary of Health and Human Services to implement such amendment, or upon the expiration of the 24-month period beginning on the date of the enactment of this Act, whichever occurs first'' (section 116(b) of the Modernization Act). Since November 20, 1999, FDA's regulation of NDA and ANDA postapproval changes has been based on section 506A of the act. The guidance entitled "Changes to an Approved NDA or ANDA'' has represented FDA's current thinking on how to apply the requirements of section 506A of the act. FDA has allowed for public participation consistent with applicable regulations and statutes.

(Comment 122) One comment requested that FDA consider "grandfathering'' changes already in progress by industry based upon already approved SUPAC guidances. The comment said that its ability to continue to supply product to the marketplace can be adversely affected by now having

to redefine the reporting requirements and extend the time to implementation.

FDA declines to provide for grandfathering of changes already in progress. FDA does not believe that this is necessary. FDA carefully considered the existing SUPAC guidances when developing the regulations and the guidance "Changes to an Approved NDA or ANDA'' and does not believe that there will be situations where implementation time will be significantly extended. There may be a limited number of cases where implementation may be delayed for 30 days because of the new reporting category specified in section 506A of the act "Supplement—changes being effected in 30 days,'' but FDA does not believe this is an undue hardship.

(Comment 123) A comment noted that a number of relevant guidance documents required to support the proposed regulations are not yet implemented (e.g., stability), nor is the guidance "Changes to an Approved NDA or ANDA.'' The comment recommended that a finite period be established in which these guidance documents be completed and issued. A few comments recommended that all affected guidance documents, such as the SUPAC guidances, be revised expeditiously to minimize confusion regarding conflicting information. One comment recommended related guidances be reviewed within 60 days after issuance of the final rule.

In the **Federal Register** of November 23, 1999, FDA announced the availability of a final version of the guidance for industry entitled "Changes to an Approved NDA or ANDA.'' This guidance has been revised to conform to this final rule revising § 314.70. FDA continues to update and develop guidances to address particular regulatory and scientific issues. FDA publishes these guidances as expeditiously as possible given its resources and priorities. If guidance for either recommended filing categories and/or information that should be submitted to support a particular postapproval manufacturing change is not available, the appropriate FDA staff can be consulted for advice.

(Comment 124) One comment requested that during the transition period, FDA permit industry to use the guidance document that provides the least burdensome regulatory requirement and the lowest reporting category.

Section 506A of the act and the final regulations provide for a new approach to establishing the reporting category for postapproval changes and for an additional reporting category. To accommodate these changes, FDA has stated that to the extent the recommendations on reporting categories in the guidance "Changes to an Approved NDA or ANDA'' are found to be inconsistent with guidance published before the "Changes to an Approved NDA or ANDA'' guidance was finalized, the recommended reporting categories in the previously published guidances are superseded.

(Comment 125) One comment noted that the preamble to the June 1999 proposal stated that to the extent that the recommendations on reporting categories in the draft guidance, when finalized, are inconsistent with previously published guidance, such as the SUPAC guidances, the recommended reporting categories in such prior guidance will be superseded by this new guidance upon its publication in final form. The comment said that CDER intends to update the previously published guidances such as SUPAC, to make them consistent with this new guidance. The comment said it wholly supports the creation and use of guidance documents and, in this particular instance, recommends that the SUPAC provisions relating to changes in the qualitative or quantitative formulation of the drug be retained. The comment said that any revisions to current guidance documents should not result in more burdensome requirements.

The recommendations in the SUPAC guidances regarding qualitative and quantitative formulation changes can still be used. FDA intends to revise current documents as appropriate.

*J. Comments Specific to Biological Products*

(Comment 126) A few comments discussed the need for FDA to issue guidance for the blood banking industry for changes to an approved application. The comments specifically requested clarification on the submission of information pertaining to annual reports, comparability protocols, changes in the site of testing from one facility to another, and equipment upgrades even when a change is due to equipment upgrades that have already received 501(k) clearance. In addition, the comments said that FDA needed to consider the least burdensome mechanism for submitting the various changes.

FDA agrees that guidance for the blood banking industry is needed in this area, and in the **Federal Register** of August 7, 2001 (66 FR 41247), FDA issued the guidance "Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture.''

The guidance is intended to assist manufacturers of Whole Blood, Blood Components, Source Plasma, and Source Leukocytes in determining which reporting mechanism is appropriate for a change to an approved license application. Under each section of the guidance, FDA provides categories of changes to be reported under § 601.12. A list of various changes that falls under each category is also provided. The lists are not intended to be all-inclusive. The guidance describes the format for the annual report and further explains the comparability protocol. The guidance also addresses facility and equipment changes.

The 510(k) clearance of a device to be used in a blood bank setting provides assurance that the device is substantially equivalent to a legally marketed device for which premarket approval was not required. For equipment upgrades related to a 510(k) device, the clearance of the device does not address implementation of the device in a specific blood bank setting nor does it address the procedures used by the establishment, the qualification and training of staff operating the equipment, onsite validation of processes, and ongoing process control and quality control. The category for which a change is to be reported depends on the impact of the change upon the specific biological product.

(Comment 127) One comment asked what analysis FDA has performed to determine what types of changes should be reviewed by the agency. For example, in the **Federal Register** of August 3, 1993 (58 FR 41348), FDA, in adding requirements to the labeling CGMP regulations, provided an analysis that labeling errors accounted for an inordinate number of recalls. FDA then issued regulations to address this problem. The comment said, however, that labeling changes are not addressed in CBER's guidance on change control and historically have not been emphasized during review of supplements and other changes to an approved application. The comment asked if CBER has done any systematic, methodical, written review of warning letters, revocations, suspensions, recalls, injunctions, 483-items, and so forth, so that review of supplements is focused on problems that FDA knows are likely to result in public health concerns, regulatory, or legal action.

Prior to the January 29, 1996 (61 FR 2739), proposed revision of § 601.12, FDA performed an informal retrospective review of supplements. It

was the intent of that review to focus the review of manufacturing changes on those with the greatest potential for adverse effect on the products. Labeling changes, although not generally tracked as supplements at that time, were also considered in the review. FDA does not agree with the comment that labeling changes have not been emphasized during review of supplements. Until the publication of the July 24, 1997 final rule (62 FR 39890) (the July 1997 final rule) that revised § 601.12, all labeling changes required approval prior to implementation. The July 1997 final rule allowed certain minor editorial changes to be part of an annual report. Other changes intended to enhance the safety of use of the product could be reported as a changes-being-effected supplement. Substantive changes to labeling still require approval prior to implementation.

(Comment 128) One comment said that in the July 1997 final rule, FDA has asserted that revision of the change-reporting regulations will reduce the burden of reporting changes to the agency. The comment asked whether this is synonymous with reducing the number of reports of changes to the agency. If not, the comment asked what is meant by "reducing the burden:'' for example, reduction of the amount of time between submission and approval, or reduction of the amount of data submitted. The comment asked whether FDA has actually analyzed the number of supplements submitted since the original changes to the reporting requirements, and whether the number of supplements has been reduced. The comment asked whether the analysis includes supplements due to labeling changes. The comment noted that FDA allowed for the submission of "comparability protocols.'' The comment said that once a comparability protocol is reviewed and approved, the change still must be reported, albeit a preapproval supplement may be reduced to a changes-being-effected supplement, and so forth, for each category of change. The comment asked whether FDA has considered these types of submissions in determining if the number of submissions has been reduced and if the total review time for a change has been reduced.

Fewer reports was only part of the reduction of reporting burden mentioned in the July 1997 final rule. The revision of § 601.12 was also intended to allow for more rapid implementation of certain manufacturing changes and to decrease the amount of information required for those changes contained in an annual report. While the comparability protocol was included in the assessment, without experience it was difficult to determine whether it would actually result in decreased reporting or increased efficiency. There is still insufficient experience with these supplements to make a clear determination on that point.

No formal comparison has been made of numbers of supplements received in CBER before and after the revision of § 601.12. Multiple changes to regulatory approaches make a direct comparison very difficult. Labeling changes, while requiring approval, were not tracked as supplements prior to the revision. Consequently, numbers of labeling changes are not readily available through an automated data system. The change to the Biologics License Application from the Product License Application/Establishment License Application approach also has had an effect on the number of submissions to CBER. Further, as the comment points out, there are now more applicants submitting supplements on more products. Even if a comparison of supplement submission numbers were done, the results would be difficult to evaluate.

(Comment 129) One comment said that the June 1999 proposal may perpetuate some existing confusion about the applicability of the regulations set forth in part 600 (21 CFR part 600). Current part 600 does not include the term drug; however, in the definitions section of proposed § 600.3(hh) and (ii), as well as in several other places in the June 1999 proposal, the term "drug'' is used rather than biological product. The comment requested that FDA revise the June 1999 proposal to clarify those sections that apply exclusively to biological products, and those that apply to both drugs and biological products.

FDA agrees with the comment. FDA is clarifying the definitions in proposed § 600.3(hh) and (ii) (new § 600.3(jj) and (kk)) by replacing the terms "drug substance(s)'' and "drug product(s)'' with "product(s).'' The term "products'' is defined in § 600.3(g). For new drugs, the terms "drug substance(s)'' or "drug product(s)'' are now used consistently throughout part 314 in this rule.

(Comment 130) One comment said that § 601.12(d)(3)(iii) would require blood establishments to submit a statement that the effects of the change have been validated. The comment said that this is an additional, although minor, increase in the documentation and reporting burden for the blood industry. Because blood establishments are already required to keep validation documentation on file, and blood establishments are inspected on a regular basis, the comment requested that the requirement to submit such a statement be deleted for blood establishments.

FDA disagrees with the comment that blood establishments should be exempt from the requirements of § 601.12(d)(3)(iii). These establishments are already required to report the items listed in § 601.12(d)(3)(i) and (d)(3)(ii). Adding a statement that the effects of the change have been assessed does not add burden beyond the existing requirement and provides valuable information to the agency concerning the establishment's change controls.

(Comment 131) One comment said that the June 1999 proposal would require that a supplement or annual report include in the cover letter a list of all changes contained in the supplement or annual report. The comment said that this new requirement will increase the reporting burden for blood establishments. The comment said that CBER has stated that Form FDA 356h is a cover letter. The comment asked why then must blood establishments fill out this additional new "cover letter.'' The comment also said that to require blood establishments to reiterate all of the changes that they have compiled and reported in their annual reports in a cover letter accompanying that annual report is duplication of effort. The comment said that the annual report itself is an increase in the reporting burden of blood establishments and was not required before the implementation of the form with its intended paperwork reduction and regulatory efficiency goals. The comment requested that multiple cover letters and the requirement to reiterate all of the changes contained in the report be deleted.

FDA agrees in part with the comment. Proposed § 601.12(a)(5) has been revised to remove the reference to a cover letter for annual reports. The need for a list of the changes contained in the supplement results from the practice of including more than a single change in a supplement. This list is necessary to ensure that all changes are properly identified and addressed in a timely manner. The comment misinterprets statements by CBER on the nature and use of Form FDA 356h. FDA has explained that Form FDA 356h is essentially a cover sheet that provides FDA with information necessary for the identification and administrative processing of a submission. It does not provide detailed information on the content of a submission, such as the number of changes that might be

covered. This necessary information may be conveyed most easily in a simple cover letter that is provided with the supplemental application. It is not FDA's intent that information in the completed Form FDA 356h be duplicated in a cover letter.

(Comment 132) One comment said FDA requires that a field copy of a supplement (except for labeling) be provided to an applicant's local FDA office. As the field inspection force is now routinely involved in the inspection of biologics, the comment asked whether FDA has considered making this a requirement with regard to CBER supplements.

FDA disagrees with the comment. FDA has considered extending the field copy requirement to CBER supplements. The field inspection force is involved in the inspection of biological products through the Team Biologics Initiative. Under this program, a cadre of inspectors has been drawn from field offices throughout FDA. Consequently, it is unlikely that the personnel participating in a given inspection would be assigned to that applicant's home FDA office. FDA does not believe that extending the field copy requirement to CBER supplements has sufficient benefit to the agency to justify the additional paperwork requirements.

(Comment 133) One comment said that the proposal to allow an applicant to request an expedited review of a supplement if a delay in making the change would impose an extraordinary hardship or for public health reasons should be reserved for manufacturing changes made necessary by catastrophic events (for example, fire). These requests should be limited to events that could not be reasonably foreseen and for which the applicant could not plan.

The policy of CBER and CDER has been that applicants requesting expedited review because of catastrophic events should do so only when the event could not be reasonably foreseen. Requests for expedited review will be evaluated on a case-by-case basis and it should be understood that not all requests will be granted.

(Comment 134) One comment noted that the proposal states that if FDA disapproves a supplemental application, FDA may order the manufacturer to cease distribution of the drug products made using the manufacturing change. The comment said that many blood establishments will not even attempt to use this provision because of the possibility of a recall being required by FDA if the manufacturer has misjudged the categorization of the supplement. The comment said that this uncertainty has already resulted in blood establishments pursuing an unnecessarily conservative approach to reporting certain types of changes and, consequently, implementing new technologies slower than necessary. The comment said that to help blood establishments implement process improvements more efficiently, the proposal should be revised to include examples of circumstances under which a cease distribution and subsequent recall would likely be ordered and those under which it would not.

FDA disagrees with the comment about the blood industry's failure to use the provision. The reason for the 30-day delay associated with the changes-being-effected-in-30-days supplement is to allow the agency to notify the applicant before the product is distributed that they have selected the wrong category for the supplement. In the case where the category is correctly chosen but the supplement cannot be approved, the agency will work with the applicant to minimize the impact of that decision. As discussed previously in this document, CBER has published a guidance for the Blood Industry that clarifies what categories changes should fall into and what information should be submitted to decrease the possibility of an error that might result in a recall. As previously mentioned in this document, the availability of the guidance was announced in the **Federal Register** of August 7, 2001 (66 FR 41247).

(Comment 135) One comment noted that the June 1999 proposal states that additions, deletions, or revisions to alternative analytical procedures (that provide the same or increased assurance of the identical strength, quality, purity, or potency of the material being tested as the analytical procedure described in the approved application) be included in the annual report. The comment said that blood establishments currently are permitted to use § 640.120 to obtain approval for alternate procedures. The comment said that since FDA will already be aware of this change on the date they have granted the approval, such change should not need to be included in blood industry annual reports. The comment said that in keeping with the paperwork reduction principles of the Modernization Act, this section should be revised so reporting of changes already approved under § 640.120 requests is not required in an annual report.

The comment has misinterpreted the concept of an "alternative'' analytical procedure (one procedure that can be substituted for another) with the concept of an alternative or an exception to a requirement in the regulations that the applicant views as providing equivalent safety or efficacy. In the case of the latter, the applicant must request approval under § 640.120 before implementing otherwise they will be in violation of the regulatory requirement. An alternative or exception approved under § 640.120 does not have to be included in an annual report.

(Comment 136) One comment concerned proposed § 601.12(f)(2)(i)(E) which provides that labeling changes that normally require a prior approval supplement be submitted in a changes being effected supplement when FDA specifically requests the change. The comment said that industry-wide labeling changes should be categorized as an annual report for blood establishments since uniform labeling requirements already exist, and the blood establishment would simply be reporting that they have adopted the change. In addition, FDA already permits reporting of changes to procedures initiated at the request of FDA to be reported in an annual report. The comment requested that for blood establishments, FDA require that industry-wide labeling changes be reported to FDA in an annual report.

FDA agrees in part with the comment. Many industry-wide labeling changes are initiated by the agency through guidance. If labeling changes include specific language consistent with FDA recommendations, changes to that specific labeling may be reported in the annual report. For example, a majority of the blood industry uses the American Association of Blood Banks circular of information that FDA reviews and recognizes as acceptable before it is printed for use by the blood industry. In this case, FDA does not need to review individual submissions. However, if an establishment uses an individually prepared circular, FDA would want any change to be submitted to FDA, at a minimum, at the time the change is effected because of the impact the change may have on the safe and effective use of a product. Generally, guidance on recommended changes to labeling will include information on how to report the change.

## IV. Conforming Amendments

The regulations on supplements and changes to an approved application or license are cited throughout FDA's regulations. Because FDA is revising these regulations, the agency is taking this opportunity to make conforming amendments to 21 CFR parts 5, 206, 250, 314, 600, and 601 to reflect this final rule. These conforming amendments will ensure the accuracy and consistency of the regulations.

## V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and 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). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs. Under the Regulatory Flexibility Act, if a rule has a significant economic impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. Section 202 of the Unfunded Mandates Reform Act requires that agencies prepare a written assessment 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. As shown in the following paragraphs, the rule will not be significant as defined by the Executive order and the Unfunded Mandates Reform Act, and the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

The purpose of the rule is to implement section 506A of the act and to reduce the number of manufacturing changes subject to supplements requiring FDA approval prior to product distribution. The rule affects all drug manufacturers that submit manufacturing supplements and will result in a substantial reduction in burdens to applicants making manufacturing changes subject to the regulation. The rule permits earlier implementation of the changes and quicker marketing of products improved by manufacturing or labeling modifications. Faster implementation can result in marked gains in production efficiency. For example, a report by the Eastern Research Group, Inc. (ERG), an FDA contractor, on the effects of the SUPAC–IR found that reducing the number of changes that require preapproval gives companies greater control over their production resources, which could lead to significant net savings to industry (ERG, *Pharmaceutical Industry Cost Savings Through Use of the Scale-Up and Post-Approval Guidance for Immediate Release Solid Oral Dosage Forms (SUPAC–IR)*, January 7, 1998, Contract No. 223–94–8301). ERG estimated that companies may already have saved $71 million in 1997 due to the agency's implementation of more flexible reporting procedures for chemistry, manufacturing, and control changes. This rule would lead to additional savings because it expands these changes to other drug products to improve product labeling and manufacturing methods.

Because the rule will benefit manufacturers regardless of size and impose no additional costs, the agency certifies that this rule will not have a significant adverse economic impact on a substantial number of small entities.

## VI. Paperwork Reduction Act of 1995

This final rule contains collections of information that are subject to review by OMB under the PRA (44 U.S.C. 3501–3520). "Collection of information" includes any request or requirement that persons obtain, maintain, retain, or report information to the agency, or disclose information to a third party or to the public (44 U.S.C. 3502(3) and 5 CFR 1320.3(c)). The title, description, and respondent description of the information collection are shown under this section of the document with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information.

*Title*: Supplements and Other Changes to an Approved Application.

*Description*: The final rule sets forth requirements for manufacturing changes requiring supplement submission and FDA approval prior to the distribution of the product made using the change, changes requiring supplement submission at least 30 days prior to the distribution of the product, changes requiring supplement submission at the time of distribution, and changes to be described in an annual report. The regulation reduces the rate of increase in the number of manufacturing changes subject to supplements and the overall number of supplements requiring FDA approval prior to product distribution. Many changes that are currently reported in supplements will be able to be reported in annual reports. Supplement submissions contain more burdensome reporting requirements than a submission through an annual report. The regulation will not increase the number of annual reports but will allow applicants to include in an annual report information currently required to be reported to the agency in a supplemental application. The number of manufacturing changes currently reported in supplements that will be reported in annual reports is approximately 1,283.

Sections 314.70(a)(2) and 601.12(a)(2) require, generally, that the holder of an approved application must assess the effects of a manufacturing change before distributing a drug product made with the change. This section implements section 506A(a)(1) and 506A(b) of the act, which require the holder of an approved application to validate the effects of a manufacturing change on the identity, strength, quality, purity, or potency of the drug as these factors may relate to the safety or effectiveness of the drug before distributing a drug made with the change. Under section 506A(d)(3)(A) of the act, information developed by the applicant to validate the effects of the change regarding identity, strength, quality, purity, and potency is required to be submitted to FDA as part of the supplement or annual report. Thus, estimates for validation requirements are included in the estimates for supplements and annual reports; no separate estimates are provided for §§ 314.70(a)(2) and 601.12(a)(2) in table 1 of this document. Furthermore, no estimates are required for the guidance entitled "Changes to an Approved NDA or ANDA," because it does not provide recommendations on the specific information that should be developed by the applicant to validate the effect of the change on the identity, strength (e.g., assay, content uniformity), quality (e.g., physical, chemical, and biological properties), purity (e.g., impurities and degradation products), or potency (e.g., biological activity, bioavailability, bioequivalence) of a product as they may relate to the safety or effectiveness of the product.

Sections 314.70(a)(4) and 601.12(a)(4) require, generally, that the applicant must promptly revise all promotional labeling and advertising to make it consistent with any labeling changes implemented. The transmittal to FDA of advertisements and promotional labeling for drugs and biologics is accompanied by Form FDA 2253 and regulated by §§ 314.81(b)(3)(i) and 601.12(f)(4). This information collection

is approved by OMB until October 31, 2004, under OMB control number 0910–0376. Therefore, the burden for this requirement is not estimated in table 1 of this document.

Section 314.70(a)(5) requires the applicant to include in each supplement (except for a supplement providing for a change in the labeling) and amendment to each supplement a statement certifying that a field copy has been provided in accordance with § 314.440(a)(4). The information collection for submitting a field copy under § 314.440(a)(4) is approved by OMB until March 31, 2005, under OMB control number 0910–0001. Based on data concerning the number of supplements and amendments to supplements currently received by the agency, FDA estimates that approximately 8,556 certifications will be submitted annually as required by § 314.70(a)(5). FDA estimates that approximately 594 applicants will submit these certifications. FDA estimates that preparation of a statement certifying the field copy will take applicants an average of 5 minutes.

Sections 314.70(a)(6) and 601.12(a)(5) require the applicant to include a list of all changes contained in the supplement or annual report; for supplements, this list must be provided in the cover letter. The information collection for submitting an annual report under § 314.81(b)(2) is approved by OMB until March 31, 2005, under OMB control number 0910–0001. Based on data concerning the number of supplements currently received by the agency, FDA estimates that approximately 4,984 lists of all changes in the supplement will be submitted annually as required by § 314.70(a)(6). FDA estimates that approximately 594 applicants will submit these lists. Because the information required would be generated in preparing the supplement, the agency estimates that, under § 314.70(a)(6), it will take approximately 1 hour to include a list of changes in a cover letter for a supplement. FDA estimates that approximately 2,983 lists of all changes in the supplement or annual report will be submitted annually as required by § 601.12(a)(5). FDA estimates that approximately 190 applicants will submit these lists. Because the information required would be generated in preparing the supplement or annual report, the agency estimates that, under § 601.12(a)(5), it will take approximately 1 hour to include a list of changes for a supplement or an annual report.

Section 314.70(b) and current § 601.12(b) set forth requirements for changes requiring supplement submission and approval prior to distribution of the product made using the change (major changes). Section 314.70(b)(1) and current § 601.12(b)(1) provide, generally, that a supplement must be submitted for any change in the drug substance, drug product, production process, quality controls, equipment, or facilities that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product. Section 314.70(b)(3) and current § 601.12(b)(3) specify the information that must be contained in the supplement.

Based on data concerning the number of supplements currently received by the agency, FDA estimates that approximately 1,744 supplements will be submitted annually under § 314.70(b)(1) and (b)(3). FDA estimates that approximately 594 applicants will submit such supplements, and that it will take approximately 150 hours to prepare and submit to FDA each supplement. FDA estimates that approximately 903 supplements will be submitted annually under § 601.12(b)(1) and (b)(3). FDA estimates that approximately 190 applicants will submit such supplements, and that it will take approximately 150 hours to prepare and submit to FDA each supplement.

Under §§ 314.70(b)(4) and 601.12(b)(4), an applicant may ask FDA to expedite its review of a supplement for public health reasons or if a delay in making the change described in it would impose an extraordinary hardship on the applicant. Such a supplement and its mailing cover should be marked: "Prior Approval Supplement-Expedited Review Requested.'' The burden for an applicant's request for an expedited review of a supplement by marking the mailing cover is minimal and is included in the burden hour estimates for submitting a supplement under § 314.70(b)(1) and (b)(3) and § 601.12(b)(1) and (b)(3).

Section 314.70(c) and current § 601.12(c) set forth requirements for changes requiring supplement submission at least 30 days prior to distribution of the product made using the change (moderate changes). Section 314.70(c)(1) and current § 601.12(c)(1) require, generally, that a supplement must be submitted for any change in the drug substance, drug product, production process, quality controls, equipment, or facilities that has a moderate potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product. Under § 314.70(c)(3) and current § 601.12(c)(1), the supplement must give a full explanation of the basis for the change and identify the date on which the change is to be made. The supplement must be labeled "Supplement—Changes Being Effected in 30 Days.'' Under § 314.70(c)(4) and current § 601.12(c)(3), the information listed previously for § 314.70(b)(3) and current § 601.12(b)(3) must be contained in the supplement.

Based on data concerning the number of supplements currently received by the agency, FDA estimates that approximately 2,754 supplements will be submitted annually under § 314.70(c)(1), (c)(3), and (c)(4). FDA estimates that approximately 594 applicants will submit such supplements, and that it will take approximately 95 hours to prepare and submit to FDA each supplement. FDA estimates that approximately 255 supplements will be submitted annually under § 601.12(c)(1) and (c)(3). FDA estimates that approximately 98 applicants will submit such supplements, and that it will take approximately 95 hours to prepare and submit to FDA each supplement.

Under § 314.70(c)(6) and current § 601.12(c)(5), FDA may designate a category of changes for the purpose of providing that, in the case of a change in such category, the holder of an approved application may commence distribution of the drug product upon receipt by the agency of a supplement for the change. The supplement must be labeled "Supplement—Changes Being Effected.'' If the supplement provides for a labeling change, 12 copies of the final printed labeling must be included.

Based on data concerning the number of supplements currently received by the agency, FDA estimates that approximately 486 supplements will be submitted annually under § 314.70(c)(6). FDA estimates that approximately 486 applicants will submit such supplements, and that it will take approximately 95 hours to prepare and submit to FDA each supplement. FDA estimates that approximately 47 supplements will be submitted annually under § 601.12(c)(5). FDA estimates that approximately 34 applicants will submit such supplements, and that it will take approximately 95 hours to prepare and submit to FDA each supplement.

Section 314.70(d) and current § 601.12(d) set forth requirements for changes to be described in an annual report (minor changes). Section 314.70(d)(1) and current § 601.12(d)(1)

provide, generally, that changes in the drug substance, drug product, production process, quality controls, equipment, or facilities that have a minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product must be documented in the next annual report. Section 314.70(d)(3) and current § 601.12(d)(3) (including proposed § 601.12(d)(3)(iii)) list the information that must be included in the annual report for describing changes under this section.

Based on data concerning the number of supplements and annual reports currently received by the agency, FDA estimates that approximately 6,929 annual reports will include documentation of certain manufacturing changes as required under § 314.70(d)(1) and (d)(3). FDA estimates that approximately 704 applicants will submit such information, and that it will take approximately 35 hours to prepare and submit to FDA the information for each annual report. FDA estimates that approximately 227 annual reports will include documentation of certain manufacturing changes as required under current § 601.12(d)(1) and (d)(3). FDA estimates that approximately 166 applicants will submit such information, and that it takes approximately 35 hours to prepare and submit to FDA the information for each annual report.

Section 314.70(e) and current § 601.12(e) state, generally, that an applicant may submit one or more protocols describing the specific tests and studies and acceptance criteria to be achieved to demonstrate the lack of adverse effect for specified types of manufacturing changes on the identity, strength, quality, purity, and potency of the drug product as these factors may relate to the safety or effectiveness of the drug product. Any such protocols, if not included in the approved application, or changes to an approved protocol, must be submitted as a supplement requiring approval from FDA prior to distribution of a drug product produced with the manufacturing change. The supplement, if approved, may subsequently justify a reduced reporting category for the particular change because the use of the protocol for that type of change reduces the potential risk of an adverse effect.

Based on data concerning the number of supplements currently received by the agency, FDA estimates that approximately 50 protocols will be submitted annually under § 314.70(e). FDA estimates that approximately 50 applicants will submit such protocols, and that it will take approximately 200 hours to prepare and submit to FDA each protocol. FDA estimates that approximately 20 protocols will be submitted annually under § 601.12(e). FDA estimates that approximately 14 applicants will submit such protocols, and that it will take approximately 200 hours to prepare and submit to FDA each protocol.

Current § 601.12(f) sets forth the requirements for supplement submission for labeling changes for biological products. Current § 601.12(f)(2)(i)(A) through (f)(2)(i)(D) specify those labeling changes for which an applicant must submit a supplement to FDA at the time the change is made. Section 601.12(f)(2)(i)(E) adds to these types of changes "any labeling change normally requiring a supplement submission and approval prior to distribution of the product that FDA specifically requests be submitted under this provision." Based on data concerning the number of supplements currently received by the agency, FDA estimates that approximately 12 labeling supplements will be submitted annually under current § 601.12(f)(1). FDA estimates that approximately 12 applicants will submit these supplements, and that it will take approximately 40 hours to prepare and submit to FDA each supplement. FDA estimates that approximately 10 labeling supplements will be submitted annually under current § 601.12(f)(2), including those that will be submitted under new § 601.12(f)(2)(i)(E). FDA estimates that approximately 10 applicants will submit these supplements, and that it will take approximately 20 hours to prepare and submit to FDA each supplement. FDA estimates that approximately 100 annual reports for labeling changes will be submitted under current § 601.12(f)(3). FDA estimates that approximately 70 applicants will submit these reports, and that it will take approximately 10 hours to prepare and submit to FDA each report. FDA estimates that approximately 1,495 labeling supplements will be submitted annually under current § 601.12(f)(4). FDA estimates that approximately 61 applicants will submit these supplements, and that it will take approximately 10 hours to prepare and submit to FDA each supplement.

Section 314.70(f) states that an applicant must comply with the patent information requirements under section 505(c)(2) of the act. Section 314.70(g) states that an applicant must include any applicable exclusivity information with a supplement as required under § 314.50(j). Patent and exclusivity information collection requirements are approved by OMB until March 31, 2005, under OMB control number 0910–0001. Therefore, this requirement is not estimated in table 1 of this document.

*Comments Received on FDA's Proposed Information Collection Burden Estimates*:

Concerning the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used, one comment said that FDA has underestimated the information collection burden. The comment suggested the following revised estimates: For § 314.70(b)(1) and (b)(3), the comment estimated 160 hours per response; for § 314.70(c)(1), (c)(3), and (c)(4), 80 hours per response; for § 314.70(c)(6), 80 hours per response; for § 314.70(d)(1) and (d)(3), 25 hours per response; for § 314.70(e), 240 hours per response. The comment assumed that the number of hours estimated refers to the number of hours required by regulatory affairs personnel to collect, assemble, and prepare data required for a submission. Other related activities, such as manufacturing validation lots and conducting stability studies, are not part of the estimates, since they are manufacturing activities that would be conducted, as appropriate, regardless of the reporting requirements. The comment said its estimates are based on an average time required for submissions, and the actual time required for a particular submission can vary, based on the complexity of the submitted change. The comment said that although the proposal would change the reporting level of changes, the associated "paperwork" for these changes is not significantly reduced and in some cases is increased.

Concerning the proposed requirement in § 314.70(e) that an applicant may submit one or more protocols, the comment noted that these protocols must be submitted as a supplement requiring approval from FDA prior to distribution of a drug produced with the manufacturing change. The comment said that, based on its experience, the estimate of 20 hours for these protocol submissions is significantly underestimated and that 240 hours is a more reasonable estimate. The comment said that these protocols are, in effect, supplements requiring prior approval and, therefore, would require the same number of hours to prepare as a prior approval supplement under § 314.70(b)(1) and (b)(3). Additionally, once the data for the change has been generated, the change requires an additional submission in order to implement the change. Assuming the data generated could be submitted

under § 314.70(c), the number of hours to submit changes under proposed § 314.70(e) would be a combination of the number of hours required to submit a change under § 314.70(b) and (c).

Another comment said that the estimated time in the proposal to collect the requested information for each type of supplement is low. The comment said that FDA underestimated the time to prepare the documents addressed in the proposal and that FDA should take greater care in evaluating the necessary steps required in preparing a supplement or report, not just the document preparation. For prior approved supplements under § 314.70(b), the comment said that the estimate of 80 hours is low and should be increased by at least 10 hours. The only time saving that can be gained under this requirement is when a firm can submit multiple supplements for the same change (site change), which is an uncommon occurrence; smaller firms submit one supplement at a time. For changes-being-effected supplements under § 314.70(c), the comment said that 50 hours for these types of supplements is low. The comment asked what is the difference between this type of supplement and prior approval supplements other than the filing mechanism. For annual reports under § 314.70(d), the comment said that 10 hours is low and that the data that go into such a report is collected over the entire year before the report may be put together. The comment said that an average of 20 hours is more reasonable. Concerning protocols under § 314.70(e), the comment said that 20 hours to prepare a suitability protocol is a large underestimate, and that firms will spend a large amount of time to determine just which tests and specifications to include in the protocol, in addition to preparing the protocol itself. The comment also said that the analysis and reporting of the results of the completed protocols was not included in the estimate.

FDA has considered the above comments as well as other information it has received and has revised the proposed information collection burden estimates. The estimate for "hours per response'' for §§ 314.70(b)(1) and (b)(3) and 601.12(b)(1) and (b)(3) has been increased from 80 hours to 150 hours; the estimate for §§ 314.70(c)(1), (c)(3), and (c)(4) and 601.12(c)(1) and (c)(3) has been increased from 50 hours to 95 hours; the estimate for §§ 314.70(c)(6) and 601.12(c)(5) has been increased from 50 hours to 95 hours; the estimate for §§ 314.70(d)(1) and (d)(3) and 601.12(d)(1) and (d)(3) has been increased from 10 hours to 35 hours; and the estimate for §§ 314.70(e) and 601.12(e) has been increased from 20 hours to 200 hours.

*Description of Respondents*: Business or other for-profit organizations.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| 21 CFR Section | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 314.70(a)(5) | 594 | 14 | 8,556 | 5 minutes | 713 |
| 314.70(a)(6) | 594 | 8 | 4,984 | 1 | 4,984 |
| 314.70(b)(1), (b)(3) | 594 | 3 | 1,744 | 150 | 261,600 |
| 314.70(c)(1), (c)(3), (c)(4) | 594 | 5 | 2,754 | 95 | 261,630 |
| 314.70(c)(6) | 486 | 1 | 486 | 95 | 46,170 |
| 314.70(d)(1), (d)(3) | 704 | 10 | 6,929 | 35 | 242,515 |
| 314.70(e) | 50 | 1 | 50 | 200 | 10,000 |
| 601.12(a)(5) | 190 | 16 | 2,983 | 1 | 2,983 |
| 601.12(b)(1), (b)(3) | 190 | 5 | 903 | 150 | 135,450 |
| 601.12(c)(1), (c)(3) | 98 | 3 | 255 | 95 | 24,225 |
| 601.12(c)(5) | 34 | 1 | 47 | 95 | 4,465 |
| 601.12(d)(1), (d)(3) | 166 | 1 | 227 | 35 | 7,945 |
| 601.12(e) | 14 | 1 | 20 | 200 | 4,000 |
| 601.12(f)(1) | 12 | 1 | 12 | 40 | 480 |
| 601.12(f)(2) | 10 | 1 | 10 | 20 | 200 |
| 601.12(f)(3) | 70 | 1 | 100 | 10 | 1,000 |
| 601.12(f)(4) | 61 | 25 | 1,495 | 10 | 14,950 |
| Total | | | | | 1,023,310 |

[1] There are no capital costs or 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 0910–0538. This approval expires August 31, 2005. 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.

**VII. Environmental Impact**

The agency has determined under 21 CFR 25.30(h) 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.

**VIII. Federalism**

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies 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. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order, and, consequently, a federalism summary impact statement is not required.

**List of Subjects**

*21 CFR Parts 206 and 250*

Drugs.

*21 CFR Part 314*

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

*21 CFR Part 600*

Biologics, Reporting and recordkeeping requirements.

*21 CFR Part 601*

Administrative 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 206, 250, 314, 600, and 601 are amended as follows:

## PART 206—IMPRINTING OF SOLID ORAL DOSAGE FORM DRUG PRODUCTS FOR HUMAN USE

■ 1-3. The authority citation for 21 CFR part 206 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 355, 371; 42 U.S.C. 262.

### § 206.10 [Amended]

■ 4. Section 206.10 *Code imprint required* is amended in the first sentence of paragraph (b) by removing the phrase "§ 314.70(b)(2)(xi) or (b)(2)(xii)'' and by adding in its place the phrase "§ 314.70(b)''.

## PART 250—SPECIAL REQUIREMENTS FOR SPECIFIC HUMAN DRUGS

■ 5. The authority citation for 21 CFR part 250 continues to read as follows:

**Authority:** 21 U.S.C. 321, 336, 342, 352, 353, 355, 361(a), 362(a) and (c), 371, 375(b).

### § 250.250 [Amended]

■ 6. Section 250.250 *Hexachlorophene, as a component of drug and cosmetic products* is amended in the last sentence of paragraph (c)(4)(ii) by removing the phrase "§ 314.70(c)(2)'' and by adding in its place the phrase "§ 314.70(c)(6)(iii)''.

## PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

■ 7. 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.

■ 8. Section 314.3 is amended in paragraph (b) by alphabetically adding the definitions for "Assess the effects of the change'' and "Specification'' to read as follows:

### § 314.3 Definitions.

* * * * *

(b) * * *

*Assess the effects of the change* means to evaluate the effects of a manufacturing change on the identity, strength, quality, purity, and potency of a drug product as these factors may relate to the safety or effectiveness of the drug product.

* * * * *

*Specification* means the quality standard (i.e., tests, analytical procedures, and acceptance criteria) provided in an approved application to confirm the quality of drug substances, drug products, intermediates, raw materials, reagents, components, in-process materials, container closure systems, and other materials used in the production of a drug substance or drug product. For the purpose of this definition, *acceptance criteria*means numerical limits, ranges, or other criteria for the tests described.

* * * * *

■ 9. Section 314.50 is amended:

■ a. In paragraph (d)(1)(ii)(*b*) by removing the phrase "specifications and test procedures'' and by adding in its place the word "specification'';

■ b. In paragraph (d)(1)(v) by removing the phrase "Except for a foreign applicant, the'' and by adding in its place the word "The'';

■ c. In paragraph (d)(3)(i) by adding the word "procedures'' after the word "analytical'';

■ d. In paragraph (d)(3)(ii) by removing the phrases "specifications or analytical methods'' and "specification or analytical methods'' each time they appear and by adding in their places the phrase "tests, analytical procedures, and acceptance criteria'';

■ e. In paragraph (d)(4)(iv) by removing the word "methods'' and by adding in its place the word "procedures'';

■ f. In the last sentence of paragraph (e)(1) introductory text and in the first sentence of paragraph (e)(2)(i) by removing the word "methods'' each time it appears and by adding in its place the word "procedures''; and

■ g. By revising the first two sentences of paragraphs (d)(1)(i) and (d)(1)(ii)(*a*) to read as follows:

### § 314.50 Content and format of an application.

* * * * *

(d) * * *

(1) * * *

(i) *Drug substance*. A full description of the drug substance including its physical and chemical characteristics and stability; the name and address of its manufacturer; the method of synthesis (or isolation) and purification of the drug substance; the process controls used during manufacture and packaging; and the specifications necessary to ensure the identity, strength, quality, and purity of the drug substance and the bioavailability of the drug products made from the substance, including, for example, tests, analytical procedures, and acceptance criteria relating to stability, sterility, particle size, and crystalline form. The application may provide additionally for the use of alternatives to meet any of these requirements, including alternative sources, process controls, and analytical procedures.* * *

(ii)(a) *Drug product*. A list of all components used in the manufacture of the drug product (regardless of whether they appear in the drug product) and a statement of the composition of the drug product; the specifications for each component; the name and address of each manufacturer of the drug product; a description of the manufacturing and packaging procedures and in-process controls for the drug product; the specifications necessary to ensure the identity, strength, quality, purity, potency, and bioavailability of the drug product, including, for example, tests, analytical procedures, and acceptance criteria relating to sterility, dissolution rate, container closure systems; and stability data with proposed expiration

dating. The application may provide additionally for the use of alternatives to meet any of these requirements, including alternative components, manufacturing and packaging procedures, in-process controls, and analytical procedures. * * *

* * * * *

**§ 314.60 [Amended]**

■ 10. Section 314.60 *Amendments to an unapproved application* is amended in paragraph (c) by removing the phrase ", other than a foreign applicant,''.

■ 11. Section 314.70 is revised to read as follows:

**§ 314.70 Supplements and other changes to an approved application.**

(a) *Changes to an approved application.* (1) The applicant notify FDA about each change in each condition established in an approved application beyond the variations already provided for in the application. The notice is required to describe the change fully. Depending on the type of change, the applicant must notify FDA about it in a supplement under paragraph (b) or (c) of this section or by inclusion of the information in the annual report to the application under paragraph (d) of this section.

(2) The holder of an approved application under section 505 of the act must assess the effects of the change before distributing a drug product made with a manufacturing change.

(3) Notwithstanding the requirements of paragraphs (b) and (c) of this section, an applicant must make a change provided for in those paragraphs in accordance with a regulation or guidance that provides for a less burdensome notification of the change (for example, by submission of a supplement that does not require approval prior to distribution of the product or in an annual report).

(4) The applicant must promptly revise all promotional labeling and advertising to make it consistent with any labeling change implemented in accordance with paragraphs (b) and (c) of this section.

(5) Except for a supplement providing for a change in the labeling, the applicant must include in each supplement and amendment to a supplement providing for a change under paragraph (b) or (c) of this section a statement certifying that a field copy has been provided in accordance with § 314.440(a)(4).

(6) A supplement or annual report must include a list of all changes contained in the supplement or annual report. For supplements, this list must be provided in the cover letter.

(b) *Changes requiring supplement submission and approval prior to distribution of the product made using the change (major changes).* (1) A supplement must be submitted for any change in the drug substance, drug product, production process, quality controls, equipment, or facilities that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product.

(2) These changes include, but are not limited to:

(i) Except those described in paragraphs (c) and (d) of this section, changes in the qualitative or quantitative formulation of the drug product, including inactive ingredients, or in the specifications provided in the approved application;

(ii) Changes requiring completion of studies in accordance with part 320 of this chapter to demonstrate the equivalence of the drug product to the drug product as manufactured without the change or to the reference listed drug;

(iii) Changes that may affect drug substance or drug product sterility assurance, such as changes in drug substance, drug product, or component sterilization method(s) or an addition, deletion, or substitution of steps in an aseptic processing operation;

(iv) Changes in the synthesis or manufacture of the drug substance that may affect the impurity profile and/or the physical, chemical, or biological properties of the drug substance;

(v) The following labeling changes:

(A) Changes in labeling, except those described in paragraphs (c)(6)(iii), (d)(2)(ix), or (d)(2)(x) of this section;

(B) If applicable, any change to a Medication Guide required under part 208 of this chapter, except for changes in the information specified in § 208.20(b)(8)(iii) and (b)(8)(iv) of this chapter.

(vi) Changes in a drug product container closure system that controls the drug product delivered to a patient or changes in the type (e.g., glass to high density polyethylene (HDPE), HDPE to polyvinyl chloride, vial to syringe) or composition (e.g., one HDPE resin to another HDPE resin) of a packaging component that may affect the impurity profile of the drug product.

(vii) Changes solely affecting a natural product, a recombinant DNA-derived protein/polypeptide, or a complex or conjugate of a drug substance with a monoclonal antibody for the following:

(A) Changes in the virus or adventitious agent removal or inactivation method(s);

(B) Changes in the source material or cell line; and

(C) Establishment of a new master cell bank or seed.

(viii) Changes to a drug product under an application that is subject to a validity assessment because of significant questions regarding the integrity of the data supporting that application.

(3) The applicant must obtain approval of a supplement from FDA prior to distribution of a drug product made using a change under paragraph (b) of this section. Except for submissions under paragraph (e) of this section, the following information must be contained in the supplement:

(i) A detailed description of the proposed change;

(ii) The drug product(s) involved;

(iii) The manufacturing site(s) or area(s) affected;

(iv) A description of the methods used and studies performed to assess the effects of the change;

(v) The data derived from such studies;

(vi) For a natural product, a recombinant DNA-derived protein/polypeptide, or a complex or conjugate of a drug substance with a monoclonal antibody, relevant validation protocols and a list of relevant standard operating procedures must be provided in addition to the requirements in paragraphs (b)(3)(iv) and (b)(3)(v) of this section; and

(vii) For sterilization process and test methodologies related to sterilization process validation, relevant validation protocols and a list of relevant standard operating procedures must be provided in addition to the requirements in paragraphs (b)(3)(iv) and (b)(3)(v) of this section.

(4) An applicant may ask FDA to expedite its review of a supplement for public health reasons or if a delay in making the change described in it would impose an extraordinary hardship on the applicant. Such a supplement and its mailing cover should be plainly marked: "Prior Approval Supplement-Expedited Review Requested.''

(c) *Changes requiring supplement submission at least 30 days prior to distribution of the drug product made using the change (moderate changes).* (1) A supplement must be submitted for any change in the drug substance, drug product, production process, quality controls, equipment, or facilities that has a moderate potential to have an adverse effect on the identity, strength,

quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product. If the supplement provides for a labeling change under paragraph (c)(6)(iii) of this section, 12 copies of the final printed labeling must be included.

(2) These changes include, but are not limited to:

(i) A change in the container closure system that does not affect the quality of the drug product, except those described in paragraphs (b) and (d) of this section; and

(ii) Changes solely affecting a natural protein, a recombinant DNA-derived protein/polypeptide or a complex or conjugate of a drug substance with a monoclonal antibody, including:

(A) An increase or decrease in production scale during finishing steps that involves different equipment; and

(B) Replacement of equipment with that of a different design that does not affect the process methodology or process operating parameters.

(iii) Relaxation of an acceptance criterion or deletion of a test to comply with an official compendium that is consistent with FDA statutory and regulatory requirements.

(3) A supplement submitted under paragraph (c)(1) of this section is required to give a full explanation of the basis for the change and identify the date on which the change is to be made. The supplement must be labeled "Supplement—Changes Being Effected in 30 Days'' or, if applicable under paragraph (c)(6) of this section, "Supplement—Changes Being Effected.''

(4) Pending approval of the supplement by FDA, except as provided in paragraph (c)(6) of this section, distribution of the drug product made using the change may begin not less than 30 days after receipt of the supplement by FDA. The information listed in paragraphs (b)(3)(i) through (b)(3)(vii) of this section must be contained in the supplement.

(5) The applicant must not distribute the drug product made using the change if within 30 days following FDA's receipt of the supplement, FDA informs the applicant that either:

(i) The change requires approval prior to distribution of the drug product in accordance with paragraph (b) of this section; or

(ii) Any of the information required under paragraph (c)(4) of this section is missing; the applicant must not distribute the drug product made using the change until the supplement has been amended to provide the missing information.

(6) The agency may designate a category of changes for the purpose of providing that, in the case of a change in such category, the holder of an approved application may commence distribution of the drug product involved upon receipt by the agency of a supplement for the change. These changes include, but are not limited to:

(i) Addition to a specification or changes in the methods or controls to provide increased assurance that the drug substance or drug product will have the characteristics of identity, strength, quality, purity, or potency that it purports or is represented to possess;

(ii) A change in the size and/or shape of a container for a nonsterile drug product, except for solid dosage forms, without a change in the labeled amount of drug product or from one container closure system to another;

(iii) Changes in the labeling to accomplish any of the following:

(A) To add or strengthen a contraindication, warning, precaution, or adverse reaction;

(B) To add or strengthen a statement about drug abuse, dependence, psychological effect, or overdosage;

(C) To add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product;

(D) To delete false, misleading, or unsupported indications for use or claims for effectiveness; or

(E) Any labeling change normally requiring a supplement submission and approval prior to distribution of the drug product that FDA specifically requests be submitted under this provision.

(7) If the agency disapproves the supplemental application, it may order the manufacturer to cease distribution of the drug product(s) made with the manufacturing change.

(d) *Changes to be described in an annual report (minor changes).* (1) Changes in the drug substance, drug product, production process, quality controls, equipment, or facilities that have a minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product must be documented by the applicant in the next annual report in accordance with § 314.81(b)(2).

(2) These changes include, but are not limited to:

(i) Any change made to comply with a change to an official compendium, except a change described in paragraph (c)(2)(iii) of this section, that is consistent with FDA statutory and regulatory requirements.

(ii) The deletion or reduction of an ingredient intended to affect only the color of the drug product;

(iii) Replacement of equipment with that of the same design and operating principles except those equipment changes described in paragraph (c) of this section;

(iv) A change in the size and/or shape of a container containing the same number of dosage units for a nonsterile solid dosage form drug product, without a change from one container closure system to another;

(v) A change within the container closure system for a nonsterile drug product, based upon a showing of equivalency to the approved system under a protocol approved in the application or published in an official compendium;

(vi) An extension of an expiration dating period based upon full shelf life data on production batches obtained from a protocol approved in the application;

(vii) The addition or revision of an alternative analytical procedure that provides the same or increased assurance of the identity, strength, quality, purity, or potency of the material being tested as the analytical procedure described in the approved application, or deletion of an alternative analytical procedure;

(viii) The addition by embossing, debossing, or engraving of a code imprint to a solid oral dosage form drug product other than a modified release dosage form, or a minor change in an existing code imprint;

(ix) A change in the labeling concerning the description of the drug product or in the information about how the drug product is supplied, that does not involve a change in the dosage strength or dosage form; and

(x) An editorial or similar minor change in labeling.

(3) For changes under this category, the applicant is required to submit in the annual report:

(i) A statement by the holder of the approved application that the effects of the change have been assessed;

(ii) A full description of the manufacturing and controls changes, including the manufacturing site(s) or area(s) involved;

(iii) The date each change was implemented;

(iv) Data from studies and tests performed to assess the effects of the change; and,

(v) For a natural product, recombinant DNA-derived protein/polypeptide, complex or conjugate of a drug substance with a monoclonal antibody, sterilization process or test methodology

related to sterilization process validation, a cross-reference to relevant validation protocols and/or standard operating procedures.

(e) *Protocols*. An applicant may submit one or more protocols describing the specific tests and studies and acceptance criteria to be achieved to demonstrate the lack of adverse effect for specified types of manufacturing changes on the identity, strength, quality, purity, and potency of the drug product as these factors may relate to the safety or effectiveness of the drug product. Any such protocols, if not included in the approved application, or changes to an approved protocol, must be submitted as a supplement requiring approval from FDA prior to distribution of a drug product produced with the manufacturing change. The supplement, if approved, may subsequently justify a reduced reporting category for the particular change because the use of the protocol for that type of change reduces the potential risk of an adverse effect.

(f) *Patent information*. The applicant must comply with the patent information requirements under section 505(c)(2) of the act.

(g) *Claimed exclusivity*. If an applicant claims exclusivity under § 314.108 upon approval of a supplement for change to its previously approved drug product, the applicant must include with its supplement the information required under § 314.50(j).

**§ 314.81 [Amended]**

■ 12. Section 314.81 *Other postmarketing reports* is amended in paragraph (b)(1)(ii) by removing the word "specifications'' and by adding in its place the word "specification''.

**§ 314.94 [Amended]**

■ 13. Section 314.94 *Content and format of an abbreviated application* is amended in the second sentence of paragraph (d)(2) by removing the word "methods'' each time it appears and by adding in its place the word "procedures''.

**§ 314.410 [Amended]**

■ 14. Section 314.410 *Imports and exports of new drugs* is amended in paragraph (b)(2) by removing the word "specifications'' and by adding in its place the word "specification''.

**§ 314.430 [Amended]**

■ 15. Section 314.430 *Availability for public disclosure of data and information in an application or abbreviated application* is amended in paragraph (e)(6) by removing the word "method'' both times it appears and by adding in its place the word "procedure''.

## PART 600—BIOLOGICAL PRODUCTS: GENERAL

■ 16. The authority citation for 21 CFR part 600 continues to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 353, 355, 360, 360i, 371, 374; 42 U.S.C. 216, 262, 263, 263a, 264, 300aa–25.

■ 17. Section 600.3 is amended by adding paragraphs (jj) and (kk) to read as follows:

**§ 600.3 Definitions.**

* * * * *

(jj) *Assess the effects of the change*, as used in § 601.12 of this chapter, means to evaluate the effects of a manufacturing change on the identity, strength, quality, purity, and potency of a product as these factors may relate to the safety or effectiveness of the product.

(kk) *Specification*, as used in § 601.12 of this chapter, means the quality standard (i.e., tests, analytical procedures, and acceptance criteria) provided in an approved application to confirm the quality of products, intermediates, raw materials, reagents, components, in-process materials, container closure systems, and other materials used in the production of a product. For the purpose of this definition, *acceptance criteria* means numerical limits, ranges, or other criteria for the tests described.

## PART 601—LICENSING

■ 18. The authority citation 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).

■ 19. Section 601.12 is amended by revising paragraphs (a), (b)(2)(i), (c)(2)(ii), (d)(2)(i) through (d)(2)(v), and (d)(2)(vii); by adding paragraphs (b)(4), (c)(2)(iv), (c)(6), (d)(3)(iii), and (f)(2)(i)(E); and by removing and reserving paragraph (c)(2)(i) to read as follows:

**§ 601.12 Changes to an approved application.**

(a) *General*. (1) As provided by this section, an applicant must inform the Food and Drug Administration (FDA) about each change in the product, production process, quality controls, equipment, facilities, responsible personnel, or labeling established in the approved license application(s).

(2) Before distributing a product made using a change, an applicant must assess the effects of the change and demonstrate through appropriate validation and/or other clinical and/or nonclinical laboratory studies the lack of adverse effect of the change on the identity, strength, quality, purity, or potency of the product as they may relate to the safety or effectiveness of the product.

(3) Notwithstanding the requirements of paragraphs (b), (c), and (f) of this section, an applicant must make a change provided for in those paragraphs in accordance with a regulation or guidance that provides for a less burdensome notification of the change (for example, by submission of a supplement that does not require approval prior to distribution of the product or in an annual report).

(4) The applicant must promptly revise all promotional labeling and advertising to make it consistent with any labeling change implemented in accordance with paragraphs (f)(1) and (f)(2) of this section.

(5) A supplement or annual report must include a list of all changes contained in the supplement or annual report. For supplements, this list must be provided in the cover letter.

(b) * * *

(2) * * *

(i) Except as provided in paragraphs (c) and (d) of this section, changes in the qualitative or quantitative formulation, including inactive ingredients, or in the specifications provided in the approved application;

* * * * *

(4) An applicant may ask FDA to expedite its review of a supplement for public health reasons or if a delay in making the change described in it would impose an extraordinary hardship on the applicant. Such a supplement and its mailing cover should be plainly marked: "Prior Approval Supplement-Expedited Review Requested.

(c) * * *

(2) * * *

(i) [Reserved]

(ii) An increase or decrease in production scale during finishing steps that involves different equipment; and

* * * * *

(iv) Relaxation of an acceptance criterion or deletion of a test to comply with an official compendium that is consistent with FDA statutory and regulatory requirements.

* * * * *

(6) If the agency disapproves the supplemental application, it may order the manufacturer to cease distribution of

the products made with the manufacturing change.

(d) * * *

(2) * * *

(i) Any change made to comply with a change to an official compendium, except a change described in paragraph (c)(2)(iv) of this section, that is consistent with FDA statutory and regulatory requirements.

(ii) The deletion or reduction of an ingredient intended only to affect the color of the product, except that a change intended only to affect Blood Grouping Reagents requires supplement submission and approval prior to distribution of the product made using the change in accordance with the requirements set forth in paragraph (b) of this section;

(iii) An extension of an expiration dating period based upon full shelf life data on production batches obtained from a protocol approved in the application;

(iv) A change within the container closure system for a nonsterile product, based upon a showing of equivalency to the approved system under a protocol approved in the application or published in an official compendium;

(v) A change in the size and/or shape of a container containing the same number of dosage units for a nonsterile solid dosage form product, without a change from one container closure system to another;

* * * * *

(vii) The addition or revision of an alternative analytical procedure that provides the same or increased assurance of the identity, strength, quality, purity, or potency of the material being tested as the analytical procedure described in the approved application, or deletion of an alternative analytical procedure.

(3) * * *

(iii) A statement by the holder of the approved application or license that the effects of the change have been assessed.

* * * * *

(f) * * *

(2) * * *

(i) * * *

(E) Any labeling change normally requiring a supplement submission and approval prior to distribution of the product that FDA specifically requests be submitted under this provision.

Dated: March 24, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–7532 Filed 4–7–04; 8:45 am]

BILLING CODE 4160–01–S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 1999D–0529]**

### Guidance for Industry on Changes to an Approved NDA or ANDA; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a revised guidance for industry entitled "Changes to an Approved NDA or ANDA.'' The guidance has been revised to conform to the final rule amending the agency's regulations on changes to an approved NDA or ANDA published elsewhere in this issue of the **Federal Register**. The guidance is intended to assist applicants in determining how they should report changes to an approved new drug application (NDA) or an abbreviated new drug application (ANDA).

**DATES:** Written comments may be submitted at any time.

**ADDRESSES:** Copies of this guidance are available on the Internet at *http://www.fda.gov/cder/guidance/index.htm*. Submit written requests for single copies of this guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section of this document for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Nancy B. Sager, Center for Drug Evaluation and Research (HFD–357), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5633. The e-mail address for questions about content of the guidance is *pac314__70@cder.fda.gov*.

**SUPPLEMENTARY INFORMATION:**

## I. Background

On November 21, 1997, the President signed the Food and Drug Administration Modernization Act of 1997 (the Modernization Act) (Public Law 105–115). Section 116 of the Modernization Act amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 506A (21 U.S.C. 356a), which provides requirements for making and reporting manufacturing changes to an approved application and for distributing a drug product made with such changes. The agency's final rule amending its regulations at § 314.70 (21 CFR 314.70) to implement section 506A of the act is published elsewhere in this issue of the **Federal Register**.

FDA is announcing the availability of a revised guidance for industry entitled "Changes to an Approved NDA or ANDA.'' In the **Federal Register** of November 23, 1999 (64 FR 65716), FDA announced the availability of a guidance of the same title (November 1999 guidance). The November 1999 guidance has been revised to conform to the final rule amending § 314.70 and to include nonsubstantive corrections and clarifications. This revised guidance supersedes the November 1999 guidance.

The purpose of the guidance is to provide recommendations to holders of NDA's and ANDA's who intend to make postapproval changes in accordance with section 506A of the act and § 314.70. The guidance covers recommended reporting categories for postapproval changes for drugs, other than specified biotechnology and specified synthetic biological products. Recommendations are provided for postapproval changes in the following areas: (1) Components and composition, (2) manufacturing sites, (3) manufacturing process, (4) specifications, (5) container closure system, (6) labeling, (7) miscellaneous changes, and (8) multiple related changes. The guidance does not provide recommendations on the specific information that should be developed by the applicant to assess the effect of the change on the identity, strength (e.g., assay, content uniformity), quality (e.g., physical, chemical, and biological properties), purity (e.g., impurities and degradation products), or potency (e.g., biological activity, bioavailability, bioequivalence) of a product as these factors may relate to the safety or effectiveness of the product.

This level 1 guidance document is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. Insofar as this guidance adjusts reporting categories under section 506A of the act and § 314.70, it does have binding effect.

FDA has established an e-mail address where applicants can send questions about the content of the guidance (see **FOR FURTHER INFORMATION CONTACT**), such as requests for clarification of information in the guidance or requests for guidance on the reporting category for a particular change the applicant wants to implement.

## II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written comments on the guidance at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance 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.

## III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: March 24, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–7533 Filed 4–7–04; 8:45 am]

**BILLING CODE 4160–01–S**

Federal Register

Thursday,
April 8, 2004

# Part V

# Department of the Interior

## Fish and Wildlife Service

**50 CFR Part 17**

**Endangered and Threatened Wildlife and Plants; 12-month Finding for a Petition To List the West Coast Distinct Population Segment of the Fisher (*Martes pennanti*); Proposed Rule**

**DEPARTMENT OF THE INTERIOR**

**Fish and Wildlife Service**

**50 CFR Part 17**

## Endangered and Threatened Wildlife and Plants; 12-month Finding for a Petition to List the West Coast Distinct Population Segment of the Fisher (*Martes pennanti*)

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of 12-month petition finding.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), announce a 12-month finding for a petition to list the West Coast distinct population segment of the fisher (*Martes pennanti*) under the Endangered Species Act of 1973, as amended. After review of all available scientific and commercial information, we find that the petitioned action is warranted, but precluded by higher priority actions to amend the Lists of Endangered and Threatened Wildlife and Plants. Upon publication of this 12-month petition finding, this species will be added to our candidate species list. We will develop a proposed rule to list this population pursuant to our Listing Priority System.

**DATES:** The finding announced in this document was made on April 2, 2004. Comments and information may be submitted until further notice.

**ADDRESSES:** You may send data, information, comments, or questions concerning this finding to the Field Supervisor (Attn: FISHER), Sacramento Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2800 Cottage Way, Room W–2605, Sacramento, CA 95825 or via fax at 916/414–6710. You may inspect the petition, administrative finding, supporting information, and comments received during normal business hours by appointment at the above address.

**FOR FURTHER INFORMATION CONTACT:** Jesse Wild or Arnold Roessler at the above address (telephone: 916/414–6600; fax: 916/414–6710; electronic mail: *fisher@fws.gov*). In the event that our Internet connection is not functional, please submit your comments by the alternate methods mentioned above.

**SUPPLEMENTARY INFORMATION:**

### Background

Section 4(b)(3)(B) of the Endangered Species Act of 1973, as amended (Act) (16 U.S.C. 1531 *et seq.*), requires that, for any petition to revise the List of Threatened and Endangered Species that contains substantial scientific and commercial information that listing may be warranted, we make a finding within 12 months of the date of the receipt of the petition on whether the petitioned action is: (a) Not warranted, or (b) warranted, or (c) warranted but that the immediate proposal of a regulation implementing the petitioned action is precluded by other pending proposals to determine whether any species is threatened or endangered, and expeditious progress is being made to add or remove qualified species from the List of Threatened and Endangered Species. Section 4(b)(3)(C) of the Act requires that a petition for which the requested action is found to be warranted but precluded shall be treated as though resubmitted on the date of such finding, *i.e.*, requiring a subsequent finding to be made within 12 months. Such 12-month findings are to be published promptly in the **Federal Register**.

On December 5, 2000, we received a petition dated November 28, 2000, to list a distinct population segment (DPS) of the fisher, including portions of California, Oregon, and Washington, as endangered pursuant to the Act, and to concurrently designate critical habitat for this distinct population segment. A court order was issued on April 4, 2003, by the U.S. District Court, Northern District of California, that required us to submit for publication in the **Federal Register** a 90-day finding on the November 2000 petition (*Center for Biological Diversity, et al.* v. *Norton, et al.*, No. C 01–2950 SC). On July 10, 2003, we published a 90-day petition finding (68 FR 41169) that the petition provided substantial information that listing may be warranted and initiated a 12-month status review. Through a stipulated order, the court set a deadline of April 3, 2004, for the Service to make a 12-month finding under 16 U.S.C. 1533 (b)(3)(B).

### Taxonomy

The fisher is classified in the order Carnivora, family Mustelidae, subfamily Mustelinae, and is the largest member of the genus *Martes* (Anderson 1994). The only other North American member of the genus *Martes* is the American marten (*M. americana*). The fisher (*Martes pennanti* Erxleben 1777) is the only extant species in its subgenus *Pekania.*

Goldman (1935) recognized three subspecies of fisher, although he stated they were difficult to distinguish. Both Grinnell *et al.* (1937) and Hagmeier (1959) examined specimens from across the range of the fisher and concluded that differences in skull morphology or pelage were not sufficient to support recognition of separate subspecies. Hall (1981) retained all three subspecies in his compilation of North American mammals, as did Anderson (1994), but neither addressed Hagmeier's conclusion that the subspecies should not be recognized (Powell 1993). Several authors address genetic variation in fisher populations in their northern and eastern ranges (Williams *et al.* 1999, 2000; Kyle *et al.* 2001) and in the west (Drew *et al.* 2003; Aubry and Lewis 2003; Wisely *et al.* in litt. 2003). These analyses found patterns of population subdivision similar to the earlier described subspecies (Drew *et al.* 2003). Drew *et al.* (2003) stated that, although it is not clear whether Goldman's (1935) subspecific designations are taxonomically valid, ''* * * it is clear (based on genetic results) that population subdivision is occurring within the species, especially among populations in the western USA and Canada.''

### Description

The fisher is light brown to dark blackish brown with the face, neck, and shoulders sometimes being slightly gray. The chest and underside often has irregular white patches. The fisher has a long body with short legs and a long bushy tail. At 6.6 to 13.2 pounds (lbs) (3 to 6 kilograms (kg)), male fishers weigh about twice as much as females (3.3 to 5.5 lbs; 1.5 to 2.5 kg). Males range in length from 35 to 47 inches (in) (90 to 120 centimeters (cm)) while females range from 29 to 37 in (75 to 95 cm) in length. The fishers from the Pacific States may weigh less than fishers in the eastern United States (Seglund 1995; Dark 1997; Golightly 1997; Aubry and Lewis 2003). Fishers are estimated to live up to 10 years (Powell 1993).

### Distribution and Status

Fishers occur in the northern coniferous and mixed forests of Canada and the northern United States, from the mountainous areas in the southern Yukon and Labrador Provinces in Canada southward to central California and Wyoming, the Great Lakes and Appalachian regions, and New England (Graham and Graham 1994; Powell 1994). The fisher's range was reduced dramatically in the 1800s and early 1900s through overtrapping, predator and pest control, and alterations of forested habitats by logging, fire, and farming (Douglas and Strickland 1987; Powell 1993; Powell and Zielinski 1994; Lewis and Stinson 1998). Since the 1950s, fishers have recovered in some of the central and eastern portions of their historic range in the United States as a

result of trapping closures, changes in forested habitats (*e.g.*, forest regrowth in abandoned farmland), and reintroductions (Brander and Books 1973; Powell and Zielinski 1994). However, fishers are still absent from their former range southeast of the Great Lakes (Gibilisco 1994). Grinnell *et al.* (1937) estimated extremely low population numbers for the fisher in California at a time when trapping for the fur trade had greatly reduced populations of furbearing animals. Although it is possible that fisher populations recovered somewhat immediately following the trapping prohibitions in the 1930s and 40s, Powell and Zielinski (1994) more recently note population declines for fisher populations in the west. Fishers are believed to be extirpated from the lower mainland of British Columbia; however, they may still occupy the higher elevations of these areas in low densities (BC Species and Ecosystems Explorer 2003). In the Pacific States, fishers were historically more likely to be found in low to mid-elevation forests up to 8,200 feet (ft) (2,500 meters (m)) (Grinnell *et al.* 1937; Schempf and White 1977; Aubry and Houston 1992). In recent decades, the scarcity of detections in Washington, Oregon, and the northern Sierra Nevada indicates that the fisher may be extirpated or reduced to very low numbers in much of this area (Aubry and Houston 1992; Zielinski *et al.* 1995; Aubry and Lewis 2003).

**Washington**

The fisher historically occurred both east and west of the Cascade Crest in Washington (Scheffer 1938; Aubry and Houston 1992). Lewis and Stinson (1998) conclude that, "Based on habitat, the historical range of fishers in Washington probably included all the wet and mesic forest habitats at low to mid-elevations. The distribution of trapping reports and fisher specimens collected in Washington confirms that fishers occurred throughout the Cascades, Olympic Peninsula, and probably southwestern and northeastern Washington.'' Aubry and Houston (1992) compared current and historical records of fishers in Washington to determine their distribution in relation to major vegetation and elevation zones. In total, they found 88 reliable records, dating from 1955 to 1991. West of the Cascades, fishers occurred from 328 to 5,900 ft (100 to 1800 m), with most records from below 3,280 ft (1,000 m). On the east slope of the Cascades where precipitation is lower, fishers were recorded from 1,970 to 7,200 ft (600 to 2,200 m) (Aubry and Houston 1992). Similar to elsewhere in the range, the upper elevational limit may be determined by snow depth (Krohn *et al.* 1997). Based on a lack of recent sightings or trapping reports, the fisher is considered to be extirpated or reduced to scattered individuals in Washington (Aubry and Houston 1992; Lewis and Stinson 1998).

**Oregon**

Aubry and Houston (1992) noted that most fisher records for Washington occurred in the western hemlock and sitka spruce forest zones. Given that these forest zones occupy large portions of northwestern Oregon (Franklin and Dyrness 1988), it is likely that the fisher historically occurred in this part of the State. Based on extensive camera and track plate surveys, Lewis and Stinson (1998) concluded that the fisher is greatly reduced in Oregon. Based on extensive inquiry and review of records, Aubry and Lewis (2003) found that extant fisher populations in Oregon are restricted to two disjunct and genetically isolated populations in the southwestern portion of the State: one in the northern Siskiyou Mountains of southwestern Oregon and one in the southern Cascade Range. The fishers in the Siskiyou Mountains near the California border are probably an extension of the northern California population (Aubry and Lewis 2003). The population in the southern Cascade Range is reintroduced and is descended from fishers that were translocated to Oregon from British Columbia and Minnesota (Aubry and Lewis 2003). The Oregon Cascade Range population is separated from known populations in British Columbia by more than 404 miles (mi) (650 kilometers (km)) (Aubry and Lewis 2003).

**California**

In eastern California, the fisher historically ranged throughout the Sierra Nevada, from Greenhorn Mountain in northern Kern County northward to the southern Cascades at Mount Shasta (Grinnell *et al.* 1937). In western California, it ranged from the Klamath Mountains and north Coast Range near the Oregon border southward to Lake and Marin Counties (Grinnell *et al.* 1937). Krohn *et al.* (1997) note that the map of fisher distributions by Grinnell *et al.* (1937) suggests that fishers may have been less common in the central Sierra Nevada than elsewhere in California during the early 1900s, but it is unknown whether this distribution was the historical condition or reflects human effects on forests and fishers prior to their assessment. The map was based on the trapping records of one 5-year period prior to which there was already concern that trapping had dangerously decreased the population of fisher in California (Grinnell *et al.* 1937).

Substantial efforts have been made in recent years to assess the status of fishers and other forest carnivores in California using systematic grids of baited track and camera stations (Zielinski *et al.* 1995, 1997a, 1997b, 2000; Zielinski and Stauffer 1996; Zielinski 1997). Recent surveys indicate that fishers appear to occupy less than half of the range they did in the early 1900s in California, and this population has divided into two remnant populations that are separated by approximately 260 mi (420 km) (Zielinski *et al.* 1995), almost four times the species' maximum dispersal distance as reported by York (1996) for fishers in Massachusetts. One population is located in northwestern California and the other is in the southern Sierra Nevada Mountains. Since 1990, there have generally been no detections outside these areas except for one in 1995 in Mendocino County and one in 1995 in Plumas County (CDFG 2002, updated November 13, 2003).

Failure to detect fishers in the central and northern Sierra Nevada, despite reports of their presence there by Grinnell *et al.* (1937) and reports from the 1960s collected by Schempf and White (1977), suggests that the fisher population in this region has declined, effectively isolating fishers in the southern Sierra Nevada from fishers in northern California (Truex *et al.* 1998; Lamberson *et al.* 2000). However, prior to the recent development of a rigorous fisher survey protocol, differences in the type and quality of data available over the previous 60-year period make interpretation of distributional changes difficult (Zielinski *et al.* 1995).

**Population Size**

Although reductions in the fisher's distribution in the Pacific States are well documented (Aubry and Lewis 2003; Gibilisco 1994; Powell and Zielinski 1994), accurate information on fisher densities and abundance outside the northeastern United States is very limited. There have been no good population estimates for fisher populations in California, Oregon, and Washington, so it is unknown precisely how many fishers exist. Estimates of fisher abundance and vital rates (*e.g.*, survival, reproduction) are very difficult to obtain (Douglas and Strickland 1987) and may vary widely based on habitat composition and prey availability (York 1996). In addition, the assumptions of

many methods for estimating populations (*e.g.*, equal trapability, no learned trap response, sufficient trapability to yield adequate sample sizes) may not be valid for fishers (Powell and Zielinski 1994). Consequently, only a few estimates of local fisher population density are available for the Pacific States and British Columbia, and are summarized here.

In British Columbia, densities of fishers are estimated to be between 1 and 1.54 fishers per 38.6 $mi^2$ (100 $km^2$) in the highest quality habitats in the province (Weir 2003). Using the area of each habitat capability rank within the extent of occurrence of fishers in British Columbia, the late-winter population for the province is estimated to be between 1,113 and 2,759 fishers (Weir 2003). In a preliminary progress report of fisher studies on the Hoopa Valley Indian Reservation in the Klamath mountain range (Humboldt County, California), Higley *et al.* (1998) report high capture numbers and small home ranges, some of which overlap each other, indicating that densities in this 25 $mi^2$ (65 $km^2$) study area may be very high relative to those in the rest of the occupied West Coast range. In their analysis of two fisher studies in California, Zielinski *et al.* (in press 2003a) provided a rough estimate of approximately 5 female fishers per 38.6 $mi^2$ (100 $km^2$) for their 154 $mi^2$ (400 km) north coast study area (in the Six Rivers and Shasta-Trinity National Forests of southeastern Humboldt and southwestern Trinity Counties), whereas they estimated approximately 8 females per 100 $km^2$ in their 108 $mi^2$ (280 $km^2$) southern Sierra Nevada study area (in the Sequoia National Forest in Tulare County). For the purpose of modeling population viability, Lamberson *et al.* (2000) estimated that there were between 100 and 500 individuals in the southern Sierra Nevada fisher population. Based on trapping records from the 1920s, Grinnell and colleagues (1937) provided a dire estimate of 1 fisher per 100 $mi^2$, or 300 in California. However, although Grinnell *et al.* employed accepted methodologies at the time they conducted their research, we believe that their population estimate for California is incorrect by modern standards due to the lack of a significant sample size, survey bias, and inadequate knowledge of the historical baseline.

Despite the lack of precise empirical data on fisher numbers in the western states, the relative reduction in the range of the fisher on the West Coast, the lack of detections or sightings over much of its historical distribution, and the high degree of genetic relatedness within some populations (esp., native fishers in California) (Drew *et al.* 2003), indicate that it is likely extant fisher populations are small.

**Diet**

The fisher is an opportunistic predator with a diverse diet that includes birds, squirrels, mice, shrews, voles, reptiles, insects, carrion, vegetation, and fruit (Powell 1993; Martin 1994; Zielinski *et al.* 1999; Zielinski and Duncan, in press 2003). Fishers hunt exclusively in forested habitats and generally avoid openings (Earle 1978; Rosenberg and Raphael 1986; Powell 1993; Buskirk and Powell 1994; Jones and Garton 1994; Seglund 1995; Dark 1997). Being dietary generalists, fishers tend to forage in areas where prey is both abundant and vulnerable to capture (Powell 1993).

**Reproduction**

Except during the breeding season, fishers are solitary animals. The breeding season for the fisher is generally from late February to the end of April (Leonard 1986; Douglas and Strickland 1987; Powell 1993; Frost and Krohn 1997). Birth occurs nearly 1 year after copulation, due to delayed implantation in which the embryos remain in a state of arrested development for approximately 10 months. Arthur and Krohn (1991) and Powell (1993) speculate that this system allows adults to breed in a time when it is energetically efficient, while still giving kits adequate time to develop before winter. Raised entirely by the female, kits are completely dependent at birth and weaned by 10 weeks (Powell 1993). The mother becomes increasingly active as kits grow in order to provide enough food (Arthur and Krohn 1991; Powell 1993), and females may move their kits periodically to new dens (Arthur and Krohn 1991). At 1 year, kits will have developed their own home ranges (Powell 1993). Fishers have a low annual reproductive capacity, and reproductive rates may fluctuate widely from year to year (Truex *et al.* 1998).

**Home Range Size**

A home range is an area repeatedly traveled by an individual in its normal activities of feeding, drinking, resting, and traveling. Fishers have large home ranges and male home ranges are considerably larger than those of females (Buck *et al.* 1983; Truex *et al.* 1998). Fisher home range sizes across North America vary from 3,954 to 30,147 acres (ac) (16 to 122 $km^2$ for males and from 988 to 13,096 ac (4 to 53 $km^2$ for females (Powell and Zielinski 1994; Lewis and Stinson 1998). However, Beyer and Golightly (1996) reported that male home ranges in northern California may be as large as 31,629 ac (128 $km^2$).

Truex *et al.* (1998) compared fisher home range sizes in three study areas: the Klamath Mountains (Shasta-Trinity National Forest, the North Coast Ranges), Six Rivers National Forest, and the southern Sierra Nevada (Sequoia National Forest). They found the largest home range sizes in the eastern Klamath study area in northern California where habitat quality was generally considered poor. A preliminary summary of an unpublished study conducted in coastal redwood forests in the Coast Ranges of northwestern California indicates female home range sizes of 790 to 2050 ac (3.2 $km^2$ to 8.3 $km^2$) (Joel Thompson unpublished data; Neal Ewald, pers. comm. 2003), which is somewhat larger than range sizes reported by other researchers for the species in North America. Zielinski *et al.* (in press 2003a) found that females had home ranges that were almost three times larger in their northern California study area in the Coast Ranges than in their southern Sierra Nevada study area. They too suggest that this difference in home range size is a result of better quality habitats in the southern Sierra Nevada, which are occupied by a higher density of animals within a smaller area of suitable habitat (Zielinski *et al.*, in press 2003a). Based on northeastern fisher home range sizes, Allen (1983) assumed that a minimum of 62 $mi^2$ (161 $km^2$ of potentially suitable and connected habitat must be present before an area can sustain a population of fishers. However, Allen's estimates of amount of habitat required to support a fisher population may be an underestimate when applied to western forests, where male home ranges have been found to be somewhat larger (Beyer and Golightly 1996).

**Dispersal**

Dispersal (movement away from the natal home range) is the primary mechanism for the spread of a population. Arthur *et al.* (1993) reported an average maximum dispersal distance of 9.3 and 10.7 mi (14.9 and 17.3 km) for females and males, respectively (range = 4.7 to 14.0 mi (7.5 to 22.6 km) for females and 6.8 to 14.3 mi (10.9 to 23.0 km) for males) in a population in Maine with high trapping mortality and low density. In areas with high mortality and low density, young fishers may not have to disperse as far in order to find unoccupied home ranges (Arthur *et al.* 1993). York (1996) reported dispersal distances for juvenile male and female fishers averaging 20 mi (33

km) (range = 6 to 66 mi; 10 to 107 km) for a high-density population in Massachusetts. Based on field observation and microsatellite genotype analyses of the southern Cascades fisher population, Aubry *et al.* (USDA Forest Service, Pacific Northwest Research Station, in press 2003) found empirical evidence of male-biased juvenile dispersal and female philopatry (the drive or tendency of an individual to return to, or stay in, its home area) in fishers, which may have a direct bearing on the rate at which the fisher may be able to colonize formerly occupied areas within its historical range.

**Habitat**

Assessment of habitat relationships of fisher in current western U.S. forests is complicated by broad-scale changes in forest structure and composition over the past century. Grazing, wildfire suppression, and timber harvest have resulted in dramatic changes in forest ecosystems, including reduction of large tree component, increased dominance of shade-tolerant conifer species, increased stand density, and reduced structural diversity (McKelvey and Johnson 1992; Agee 1993; Skinner 1995; Chang 1996; Norman 2003). These effects vary among forest ecosystems, but generally are more pronounced in drier interior forests of the eastern Cascades, Sierra Nevada, and eastern Klamath Mountain ranges. The degree to which currently-described habitat relationships, particularly at broader scales, existed under historical conditions is unknown.

According to Buskirk and Powell (1994), the physical structure of the forest and prey associated with forest structures are thought to be the critical features that explain fisher habitat use, rather than specific forest types. Powell (1993) stated that forest type is probably not as important to fishers as the vegetative and structural aspects that lead to abundant prey populations and reduced fisher vulnerability to predation, and that they may select forests that have low and closed canopies. In the Klamath and north coast regions of California, Carroll *et al.* (1999) also found a strong association with high levels of tree canopy cover, tree size class, and percent conifer. Within a given region, the distribution of fishers is likely limited by elevation and snow depth (Krohn *et al.* 1997), and fisher are unlikely to occupy forest habitats in areas where elevation and snow depth act to limit their movements. However, in mid-elevation areas with intermediate snow depth, fishers may use dense forest patches with large trees because the overstory closure increases snow interception (Weir 1995a).

In a track-plate study conducted on private timberlands in the redwood-Douglas-fir transition zone of the Coast Ranges of northwestern California, Klug (1997) detected fishers on 238 occasions at 26 of 40 (65 percent) survey segments located in second-growth Douglas-fir and redwood. Fishers were detected more frequently than expected (based on availability) in areas at higher elevations, in stands where Douglas-fir was the dominant or co-dominant vegetation type, and with greater amounts of hardwoods. Klug (1997) found no relation between fisher occurrence and stand age or old-growth habitats; however there was less than 2 percent old-growth on his study area. The mean canopy cover for all stations Klug sampled was 94.7 percent, and mean stand age was 42.6 years, an age which, in productive lowland redwood and Douglas-fir habitats, often correlates with large-tree conditions. During subsequent studies in this area (Ewald, pers. comm. 2003), 24 individual fisher were captured (10 males, 14 females). Nine of 11 adult females showed signs of reproduction, and 9 natal and maternal dens were located. In their adjacent study area in Redwood National and State Parks with coastal forests dominated by redwood, Slauson *et al.* (2003) found that redwood was the dominant overstory and understory species where fishers were detected; Douglas-fir was dominant at sites where they were not. This study area had 38 percent old-growth habitat; however, fisher were detected more often in second-growth redwood stands. In contrast to forests further north and further inland, the milder temperature and higher humidity in these coastal areas may create suitable habitat conditions, at least for foraging, in younger forests.

**Fragmentation**

A number of studies have shown that the fisher avoids areas with little forest cover or significant human disturbance and conversely prefers large areas of contiguous interior forest (Coulter 1966; Kelly 1977; Buck 1982; Mullis 1985; Rosenberg and Raphael 1986; Arthur *et al.* 1989a; Powell 1993; Jones and Garton 1994; Seglund 1995; Dark 1997).

Rosenberg and Raphael (1986) assessed forest fragmentation in northwestern California and its effect on fishers. Their study shows a significant positive association with a plot's distance to a clearcut, and significant negative associations with a stand's length of edge, degree of insulation (defined as "the percentage of its perimeter that was clearcut edge''), percent clearcut, and total edge. Rosenberg and Raphael (1986) state, "Among the species suspected of being most sensitive to forest fragmentation in our study, only the fisher and spotted owl were also associated with old-growth forests.'' They show a significant positive association between fisher presence and forest stand area, detecting fishers more frequently in stands over 247 ac (100 ha) (70 percent frequency of occurrence) and stands of 126 to 247 ac (51 to 100 ha) (90 percent frequency of occurrence) than in smaller stands; fishers were detected in 55 percent of stands that were 52 to 124 ac (21 to 50 ha), in 30 percent of stands that were 27 to 49 ac (11 to 20 ha), and in 17 percent of stands under 25 ac (10 ha).

The fisher's need for overhead cover is very well-documented. Many researchers report that fishers select stands with continuous canopy cover to provide security cover from predators (de Vos 1952; Coulter 1966; Kelly 1977; Arthur *et al.* 1989; Weir and Harestad 1997, 2003). Fishers may use forest patches with large trees because the overstory closure increases snow interception (Weir 1995a). Forested areas with higher density overhead cover provide the fisher increased protection from predation and lower the energetic costs of traveling between foraging sites. Fishers probably avoid open areas because in winter open areas have deeper, less supportive snow which inhibits travel (Leonard 1980; Raine 1983; Krohn *et al.* 1997), and because they are more vulnerable to potential predators without forest cover (Powell 1993). Furthermore, preferred prey species may be more abundant or vulnerable in areas with higher canopy closure (Buskirk and Powell 1994).

Several studies have shown that fishers are associated with riparian areas (Buck 1982; Jones 1991; Aubry and Houston 1992; Seglund 1995; Dark 1997; Zielinski *et al.* 1997c; Zielinski *et al.* in press 2003b, in press 2003a). Riparian forests are in some cases protected from logging and are generally more productive, thus having the dense canopy closure, large trees and general structural complexity associated with fisher habitat (Dark 1997). According to Seglund (1995), riparian areas are important to fishers because they provide important rest site elements, such as broken tops, snags, and coarse woody debris.

**Composition of Home Ranges**

Mazzoni (2002) measured habitat composition within the home ranges of 11 fisher in the southern Sierra Nevada. Home range areas averaged 24.8 percent

coverage by "late-successional'' (greater than 50 percent canopy cover, greater than 24 in (61 cm) diameter) conifer forest habitat (range 15.0 to 32.1 percent). The mean percent of home range area with dense (greater than 50 percent canopy cover) conifers of all sizes was 53.6 percent (range 34.9 to 76 percent). Also in the southern Sierra Nevada, Zielinski *et al.* (in press 2003a) found that home ranges of 12 fishers consisted of 12.8 percent (SD=10.9) large tree (greater than 24 in (61 cm) ) conditions. Intermediate tree size classes (12–24 in dbh), dense (greater than 60 percent) canopy closure, and Sierran Mixed Conifer forest type composed the greatest proportion of the home ranges studies (60.7, 66.3, and 40.1 percent, respectively).

In the North Coast Range of northern California, Zielinski *et al.* (in press 2003a) found that home ranges of nine fishers were dominated by mid-seral Douglas-fir and white fir (42.8 percent); home ranges included 14 percent (SD=13.36) late-successional Douglas-fir on average and 13.97 percent true fir (SD=10.23), on average.

**Resting and Denning Habitat**

Powell and Zielinski (1994) and Zielinski *et al.* (2003b) suggest that habitat suitable for resting and denning sites may be more limiting for fishers than foraging habitat. Numerous studies have documented that fishers in the western United States utilize stands with certain forest characteristics for resting and denning such as large trees and snags, coarse woody-debris, dense canopy closure and multiple-canopy layers, large diameter hardwoods, and steep slopes near water (Powell and Zielinski 1994; Seglund 1995; Dark 1997; Truex *et al.* 1998; Self and Kerns 2001; Aubry *et al.* 2002; Carroll *et al.* 1999; Mazzoni 2002; Zielinski *et al.* in press 2003b).

Rest sites have structures that provide protection from unfavorable weather and predators. Fishers also use rest sites as protected locations to consume prey following a successful foraging bout (Zielinski, pers. comm.). Re-use of rest sites is relatively low (14 percent: Zielinski *et al.* in press 2003b), indicating that habitats providing suitable resting structures need to be widely distributed throughout home ranges of fishers (Powell and Zielinski 1994; Truex *et al.* 1998), and spatially interconnected with foraging habitats.

**Rest Site—Stand Characteristics**

The most influential variables affecting rest site selection in California fisher populations include maximum tree sizes and dense canopy closure, but other features are important to rest site choice as well, such as large diameter hardwoods, large conifer snags, and steep slopes near water (Zielinski *et al.* in press 2003b). Fishers select areas as rest sites where structural features are most variable but where canopy cover is least variable, suggesting that resting fishers place a premium on continuous overhead cover but prefer resting locations that also have a diversity of sizes and types of structural elements (Zielinski *et al.* in press 2003b). Seglund (1995) found that a majority of fisher rest sites (83 percent) were further than 328 ft (100 m) from human disturbance and Dark (1997) found that fishers used and rested in areas with less habitat fragmentation and less human activity. Characteristics of forest stands containing rest sites on industrial timberlands were similar to those reported elsewhere in northern California. Fishers in Shasta County used rest sites in stands of the largest tree size classes available, with mean canopy closure of 71 percent (Self and Kerns 2001).

**Rest Site Structure Type and Size**

Rest site structures used by fishers include: cavities in live trees, snags, hollow logs, fallen trees, canopies of live trees, platforms formed by mistletoe ("witches brooms'') or large or deformed branches, and to a lesser extent stick nests, rocks, ground cavities, and slash and brush piles (Heinemeyer and Jones 1994; Higley *et al.* 1998; Mazzoni 2002; Zielinski *et al.* 2003b). Tree size, age, and structural features are important characteristics of a rest structure. Zielinski *et al.* (in press 2003b) stated that rest structures in their study areas in the North Coast and the southern Sierra Nevada were among the largest diameter trees available, averaging 46.2, 47.2, and 27.2 in (117.3, 119.8, and 69.0 cm) for live conifers, conifer snags, and hardwoods, respectively. Most rest locations in the study areas of Zielinski *et al.* (2003b) were in cavities or broken tops of standing trees. Trees must be large and old enough to bear the type of stresses that initiate cavities, and the type of ecological processes (*e.g.*, decay, woodpecker activity) that form cavities of sufficient size to be useful to fishers; tree species that typically decay to form cavities in the bole are more important than those that do not (Zielinski *et al.* 2003b). Cavities in hardwoods were the most frequently used rest structure in the southern Sierra Nevada study area where Douglas-fir is absent (37.5 percent of rest structures were in black oaks); and in the North Coast study area, Douglas-firs were the most frequently used species (65.6 percent) and black oaks were used less frequently (11.4 percent) (Zielinski *et al.* 2003b). Higley *et al.* (1998) found that fishers in their Klamath study area use live hardwood trees most frequently for resting (57.14 percent) followed by live conifer trees (26.29 percent), snags and logs (14.86 percent—hardwoods and conifers combined) and the ground (1.71 percent). On managed industrial timberlands in northwestern California, fisher resting sites (N=35) were predominantly located on dwarf mistletoe in western hemlocks, large lateral branches and mammal nests in Douglas-firs, and cavities in cedars (Simpson Resource Company 2003). The majority of 34 rest sites described by Self and Kerns (2001) were located in mistletoe brooms in live Douglas-firs, whereas only 20 percent were in snags or hardwoods.

**Natal and Maternal Dens**

Most dens are found in live trees, and there is little evidence that den sites are reused over time (Campbell *et al.* 2000). The trees must be large enough for cavities that can be used for natal and maternal dens. Of 19 tree dens documented by Truex *et al.* (1998) across three study areas in California, the average diameter was 45 in (115 cm) for conifers and 25 in (63 cm) for hardwoods. Of 16 maternal and natal dens located on managed timberlands in northwestern California, nine were in cavities in hardwoods and seven were in conifer snags: diameters of den trees ranged from 24.6 in (62.5 cm) to 116 in (295 cm) (Simpson Resource Company 2003). According to Lewis and Stinson (1998), natal dens are most commonly found in tree cavities at heights of greater than 20 ft (6 m), while maternal dens may be in cavities closer to the ground so active kits can avoid injury in the event of a fall from the den. The mean height of natal and maternal dens found in British Columbia was 99 ft (26 m) above ground (Weir and Harestad 2003). The height of these dens may help prevent predation by the larger male fishers or by other species.

**Foraging Habitats**

Fishers in the Pacific States appear to be dietary generalists, and therefore, they may be flexible in their requirements for foraging habitat. Selection of foraging habitat may be driven by habitat relationships of primary prey species.

Several studies have characterized foraging habitat which, similar to resting habitat, is often typified by characteristics associated with mature and late-successional forests (Jones and Garton 1994; Zielinski *et al.* 1997c).

However, fishers have been found to use a broader range of successional stages for hunting than for resting (Jones 1991; Heinemeyer 1993; Jones and Garton 1994). Jones (1991) found that younger-aged forests appeared suitable for hunting but were rarely used for summer resting; more structurally complex forests seemed to have been preferred for both activities, but simpler stand structures were used for hunting. In their use of younger forests, fishers in Idaho still appeared to select localities with higher availability of large-diameter trees, snags, and logs (trees over 18 in (47 cm) diameter, snags over 20 in (52 cm) diameter, and logs over 18 in (47 cm)) relative to randomly-located plots in the home range (Jones 1991).

Complex down woody material including large down logs, and multi-layered vegetative cover are important habitat elements for fishers. Fishers are often detected at sites with higher amounts of downed logs than at random sites (Klug 1997; Slauson *et al.* 2003), and high volumes of coarse woody debris and structural complexity near the forest floor (Weir and Harestad 2003), at least in part because high structural diversity is associated with prey species richness and abundance (Slauson *et al.* 2003) and greater prey vulnerability to capture (Buskirk and Powell 1994). Shrubs also provide food for prey and for fishers in the form of fruits and berries. Slauson *et al.* (2003) found that sites in their study area where fishers were detected had higher shrub cover (40–60 percent) than sites where they were not detected. Fishers may also avoid areas with too much low shrub cover because it may adversely affect the hunting success of fishers (Weir and Harestad 2003).

**Conclusion**

The key aspects of fisher habitat are best expressed in forest stands with late-successional characteristics. Fishers use habitat with high canopy closure, large trees and snags, large woody debris, large hardwoods, multiple canopy layers, and avoidance of areas lacking overhead canopy cover (Aubry and Houston 1992; Buskirk and Powell 1994; Buck *et al.* 1994; Seglund 1995; Klug 1996; Dark 1997; Truex *et al.* 1998; Mazzoni 2002; Weir and Harestad 2003; Zielinski *et al.* in press 2003b, in press 2003a). Fisher also occupy and reproduce in some managed forest landscapes and forest stands not classified as late-successional that provide some of the habitat elements important to fisher, such as relatively large trees, high canopy closure, large legacy trees, and large woody debris, in second-growth forest stands (Klug 1997; Simpson Resource Company 2003). However, intensive management for fiber production on industrial timberlands does not typically provide for retention of these elements. It is unlikely that early and mid-successional forests, especially those that have resulted from timber harvest, will provide the same prey resources, rest sites and den sites as more mature forests (Zielinski and Powell 1994).

Late-successional coniferous or mixed forests provide the most suitable fisher habitat because they provide abundant potential den sites and preferred prey species (Allen 1987). Forest structure of good quality fisher habitat should provide high diversity of dense prey populations, high vulnerability of prey to fishers, and natal and maternal dens and resting sites (Powell and Zielinski 1994). Younger forests in which complex forest structural components such as large logs, snags, and tree cavities are maintained in significant numbers, and which provide a diverse prey base, may be suitable for fisher (Lewis and Stinson 1998).

**Distinct Population Segment**

In a 12-month finding, we must determine if (1) the petitioned action is warranted, in which case we would promptly publish a proposed rule to list the species; (2) the petitioned action is not warranted; or (3) the petitioned action is warranted but precluded by other higher priority listing activities. Under the Act, a species is defined as including any subspecies and any distinct population segment of a vertebrate species. To implement the measures prescribed by the Act and its Congressional guidance, we and the National Marine Fisheries Service (National Oceanic and Atmospheric Administration—Fisheries), developed a joint policy that addresses the recognition of DPSs of vertebrate species for potential listing actions (61 FR 4722). The policy allows for a more refined application of the Act that better reflects the biological needs of the taxon being considered, and avoids the inclusion of entities that do not require its protective measures. The DPS policy specifies that we are to use three elements to assess whether a population segment under consideration for listing may be recognized as a DPS: (1) the population segment's discreteness from the remainder of the species to which it belongs and (2) the significance of the population segment to the species to which it belongs. Our evaluation of significance is made in light of Congressional guidance that the authority to list DPSs be used "sparingly" while encouraging the conservation of genetic diversity. If we determine that a population segment meets the discreteness and significance standards, then the level of threat to that population segment is evaluated based on the five listing factors established by the Act to determine whether listing the DPS as either threatened or endangered is warranted.

Below, we address under our DPS policy the population segment of the fisher that occurs in the western United States in Washington, Oregon and California. The area for this DPS includes the Cascade Mountains and all areas west, to the coast in Oregon and Washington; and in California, the North Coast from Mendocino County north to Oregon, east across the Klamath (Siskiyou, Trinity, and Marble) Mountains, across the southern Cascade Mountains and south through the Sierra Nevada Mountains. The mountainous areas east of the Okanogan River in Washington and the Blue Mountains west to the Ochoco National Forest in eastern Oregon are not included in this DPS due to their geographical isolation from the remainder of the DPS.

**Discreteness**

Under our DPS policy, a population segment of a vertebrate species may be considered discrete if it satisfies either one of the following two conditions: (1) it is markedly separated from other populations of the same taxon as a consequence of physical, physiological, ecological, or behavioral factors (quantitative measures of genetic or morphological discontinuity may provide evidence of this separation); or (2) it is delimited by international governmental boundaries within which differences in control of exploitation, management of habitat, conservation status, or regulatory mechanisms exist that are significant with regard to conservation of the taxon in light of section 4(a)(1)(D) of the Act.

The proposed DPS is markedly separated from other fisher populations as a result of several factors. Native populations of the fisher in California and the reintroduced population in the southern Cascade Mountains of Oregon are physically isolated from the Canadian populations by over 200 miles (Weir 2003), given the northward contraction of the British Columbia population (Weir 2003) in Canada. Substantial information is available indicating the West Coast population is also physically separated from known populations of the fisher to the east.

The range of the fisher in Washington, Oregon, and California is separated from the Rocky Mountains and the rest of the taxon in the central and eastern United

States by natural physical barriers including the non-forested high desert areas of the Great Basin in Nevada and eastern Oregon, and the Okanogan Valley in eastern Washington. At its extreme northern (unoccupied) extent in northern Washington, the DPS is separated from the western extension of the Rocky Mountains and associated ranges by the Okanogan Valley, a distance of approximately 93 to 124 mi (150 to 200 km), which is well beyond the dispersal range for the species. Other physical barriers that separate the West Coast population from Rocky Mountain and eastern U.S. fisher populations include major highways, urban and rural open-canopied areas, agricultural development, and other nonforested areas. Fishers have a strong aversion to areas lacking in forest cover or to crossing large rivers that do not freeze in the winter (Powell 1993; Powell and Zielinski 1994; Aubry and Lewis 2003); these behavioral factors, along with the other numerous barriers identified above, represent a significant impediment to eastward or westward movement for the fisher.

We currently have limited information on dispersal distances of fishers in the western United States. However, studies conducted on fisher dispersal in the northeastern United States indicate that dispersal distances are relatively short (Arthur *et al.* 1993; York 1996). There is no evidence that fishers are successfully dispersing outside of known population areas in California and Oregon. This is possibly due to the extent of habitat fragmentation, developed or disturbed landscapes, and highways and interstate corridors (see dispersal section above).

Genetic information (Drew *et al.* 2003) indicates that the West Coast population of fisher originally colonized the Pacific states from British Columbia. The current range of fisher in British Columbia has been reduced and connection to fisher populations in the continental United States no longer exists (Weir 2003, BC Species and Ecosystems Explorer 2003). The fisher's present range in British Columbia has contracted northward from the international boundary by about 200 kilometers. (Weir 2003). Movement of fisher from British Columbia southward to areas occupied by the West Coast population is not possible based on lack of available habitat, habitat preferences, and dispersal behavior of the fisher.

The West Coast population also appears to be separated from other populations as a result of ecological factors, as they use forest types that differ in species composition, tree size, and habitat structure as compared to those used by fishers in other populations. The fisher is regarded as a habitat specialist in the western United States (Buskirk and Powell 1994), occurring only at mid to lower elevation in mature conifer and mixed conifer/hardwood forests characterized by dense canopies and abundant large trees, snags, and logs (Powell and Zielinski 1994). In contrast, fishers in the northeastern United States and the Great Lakes region inhabit areas with a large component of deciduous hardwood forest containing American beech (*Fagus grandifolia*), sugar maple (*Acer saccharum*), and other broadleaf species (Powell and Zielinski 1994). The majority of conifer forest habitat in Canada is characterized as boreal forest, which is different from the relatively dryer environmental conditions associated with Washington, Oregon, and California. In the Rocky Mountains of north central Idaho, certain all-conifer habitat types which include grand fir and Engelmann spruce appear to be important to, and preferentially selected by fishers (Jones 1991).

With regard to physiological differences, the fishers in the native northern California population are significantly smaller in size (based on condylobasal length) than fishers from western and central Canada (Hagmeier 1959; Zielinski *et al.* 1995; Aubry and Lewis 2003.

The West Coast population of the fisher is also delimited to the north by the international governmental boundary between the United States and Canada because of differences in control of exploitation, management of habitat, conservation status, and regulatory mechanisms that may be significant with respect to section 4(a)(1)(D) of the Act. Canada has no overarching forest practices laws governing management of its national lands. In contrast, lands within the National Forest System in the United States are considered under the National Forest Management Act of 1976, as amended (16 U.S.C. 1600), and associated planning regulations. The fisher is covered by British Columbia's Wildlife Act which protects virtually all vertebrate animals from direct harm, except as allowed by regulation (*e.g.*, hunting or trapping). The fisher is designated as a Class 2 furbearer in British Columbia and, as such, can be legally harvested by licensed trappers under regional regulations. However, the fisher was reclassified to the Red List in British Columbia in 2003 with a provincial conservation ranking of "S2,'' as assigned by the British Columbia Conservation Data Centre to "score'' the risk of extinction or extirpation (BC Species and Ecosystems Explorer 2003). The Red List designation means that the species is considered imperiled at the provincial level. The change in the fisher designation was the result of an estimated provincial population of fewer than 3,000 individuals and habitat loss due to logging, hydro-electric development and other land use changes (BC Species and Ecosystems Explorer 2003). Although the change in Red List designation for the fisher in British Columbia carries no legal implications, trapping seasons for it have been closed until new information is collected that indicates the population is secure (BC Ministry of Land, Water, and Air Protection 2003). Beyond this voluntary closure of the trapping season, the fisher carries no protected status in British Columbia. Trapping the species has been prohibited for decades in Washington, Oregon, and California (Lewis and Stinson 1998). For the reasons stated above, we believe that these factors collectively play a role in delimiting the northern DPS boundary along the international border with Canada from the Cascade Mountains west to the Pacific Ocean.

Based on the available information on fisher range and distribution, we conclude that the West Coast population of fisher is distinct and separate from other fisher populations in the United States and meets the requirements of our DPS policy for discreteness. The West Coast population of fisher is separated from fisher populations to the east by geographical barriers and to the north by habitat availability; it is further delineated by the international boundary with Canada, within which there are differences in control of exploitation, conservation status, and regulatory mechanisms that are significant to its conservation.

**Significance to the Species**

Under our DPS policy, once we have determined that a population segment is discrete, we consider its biological and ecological significance to the larger taxon to which it belongs. This consideration may include, but is not limited to, the following factors: (1) Persistence of the discrete population segment in an ecological setting unusual or unique for the taxon; (2) evidence that loss of the discrete population segment would result in a significant gap in the range of the taxon; (3) evidence that the population segment represents the only surviving natural occurrence of a taxon that may be more abundant elsewhere as an introduced population outside its historical range; and (4) evidence that the discrete population segment differs markedly

from other populations of the species in its genetic characteristics. Significance is not determined by a quantitative analysis, but instead by a qualitative finding. We have found substantial evidence that the West Coast DPS of the fisher meets two of the significance factors and is supported by a third significance factor, and we have described them below.

Fishers in the West Coast population persist in an ecological setting that is unusual in comparison to the rest of the taxon, with a different climate, topography, and habitat than that found in the majority of its range. The forests inhabited by fishers on the west coast lack the extensive broadleaf hardwood component that is common in the eastern portions of the species' range. The Pacific coast's wet winter followed by a dry summer is unique in comparison to climate types in the east and Canada, and produces distinctive sclerophyll forests of hardleaved evergreen trees and shrubs (Smith *et al.* 2001). This climate is characterized by mild, wet winters and warm, dry summers (Bailey 1995), while the climate in the animal's range in the Rocky Mountains consists of cold winters and cool, dry summers, and in the Great Lake States, eastern Canada, and the northeast United States it is characterized by cold winters, and warm, wet summers. Fishers on the west coast primarily occur in habitat in steep, mountainous terrain, while those in the Great Lakes region, eastern Canada, and the northeastern United States inhabit level terrain or low lying glaciated mountains. Releases of eastern fishers into western forests have generally been unsuccessful; Powell and Zielinski (1994) state that, "Roy's (1991) results [unsuccessful attempts to reintroduce Minnesota fishers to Montana] indicate that many fishers from eastern North America may lack behaviors, and perhaps genetic background, to survive in western ecological settings.'' The repeated introductions of fishers from British Columbia and Minnesota to the southern Cascade Mountains of Oregon (from 1960s to 1980s) have resulted in an apparently stable, but small population there; however, the species is not expanding and dispersing from the areas into which it was introduced.

The loss of the West Coast DPS of the fisher would eliminate the entire southwest portion of the fisher's North American range. Additionally, the West Coast DPS of the fisher represents the southernmost range of the *Martes* genus. The West Coast populations represent three of the known remaining four populations in the western United States (fourth being the Rocky Mountain population), and a significant portion of the western range of fishers in North America. Based on figures from Weir (2003), the total range of the fisher in North America has been reduced approximately 33 percent in geographical area since the 1600s. This reduction is most apparent in the fishers southern and western range—largely in the United States. Based on our review of Lewis and Stinson's (1998) maps (modified from Gibilisco 1994), these are three of only six or seven remaining areas occupied by fishers in the United States. Although these maps consider a large area of Canada to be within the 1994 range of the fisher, distribution has diminished in some areas of southeastern Ontario and Quebec, in the prairie provinces (Alberta, Saskatchewan, and Manitoba), and in the western United States (Gibilisco 1994); and because of the lack of inventories for the species in Canada, it is not known to what extent the range in Canada is occupied. Additionally, the populations in the southern Sierra Nevada and northern California/southern Oregon appear to be the only native populations of the fisher remaining in the west (Truex *et al.* 1998; Aubry *et al.* in press 2003; Drew *et al.* 2003), and are "the only populations that have not been augmented with individuals (and genes) from other regions'' (Zielinski *et al.* 2003b).

As stated earlier (see distribution section), the extent of area known to be currently occupied by fishers in Washington, Oregon, and California is roughly 20 percent of their historical extent in these States. The loss of the species from the United States west of the Rocky Mountains and south of British Columbia would result in a significant gap in the range of the species as a whole and represent the loss of a major geographical area of the range of the taxon. It would represent a loss of the species from about 20 percent of its historical range in the United States, a significant portion of its North American range, recognizing that the historical range was not continuously occupied spatially or temporally, and that the present range we identify is also not occupied continuously nor is all of the historical habitat still available, especially in the midwest and east.

The extinction of fishers in their west coast range would also result in the loss of a significant genetic entity, since they have been described as being genetically distinct from fishers in the remainder of North America. More specifically, native fishers in California have reduced genetic diversity compared to other populations (Drew *et al.* 2003). Additionally, the extant native populations in California share one haplotype that is not found in any other populations (Drew *et al.* 2003).

Quantitative measures of genetic discontinuity indicate that there is no naturally occurring genetic interchange with the California fisher populations. Based on genetic evidence, and supported by paleontological and archeological evidence, Wisely *et al.* (in litt. 2003) theorize that fishers probably colonized the Pacific peninsula from the north, not the east. The fisher was once distributed throughout much of the dense coniferous forests in British Columbia, Washington, Oregon, and California (Drew *et al.* 2003). This historical connectivity among populations along the Pacific Coast is evidenced by the presence of British Columbia haplotypes in museum specimens from California and Washington (Drew *et al.* 2003). The historical continuity in fisher distribution no longer exists, as discussed above. Genetic variation shows the Oregon southern Cascade population is a reintroduced population descended from fishers translocated to Oregon from British Columbia and Minnesota (Drew *et al.* 2003). There is evidence that there has been no genetic interchange between the native northern California/southwestern Oregon Siskiyou population and the reintroduced southern Cascade Oregon population (Aubry *et al.* in press 2003).

**Conclusion**

We have evaluated as a DPS the population of fishers in the West Coast range and have addressed the elements our policy requires us to consider in deciding whether a vertebrate population may be recognized as a DPS and considered for listing under the Act. In assessing the population segment's discreteness from the remainder of the taxon, we have described the factors separating it from other populations. We considered distributional, ecological, behavioral, morphological, and genetic information, information from status surveys, and geographical and biogeographical patterns, and have concluded that this population segment is discrete under our DPS policy. In assessing the population segment's significance to the taxon to which it belongs, we have considered the geographical area represented by the western DPS, its genetic distinctness from fisher populations in the central and eastern United States, its unique ecological setting, and other considerations and factors as they relate to the species as a whole. We conclude that loss of the species from the west

coast range in the United States would represent (1) a significant gap in the species' range, (2) the loss of genetic differences from fisher in the central and eastern United States, and (3) the loss of the species from a unique ecological setting. Therefore, as the population segment meets both the discreteness and significance criteria of our DPS policy, it qualifies as an entity that may be considered for listing. We now evaluate its status as endangered or threatened. In making this determination, we evaluate the factors enumerated in section 4(a)(1) of the Act (16 U.S.C. 1533 (a)(1)).

**Summary of Factors Affecting the Species**

Section 4 of the Act (16 U.S.C. 1533), and implementing regulations at 50 CFR 424, set forth procedures for adding species to the Federal endangered and threatened species list. In making this finding, information regarding the status and threats to this species in relation to the five factors in section 4 of the Act is summarized below.

*Factor A. The Present or Threatened Destruction, Modification, or Curtailment of the Species' Habitat or Range.* Vegetation management activities such as timber harvest and fuels reduction treatments, stand-replacing fire, large-scale forest disease outbreaks or insect infestations (*e.g.*, pine beetle), and development can destroy, alter, or fragment forest habitat suitable for fishers.

*Timber Harvest*

The extent of past timber harvest is one of the primary causes of fisher decline across the United States (Powell 1993), and may be one of the main reasons fishers have not recovered in Washington, Oregon, and portions of California as compared to the northeastern United States (Aubry and Houston 1992; Powell and Zielinski 1994; Lewis and Stinson 1998; Truex *et al.* 1998). Timber harvest can fragment fisher habitat, reduce it in size, or change the forest structure to be unsuitable for fishers.

Habitat fragmentation has contributed to the decline of fisher populations because they have limited dispersal distances and are reluctant to cross open areas to recolonize historical habitat. Based on northeastern fisher home range sizes, Allen (1983) estimated that a minimum of 161 $km^2$ (39,780 ac) of potentially suitable and contiguous habitat must be present before an area can sustain a population of fishers. However, fisher populations in western forests may need even larger areas because male home ranges in northern California have been reported to be as large as 128 $km^2$ (Beyer and Golightly 1996). A habitat suitability model developed in British Columbia figures that a minimum of 259 $km^5$ of contiguous habitat is required for fisher transplant attempts (Apps 1996 as cited in Craighead *et al.* 1999).

Fishers use large areas of primarily coniferous forests with fairly dense canopies and large trees, snags, and down logs; vegetated understory and large woody debris appear important for their prey species. Fishers in the Pacific Northwest use late-successional forest more frequently than the early to mid-successional forests that result from timber harvest (Aubry and Houston 1992; Buck *et al.* 1994; Rosenberg and Raphael 1986). Elimination of late-successional forest from large portions of the Sierra Nevada and Pacific Northwest (Morrison *et al.* 1991; Aubry and Houston 1992; McKelvey and Johnston 1992; Franklin and Fites-Kauffman 1996) has probably significantly diminished the fisher's historical range on the west coast (Lewis and Stinson 1998).

Several studies have found sharp declines in late-successional/old-growth forests (Beardsley *et al.* 1999, Bolsinger and Waddell 1993, the Report of the Forest Ecosystem Management Assessment Team (FEMAT) 1993, Franklin and Fites-Kaufmann 1996, Morrison *et al.* 1991, Service 1990). Old growth comprised about 50 percent of the forests of Washington, Oregon, and California in the 1930s and 1940s, but made up less than 20 percent of those forests in 1992 (about 10.3 million ac; 41,683 $km^2$) (Bolsinger and Waddell 1993).

Franklin and Fites-Kaufman (1996) find that forests with high late successional/old-growth structural rankings are now uncommon in the Sierra Nevada of California (8 percent of mapped area). Mixed conifer forests are a particularly poorly represented forest type as a result of past timber harvesting, and key structural features of late successional/old-growth forests, such as large-diameter trees, snags, and logs, are generally at low levels (Franklin and Fites-Kaufman 1996). The loss of structurally complex forest and the loss and fragmentation of suitable habitat by roads and residential development have likely played significant roles in both the loss of fishers from the central and northern Sierra Nevada and the fisher's failure to recolonize these areas (USDA Forest Service 2000).

Within the Northwest Forest Plan area, 60 to 70 percent of the forested area of the region was historically dominated by late-successional and old-growth forest conditions. Most of the forest (perhaps 80 percent) probably occurred in relatively large contiguous areas (greater than 1000 ac; 4 $km^2$) (Bolsinger and Waddell 1993, USDA Forest Service and U.S. Department of Interior Bureau of Land Management (USDI BLM) 1994a). Franklin and Spies (1986) estimated that 15 million ac (60,703 $km^2$) of old-growth forest existed west of the Cascade Mountains in Oregon and Washington in the 1800s, and only about 5 million ac (20,234 $km^2$; 33 percent) remain. FEMAT (1993) reports the status of forests in several regions: private and State lands within western Washington and western Oregon Cascades have mostly been harvested, whereas Forest Service and Bureau of Land Management lands (BLM) still include significant areas (albeit highly fragmented) of late successional/old-growth forest; the Klamath Provinces of southwestern Oregon and northwestern California have forests that are highly fragmented by timber harvest and natural factors (poor soils, dry climate, wildfires); the southern end of the Cascades Range in Oregon extending into California has forests that are highly fragmented due to harvest activities and natural factors.

The NWFP states that fisher populations are believed to have declined on Federal lands in old-growth habitat for two primary reasons: (1) Loss of habitat due to forest fragmentation resulting from clearcutting, and (2) the removal of large down coarse woody debris and snags from the cutting units (USDA Forest Service and USDI BLM 1994). Fishers in the eastern Klamath area of northern California have lower population densities, larger home ranges, lower capture rates, and a higher proportion of juveniles than other populations studied, possibly due in part to timber harvest having decreased habitat quality for the fisher in this area (Truex *et al.* 1998).

The conversion of low-elevation forests in western Washington to plantations and non-forest uses may have eliminated a large portion of the fisher habitat in the state (Powell and Zielinski 1994). There were historically many mature and old-growth stands (Aubry and Houston 1992). Over 60 percent of the 24.7 million ac (100,000 $km^2$) of forest believed to be present in Washington when white settlers first arrived were potential fisher habitat (Lewis and Stinson 1998). By 1992, the area of old-growth forest was reduced to 2.7 million ac (10,927 $km^2$) (Bolsinger and Waddell 1993). During the last 50 years, the structure, composition, and landscape context of much of

Washington's 16,803,100 ac (68,000 km$^2$) of commercial timberland has significantly changed because of intensive timber harvesting activities (Morrison 1988). Most of the remaining younger low and mid-elevation forest is fragmented and has reduced amounts of large snags and coarse woody debris, and may not be able to sustain fisher populations (Rosenberg and Raphael 1986; Lyon *et al.* 1994; Powell and Zielinski 1994). The higher elevation forests are less suitable for fishers because of deep snowpacks (Aubry and Houston 1992; FEMAT 1993).

Some forest management practices change the dominance of certain forest subtypes in western states (Lewis and Stinson 1998, Bouldin 1999). This change in forest structure is important because certain habitat types or tree species are suitable for fishers. In addition, logging and fire suppression have created higher densities of small trees which have led to higher insect and pathogen-induced mortality and the loss of structural diversity, and increased chances for stand-destroying fires (Bouldin 1999), the effects of which are discussed below.

Mazzoni (2002) found that timber harvest, fire, and succession resulted in fisher habitat fragmentation in the southern Sierra Nevada from 1958 to 1997. Rosenberg and Raphael (1986) emphasize that the fragmentation of northwestern California Douglas-fir forests is relatively recent in comparison with forests of other regions, and that the true long-term responses of species to the break-up of their habitat cannot yet be discerned.

The effects of timber harvest on fisher habitat depend on the silvicultural prescriptions used and the condition of the habitat prior to harvest. Habitat fragmentation is a concern. Clearcutting, selective logging, and thinning change the suitability of fisher habitat by removing overhead cover and insulating canopy, exposing the site to the drying effects of sun and wind (Buck *et al.* 1994) or to increased snow deposition, removing prime resting and denning trees, and increasing exposure of the fisher to predators.

*Fuels Reduction and Loss of Habitat From Fire*

Mechanical thinning or prescribed fire negatively affect fishers if it impacts habitat quality by reducing canopy cover and coarse woody debris over large areas or fragment habitat. Fuels reduction treatments, including thinning and the removal of down woody debris, dense understory, snags, and low overstory tree crowns may significantly affect fishers in the immediate area. Prescribed burning generally promotes forest health, and can enhance suitability for wildlife, but may vary in its effect on fishers. Small fires should not be detrimental to fishers because of the fishers' large home ranges (unless they impact natal dens during breeding season); however, hotter or more widespread fires may displace fishers or destroy habitat. Prescribed fire can also consume habitat structural elements such as snags and downed logs that are important to fishers.

The potential for stand-replacing wildfire has increased in areas where fire suppression has played a role in raising fuel load to levels that place late successional forest-dependent species at a higher risk of habitat loss (USDA Forest Service and USDI BLM 1994b). Stand replacing fires can impact large areas and render them unsuitable for fisher for several decades (Lewis and Stinson 1998). The combination of increased tree density and standing tree mortality (with associated increased surface/ground fuel loads) over the past century presents the greatest single threat to the integrity of Sierra Nevada forest ecosystems (McKelvey *et al.* 1996, USDA Forest Service 2000). On the other hand, while increased density of trees and woody debris ("fuel loading") increases the risk of stand-replacing fire, they may also enhance habitat for the fisher in the short term.

*Forest Disease and Insect Outbreaks*

Although large area epidemics may displace fishers if canopy cover is lost, the usual pattern of localized outbreaks and low density of insect and disease damage is probably not a great threat to fisher habitat. In some cases, the diseased trees are beneficial, providing structures conducive to resting and denning. However, timber removal and thinning prescriptions in response to outbreaks may fragment or degrade habitat in the short term in order to prevent catastrophic fire that will eliminate habitat altogether for decades (see previous discussion). In addressing outbreaks of the mountain pine beetle (*Dendroctonus ponderosae*) and other insects in British Columbia, Weir (2003) states that reduction in overhead cover may be detrimental to fishers and that wide-scale salvage operations may substantially reduce the availability and suitability of fisher habitat.

Sudden Oak Death Phytophthora affects oaks and redwoods and may affect tanoak, evergreen huckleberry, and Pacific rhododendron (*Rhododendron macrophyllum*). Four sites on Federal, private industrial, and private nonindustrial forestlands in Oregon (near Brookings) have been confirmed as having Sudden Oak Death. The outbreaks at these sites affect from less than 1 ac (0.4 ha) to approximately 8 ac (3 ha) in size. Chances of continued introductions and establishment of the disease appear high in southwestern Oregon and northwestern California because these areas have the hosts, the climatic conditions preferred by the pathogen, and many potential pathways for its movement. It is a potentially significant threat if it spreads into areas in which oaks are the primary trees used for fisher denning.

*Development, Recreation, and Roads*

Urban Development and Recreation

Forested area in the Pacific coast region decreased by about 8.5 million ac (34,400 km$^2$) between 1953 and 1997 (Smith *et al.* 2001). Alig *et al.* (2003) state that "Forest cover area [in the Pacific coast states] is projected to continue to decrease through 2050, with timberland area projected to be about 6 percent smaller in 2050 than in 1997. Forest area is projected to decline in all three subregions [Washington, Oregon, and California]. Population and income are expected to further fuel development in the region, as population is projected to increase at rates above the national average, leading to more conversion of forest to nonforest uses.''

Rural and recreational development, such as campgrounds, recreation areas, and hiking, biking, off-road vehicle and snowmobile trails, may adversely affect fishers. Recreational activities can alter wildlife behavior, cause displacement from preferred habitat, and decrease reproductive success and individual vigor (USDA Forest Service 2000). A study of fisher habitat use on the Shasta-Trinity National Forest indicates that fishers use landscapes with more contiguous, unfragmented Douglas-fir forest and less human activity (Dark 1997).

Roads

Highways and associated developments can substantially influence movement patterns of wildlife (Bier 1995). The adverse effects of roads include direct loss of habitat, displacement from noise and human activity, direct mortality, secondary loss of habitat due to the spread of human development, increased exotic species invasion, and creation of barriers to fisher dispersal. The impacts of these effects on low density carnivores like fishers are more severe than most other wildlife species due to their large home ranges, relatively low fecundity, and low natural population density

(Ruediger *et al.* 1999), and their general avoidance of non-forested habitats. Disruption of movement can contribute to a loss of available habitat (Mansergh and Scotts 1989), isolate populations, and increase the probability of local extinctions (Mader 1984). The loss of structurally complex forest (Beesley 1996) and the loss and fragmentation of suitable habitat by roads and residential development (Duane 1996) has likely played a significant role in both the loss of fishers from the central and northern Sierra Nevada and its failure to recolonize these areas.

Areas with more roads may have increased fisher mortality due to road kill (Heinemeyer and Jones 1994). Given patterns of human population growth in areas near and within fisher habitat, road development and traffic, and associated mortality, can be expected to increase. Campbell *et al.* (2000) stated that many records of fisher locations come from roadkills; for example, Yosemite National Park reported four fishers killed by automobiles between 1992 and 1998. Proulx *et al.* (1994), York (1996), and Zielinski *et al.* (1995, 1997a) all cite the risk of fishers being struck and killed by vehicles as a potential threat to populations. The potential for vehicle collisions increases with the density of open roads in suitable habitat. Vehicles caused the death of two of the 50 radio-collared fishers in a 5-year Maine study (Krohn *et al.* 1994), and three of 97 fishers in a 3-year study in Massachusetts (York 1996). Vehicle collisions could be a significant mortality factor, especially for small fisher populations. Off-highway and over-snow vehicles are used throughout the range of the fisher, and can also directly kill fishers or cause behavioral changes due to disturbance.

Vehicle traffic during the breeding season in suitable habitat may impact foraging and breeding activity. Dark (1997) found that fishers more often used areas with a greater than average density of low use roads, and may not have used areas that were dissected by moderate to high use roads. Campbell (2004) found that sample units within the central and southern Sierra Nevada region occupied by fishers were negatively associated with road density. This relationship was significant at multiple spatial scales (from 494 to 7,413 ac (2 to 30 $km^2$). In a stand-scale level study, Robitaille and Aubry (2000) found that martens, close relatives of fishers, were less active near roads. Paved roads are expected to cause more mortality than unpaved roads because of the higher use and speeds associated.

The access to forest areas provided by roads leads to increased human disturbances from resource use and extractive activities. These disturbances result in an overall degradation of habitat. Because fishers occur at relatively low elevations, they are likely to be directly affected by human activities (Campbell *et al.* 2000). Roads also provide access for trappers who target other species, but might incidentally trap fishers (Lewis and Zielinski 1996).

In conclusion, habitat loss and fragmentation appear to be significant threats to the fisher. Forested habitat in the Pacific coast region decreased by about 8.5 million ac (34,400 $km^2$) between 1953 and 1997 (Smith *et al.* 2001). Forest cover in the Pacific coast is projected to continue to decrease through 2050, with timberland area projected to be about 6 percent smaller in 2050 than in 1997 (Alig *et al.* 2003). Thus fisher habitat is projected to decline in Washington, Oregon, and California in the foreseeable future.

*Factor B. Overutilization for commercial, recreational, scientific, or educational purposes.* The fisher has been commercially trapped since the early-1800s. Although exact numbers are unknown, trapping caused a severe decline in fisher populations. Aubry and Lewis (2003) state that overtrapping appears to have been the primary initial cause of fisher population losses in southwestern Oregon. The high value of the skins, the ease of trapping fishers (Powell 1993), year-round accessibility in the low to mid-elevation coniferous forests, and the lack of trapping regulations resulted in heavy trapping pressure on fishers in the late 1800s and early 1900s (Aubry and Lewis 2003).

In 1936, the Chief of the U.S. Biological Survey urged closing the hunting/trapping season for 5 years to save fisher and other furbearers from joining the list of extinct wild animals, noting that these species had disappeared from much of their former range in Oregon, Washington, and other states (USDA 1936). Commercial trapping of fishers has been prohibited in Oregon since 1937, in California since 1946 (Aubry and Lewis 2003), and in Washington since 1933 (Lewis and Stinson 1998). Where trapping is legal in other states and in Canada, it is a significant source of mortality. Krohn *et al.* (1994), for example, found that over a 5-year period, trapping was responsible for 94 percent of all mortality for a population of the fisher in Maine. In British Columbia, the fisher is classified as a furbearing mammal that may be legally harvested; however, due to a recent change in conservation status, the trapping season has been closed until it can be determined that the populations can withstand trapping pressure.

Although it is currently not legal to trap fishers intentionally in California, Oregon and Washington, they are often incidentally captured in traps set for other species (Earle 1978; Luque 1983; Lewis and Zielinski 1996). It is legal to harvest many mammals that are found in fisher habitat, including bobcat (*Lynx rufus*), gray fox (*Urocyon cinereoargenteus*), coyote (*Canis latrans*), mink (*Mustela vison*) and other furbearers. Red fox (*Vulpes vulpes*) and marten (*Martes americana*) may also be trapped in Oregon and Washington. Incidental captures often result in crippling injury or mortality (Luque 1983; Strickland and Douglas 1984; Cole and Proulx 1994). Lewis and Zielinski (1996) estimated an incidental capture of 1 per 407 trap set-nights (number of set locations—where usually 1 or 2 leg-hold traps were set—multiplied by the number of nights when traps were set) and an average mortality-injury rate of 24 percent, based on reports from five practicing trappers in California (72 incidental fisher captures over 50,908 set-nights).

Even low rates of additive mortality from trapping have been predicted to affect fisher population stability (Powell 1979, Lewis and Stinson 1998), and may slow or negate population responses to habitat improvement (Powell and Zielinski 1994). Powell (1979) reported that as few as one to four additional mortalities per year due to trapping over a 100 $km^2$ (39 $mi^2$) area could cause a significant decline in a reduced fisher population. The potential effects on fishers of legal trapping of other species may be significant when considered in conjunction with habitat loss and other sources of mortality.

In summary, information available suggests that historical trapping caused a severe population decline, and current mortalities and injuries from incidental captures of fishers could be frequent and widespread enough to prevent local recovery of populations, or prevent the re-occupation of suitable habitat.

*Factor C. Disease or Predation.* Fishers are susceptible to many viral-borne diseases, including rabies (Family *Rhabdoviridae*), canine and feline distemper (*Mobillivirus* sp.), and plague (*Yersinia pestis*). Contact between fishers and domesticated dogs and cats and other wild animals susceptible to such diseases (raccoons, coyotes, martens, bobcats, chipmunks, squirrels, *etc.*) may lead to infection in fishers. Although specific information on fisher diseases is limited, populations of three

other mustelids, the black-footed ferret (*Mustela nigripes*), the marten, and the sea otter (*Enhydra lutris*), have experienced outbreaks of various parasitic, fungal, or bacterial diseases. An epidemic of canine distemper in black-footed ferret in 1985 led to the extirpation of the species from the wild (Thorne and Williams 1988). Evidence of plague was found in martens in California through detection of plague antibodies and host fleas (Zielinski 1984). In a study on sea otter, it was determined that infectious disease caused the deaths of 38.5 percent of the sea otters examined at the National Wildlife Health Center collected in California from 1992–1995 (Thomas and Cole 1996).

Studies in the urban-wildland interface suggest a correlation between the prevalence of disease in wild populations and contact with domestic animals, however fisher populations do not currently appear to be at risk.

Mortality from predation could be a significant threat to fishers. Potential predators include mountain lions (*Puma concolor*), bobcats, coyotes, and large raptors (Powell 1993; Powell and Zielinski 1994; Truex *et al.* 1998). Although generalist predators such as bobcats and mountain lions are not common in dense forest environments, they can invade disturbed habitat. Healthy adult fishers are apparently not usually subject to predation, except for those that have been translocated (Powell and Zielinski 1994) to an unfamiliar area, or those in areas with less canopy cover and forest structure (Buck *et al.* 1994). However, Powell and Zielinski (1994) and Truex *et al.* (1998), report that predation as well as human-caused death are significant sources of mortality. Of mortalities recorded by Truex *et al.* (1998), nine were suspected to be from predation and five were suspected to be human-caused, including two vehicle collisions, two cases where the collar was cut (indicating poaching), and one fisher that died after being trapped in a water tank. Four fishers out of seven that died during a study by Buck *et al.* (1994) were killed by other carnivores; the death of one juvenile was suspected to have been caused by another fisher.

In conclusion, mortality from disease and predation does not appear to be a significant threat unless populations are extremely small as is the case of the West Coast population of the fisher. Diseases in other mustelids affect this species and there is the potential for such disease outbreaks to occur in fisher populations.

*Factor D. The Inadequacy of Existing Regulatory Mechanisms.* Existing regulatory mechanisms that could provide some protection for the fisher include: (1) Federal laws and regulations; (2) State laws and regulations; and (3) local land use processes and ordinances. However, these regulatory mechanisms have not prevented continued habitat fragmentation and modification, incidental trapping, and predator control programs all of which result in population declines of fisher in the west. Although many States, Tribes, and Federal agencies recognize the fisher as a species which has declined substantially, their use of available regulatory mechanisms to conserve the species is limited. There are no regulatory mechanisms that specifically address the management or conservation of functional fisher habitat. However, the states in the petitioned area provide the fisher with protections from hunting and trapping, and regulatory mechanisms governing timber harvests incidentally provide conservation benefits for the fisher. The fisher is regulated under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), a treaty established to prevent international trade that may be detrimental to the survival of wild plants and animals.

*Federal Regulations*

National Forests

Federal activities on National Forest lands are subject to compliance with Federal environmental laws including the Multiple-Use Sustained-Yield Act of 1960 (16 U.S.C. 528 *et seq.*), National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), and Clean Water Act of 1972 as amended (33 U.S.C. 1251 *et seq.* 1323 *et seq.*), as well as the National Forest Management Act of 1976 (90 Stat. 2949 *et seq.*; 16 U.S.C. 1601–1614) (NFMA).

The 1982 NFMA planning rules currently in effect require the Forest Service to "maintain viable populations of existing native and desired non-native vertebrates in the planning area [National Forests System lands]'' (30 CFR 219.19). The 2000 planning rule shifted the emphasis from maintaining viable populations of individual vertebrate species to providing ecological conditions that provide a high likelihood of supporting the viability of native and desired non-native species well distributed throughout their ranges within the plan area (§ 219.20). The viable population mandate, with associated monitoring requirements, could serve as the basis for forest management consistent with maintaining fishers. The viability requirement was integral in guiding the protection and management of late successional forest through the NWFP process, and through the SNFPA amendment process; the regulatory contributions of both plans to fisher conservation is discussed below.

The Forest Service's Sensitive Species Policy (Forest Service Manual 2670.32) calls National Forests to assist and coordinate with states, the Service, and NOAA Fisheries in conserving species with viability concerns. The fisher has been identified as a sensitive species by the Region 5 (Pacific Southwest Region) Regional Forester. The Forest Service defines Sensitive Species as "those plant and animal species identified by a Regional Forester for which population viability is a concern as evidenced by significant current or predicted downward trend in numbers or density.''

On December 6, 2002, the Forest Service published a proposed rule to revise the 2000 NFMA planning rule. It is uncertain how the proposed rule, if and when implemented, will affect the interpretation of viability and the implementation of management for species viability.

National Environmental Policy Act

The National Environmental Policy Act of 1969, as amended (NEPA), requires all Federal agencies to formally document, consider, and publicly disclose the environmental impacts of major federal actions and management decisions significantly affecting the human environment. The resulting documents are primarily disclosure documents, and NEPA does not require or guide mitigation for impacts.

Projects that are covered by certain "categorical exclusions'' are exempt from NEPA biological evaluation. The Forest Service and the Department of Interior have recently revised their internal implementing procedures describing categorical exclusions under NEPA 68 FR 33813 (June 5, 2003). The joint notice of NEPA implementing procedures adds two categories of actions to the agency lists of categorical exclusions: (1) Hazardous fuels reduction activities; and (2) rehabilitation activities for lands and infrastructure impacted by fires or fire suppression. These exclusions apply only to activities meeting certain criteria: mechanical hazardous fuels reduction projects up to 1,000 ac (4 $km^2$) in size can be exempt, and hazardous fuels reduction projects using fire can be exempt if less than 4,500 ac (18.2 $km^2$). See 68 FR 33814 for other applicable criteria. Exempt post-fire

rehabilitation activities may affect up to 4,200 ac (17 $km^2$). As stated above under Factor A, fuels reduction activities can reduce key fisher habitat elements such as large down logs and woody debris, large snags, but have counter-balancing benefits of reducing fire probability and brushy undergrowth which is not favored by fishers.

On July 29, 2003, the Forest Service published a notice of final interim directive (68 FR 44597) that adds three categories of small timber harvesting actions to the Forest Service's list of NEPA categorical exclusions: (1) The harvest of up to 70 ac (28 ha) of live trees with no more than 0.5 mi (.8 km) of temporary road construction; (2) the salvage of dead and/or dying trees not to exceed 250 ac (101 ha) with no more than 0.5 mi (.8 km) of temporary road construction; and (3) felling and removal of any trees necessary to control the spread of insects and disease on not more than 250 ac (101 ha) with no more than 0.5 mi (.8 km) of temporary road construction. Again, as stated above under Factor A, timber harvest and road construction can reduce key habitat elements for the fisher such as dense canopy cover and large trees, and results in at least temporary habitat fragmentation, but have corresponding long-term benefits.

Northwest Forest Plan

The NWFP was adopted in 1994 to guide the management of 24 million ac (97,125 $km^2$) of Federal lands in portions of western Washington, Oregon, and northwestern California. The NWFP represents a 100-year strategy intended to provide the basis for conservation of the northern spotted owl (spotted owl) and other late-successional and old-growth forest-associated species on Federal lands (USDA *et al.* 1993).

Implementation of the NWFP (November 2003) would over time provide a network of connected reserves of late successional forest habitat surrounded by younger forest. Implementation of the plan will lead to a substantial improvement in current habitat conditions for the fisher on Federal lands. However, the assessment of NWFP implementation on the fisher projected a 63 percent likelihood of achieving an outcome in which habitat is of sufficient quality, distribution, and abundance to allow the fisher population to stabilize and be well distributed across Federal lands. We will need to reassess this prediction as the NWFP is implemented and other fisher conservation efforts (*e.g.*, reintroductions) are initiated.

Sierra Nevada Forest Plan Amendment (SNFPA)

The SNFPA was adopted in January 2001 as a guidance and policy document for managing 11 national forests and about 11 million ac (44,516 $km^2$) of California's National Forest lands in the Sierra Nevada and Modoc Plateau. The SNFPA includes measures expected to lead to an increase over time of late-successional forest; these measures include requirements to retain conifers greater than 30 in (76.2 cm) DBH and hardwoods greater than 12 in (30.5 cm) DBH in westside forests, retention of important wildlife structures such as large diameter snags and coarse downed wood, and management of about 40 percent of the plan area as old forest emphasis areas (USDA Forest Service 2001). The SNFPA also established a Southern Sierra Fisher Conservation Area with additional requirements intended to maintain and expand the fisher population of the southern Sierra Nevada. Conservation measures for the fisher conservation area include maintaining at least 60 percent of each watershed in mid-to-late successional forest (11 to 24 in (28 to 61 cm) dbh and greater) with forest canopy closure of 50 percent or more. The plan also includes protections for den sites; as discussed elsewhere in this document, this tends to provide limited conservation value. Implementation of the 2001 plan was expected to maintain and restore fisher habitat in Southern Sierra Fisher Conservation Area, and encourage recovery to its historic range (USDA Forest Service 2001).

In response to appeals to the adoption of the SNFPA, the Regional Forester assembled a review team to evaluate specific plan elements, including the fuels treatment strategy, consistency with the National Fire Plan, and agreement with the Herger-Feinstein Quincy Library Group Recovery Act. The review was completed in March 2003 (USDA Forest Service 2003b), and in June 2003, the Forest Service issued a Draft Supplemental Environmental Impact Statement (DSEIS) for proposed changes to the SNFPA (USDA Forest Service 2003a). The Final Supplemental Environmental Impact Statement (FSEIS) was issued in January 2004, and the new Record of Decision was issued on January 21, 2004 (USDA Forest Service 2004).

The preferred alternative in the FSEIS, Alternative S2, was chosen in the final Record of Decision. This alternative includes an objective to retain 30 in (76.2 cm) and larger trees (with exceptions allowed to meet needs for equipment operability) and a desired condition for the Southern Sierra Conservation Area which states that outside of any Wildland Urban Interface areas, a minimum of 50 percent of the forested area has at least 60 percent canopy cover for known or estimated female fisher home ranges (USDA Forest Service 2004, Record of Decision p. 41). Furthermore, it directs that where home range information is lacking, the watershed mapped at the Hydrologic Unit Code 6 level be used as the analysis area for this desired condition. The Record of Decision also states that if fishers are detected outside of the Southern Fisher Conservation Area, habitat conditions should be evaluated and appropriate mitigation measures implemented to retain suitable habitat within the estimated home range.

The FSEIS preferred alternative includes standards and guidelines which apply to fishers and provide protections for verified fisher den sites, including a 700 ac (2.8 $km^2$) buffer around confirmed fisher birthing and rearing dens during March 1 through June 30. However, the guidelines would provide little protection to fishers or their habitat, because: (1) Den sites are difficult to detect even in studies using radio-collared fishers (fewer than 10 den sites have been found to date) and project-level surveys are unlikely to locate dens (USDA Forest Service 2000); (2) there is little evidence that den sites are reused over time (Campbell *et al.* 2000), limiting the value of protecting past den sites; (3) some restrictions can be waived, including the limited operating period for vegetation treatments; and (4) it is unclear how and to what extent the impacts of roads, off highway vehicles, and recreation would be minimized.

National Forest Land and Resource Management Plans

Each National Forest is operated under a Land and Resource Management Plan (LRMP). The NWFP standards and guidelines apply for National Forests within the range of the northern spotted owl except when the standards and guidelines of LRMPs are more restrictive or provide greater benefits to late-successional forest species. Most National Forests within the range of the fisher in its west coast range have LRMPs that incorporate the provisions of the NWFP or are amended by the SNFPA, and therefore implement the standards and guidelines of the applicable plan. Most individual Forest LRMPs do not provide any additional protections to fisher or fisher habitat; therefore, the above discussion regarding the NWFP and SNFPA

summarizes the primary regulatory mechanisms in place on National Forest lands within the DPS area.

In California, the Humboldt-Toiyabe, Modoc, Lassen, Plumas, Tahoe, Eldorado, Stanislaus, Sierra, Inyo, and Sequoia National Forests and the Lake Tahoe Basin Management Unit are within the area covered by the SNFPA.

In Oregon, National Forests located on the west side of the Cascade Mountains (Mt. Hood, Willamette, Umpqua, Rogue, Siuslaw, Siskiyou National Forests) are within the boundaries of the NWFP.

Forests on the east side of the Cascade Mountains (Winema, Deschutes, Fremont National Forests) only partially overlap the NWFP area. Outside of the NWFP boundaries, the Inland Native Fish Strategy (INFISH) and Interim Management Direction Establishing Riparian, Ecosystem, and Wildlife Standards for Timber Sales (Eastside Screens) amend the LRMPs for the eastern portion of the Winema National Forest and all of the Fremont National Forest. The guidelines, developed to protect fish habitat, may also provide benefits to fisher by protecting riparian corridors; establishing large woody debris requirements (greater than 20 pieces per mi (12.4 pieces per km); greater than 12 in (30.5 cm) diameter; greater than 35 ft (10.7 m) long); and delineating Riparian Habitat Conservation Areas (RHCAs), which would prohibit timber harvests within them in most situations. Minimum widths for RHCAs range from a minimum of 300 ft (91 m) slope distance on either side of fish-bearing streams to 150 ft (46 m) on either side of perennial non-fish-bearing streams and around most lakes, ponds, reservoirs and wetlands. Seasonally flowing or intermittent streams, wetlands less than an acre, landslides, and landslide-prone areas would have protections ranging from about 50 to 100 ft (15 m to 30 m) or one site-potential tree height, depending on watershed priority.

The Eastside Screens provide interim direction for timber harvest associated with forest health and prohibit the harvest of large diameter trees (21 in (53 cm) DBH or larger) and protect snags and large woody debris for wildlife. Both INFISH and the Eastside Screens were expected to be short-term strategies to be replaced once LRMPs are amended by other guidance, such as the Interior Columbia Basin Ecosystem Management Project (ICBEMP).

At this time, a decision notice for ICBEMP has not been issued, although a Memorandum of Understanding (MOU) has been signed which implements the associated Interior Columbia Basin Strategy (Strategy). The purpose of the MOU is to cooperatively implement the Interior Columbia Basin Strategy guiding the amendment and revision of Forest Service National Forest and BLM LRMPs and project implementation on public lands. The plans and MOU currently being implemented could maintain or enhance fisher habitat by preventing the loss of old-growth forests and promoting long-term sustainability of old forest habitat, although short-term adverse impacts may occur as a result of activities including thinning and silvicultural treatments. Maintaining wildlife movement corridors primarily associated with deer and elk are usually included as part of project designs and may also benefit fishers.

Potential fisher habitat in Washington State is located on the Olympic, Mount Baker-Snoqualmie, Gifford Pinchot, Wenatchee, and Okanogan National Forests. There are approximately 1,479,749 ac (5,987 km$^2$) of fisher habitat on Federal lands in Washington State, of which 1,108,994 ac (4,489 km$^2$; 75 percent) are in National Forests and the remainder is in National Parks.

Most of the potential fisher habitat in Washington State is within the range of the northern spotted owl and thus also within the NWFP Area. Over 80 percent of the habitat is in areas that are designated as reserves (Congressionally withdrawn, LSRs, or natural areas). Logging within these areas is restricted and limited to thinning or individual tree removal. The WDFW recently conducted a feasibility analysis to determine areas for potential reintroduction of the fisher. Based on this analysis, the largest blocks of suitable habitat are located in the Olympic NF, areas around the Goat Rocks and Indian Heaven Wilderness on the Gifford Pinchot NF, portions of the Wenatchee NF east of Mount Rainier National Park, and the foothills to the west of the Alpine Lakes and Glacier Peak Wilderness Areas on the Mount Baker-Snoqualmie NF. Approximately 81 percent of the Olympic, 75 percent of the Gifford Pinchot, 63 percent of the Mount Baker-Snoqualmie, 40 percent of the Wenatchee, and 22 percent of the Okanogan National Forests are below 4000 ft (1,220 m) in elevation. Although most of the remaining fisher habitat will be protected as long as the NWFP remains in effect, the landscape remains fragmented.

Bureau of Land Management (BLM) Lands

The NWFP standards and guidelines apply to BLM lands within the range of the northern spotted owl except when the standards and guidelines of Resource Management Plans (RMPs) are more restrictive or provide greater benefits to late-successional forest species. The BLM's Alturas District in northern California is currently in the process of rewriting its RMP. However, the District has very little land with potential fisher habitat. Neither fishers nor their potential habitat are mentioned in the RMP, and the RMP is not affected by the SNFPA or NWFP. The RMPs for the Arcata, Redding, and Ukiah Field Offices also do not contain any protective measures for fisher or require pre-project surveys. In Oregon, BLM Resource Management Plans were amended by the NWFP in the west Cascades, and by INFISH and Eastside Screen interim guidance in the east Cascades. Therefore, management would be similar to that described above for the National Forests. The BLM and U.S. Timberlands (private landowner) are working together, where their land ownerships are checkerboarded, to reduce wildlife impacts by restricting access and closing roads. BLM lands are limited in Washington state and do not contribute to fisher habitat.

National Park Lands

The land management plan for Redwood National Park does not contain any protective measures for fishers and does not require pre-project surveys. Undeveloped areas of Crater Lake National Park are managed toward natural processes and are expected to maintain fisher habitat. Hunting and trapping are not allowed in the park, and park facilities are currently confined to certain areas, primarily in the higher elevations above fisher habitat. Studies are planned to evaluate snowmobile use in the park.

The Columbia River Gorge National Scenic Area in Oregon (and Washington) encompasses about 292,500 ac (1,184 km$^2$) and is operated under a land use management plan that provides protection to all lands in the gorge. About half of the land in the Gorge is state or federally owned and has special management area guidelines dedicated to scenic and natural values. The remainder of the Gorge is private lands managed under general guidelines that are currently being revised. The fisher is a protected species within the area covered by the Columbia River Gorge management plan. On Federal lands, the restriction against removal of old-growth forests and clearcut logging would protect fisher habitat. After the Gorge forest practices guidelines are revised it is expected that habitat conditions will be retained for fisher because of the priority concept of

retaining old growth, scenic, and natural values in the Gorge.

Fisher habitat occurs in the Olympic, North Cascades and Mount Rainier National Parks. However, the interiors of all three parks are classified as alpine and are too steep and rugged to be suitable for fishers. Approximately 33 percent of the 1 million ac (4,047 $km^2$) Olympic National Park, 30 percent of the North Cascades NP and Ross Lake National Recreation Area (just over 500,000 ac (2,023 $km^2$), combined), and less than 15 percent of Mount Rainier National Park (235,500 ac; 953 $km^2$) is typed as fisher habitat. The largest blocks of habitat occur in a ring around the mountainous interior of the Olympic Peninsula, in areas to the south and east of Mount Rainier National Park, in the Ross Lake National Recreation Area, and in river valleys on the west side of the North Cascades National Park.

Because the interior of the Cascades and Olympic Peninsula are alpine, fisher habitat is limited to a relatively narrow band along the foothills. In addition, most of the low elevation passes are bisected by major transportation corridors. Efforts are currently under way to provide wildlife corridors (under or overpasses) along Interstate 90 to facilitate north-south movement of wildlife through the Washington Cascades.

National Resource Conservation Service (NRCS)

The NRCS does not manage lands, and has not been involved with forest related work, but plans to develop forest-related projects in the near future. Initial projects will likely be east of the NWFP boundary, along the Sprague River in Oregon and elsewhere. Focus would be on thinning projects to enhance wildlife habitat and could enhance potential fisher habitat where it exists. The NRCS would be subject to NEPA and other existing regulatory mechanisms discussed elsewhere.

Tribal

In California, the Hoopa Valley Indian Reservation forest management plan (Tribal Forestry 1994) addresses the 88,958 ac (360 $km^2$) where fishers are known to be present, and which contains about 75,000 ac (303.5 $km^2$) of commercial timberland. The forest management plan also recognizes the fisher as a traditional and culturally important species and designates the fisher as a species of special concern, and forest management activities are not allowed to knowingly result in "take'' of species of concern unless approved by the Tribal Council. The plan contains some protective measures for fisher such as setting aside three to seven habitat reserves (each 50 ac (20 ha) or less in size) for pileated woodpeckers, mink, and fishers. Intensive timber harvest will not occur within the reserves. The plan establishes 32 no-harvest reserves (minimum of 60 ac (24 ha) each) for late-seral, cultural, sensitive, and listed species.

The Yurok Tribe manages roughly 4,000 ac (16 $km^2$) of collective Tribal land holdings, held in trust by the Department of the Interior. Tribal lands include about 1,000 ac (4 $km^2$) of late-seral redwood forest. The land management plan for the Yurok Tribe does not contain specific protective measures for fishers and does not require pre-project surveys. It is unclear to what extent this plan will help to maintain appropriate habitat elements for the fisher.

The Tule River Reservation in the southern Sierra Nevada includes about 56,000 ac (227 $km^2$) of lands, which includes forest lands managed for timber and firewood. Information is not available regarding regulatory mechanisms for these Tribal lands.

The Warm Springs Reservation of Oregon encompasses almost 1,000 $mi^2$ (2,590 $km^2$) on the western slope of the Cascade Range. The Integrated Resource Management Plan (IRMP) for forested areas of the Warm Springs Reservation of the Confederated Tribes includes guidelines that ensure buffers of 30 to 100 ft (9 to 30 m) (depending on the size of the feature) for riparian features such streams, wetlands, seeps, springs, or bogs. Standards to protect wildlife habitats and species include protection of at least four overstory trees per acre, retaining a minimum of ten class 1–3 logs per ac (12 in (30 cm)) diameter and 20 ft (6 m) long), and a 60:40 forage to cover ratio in wildlife management zones. The IRMP identifies conditional use areas that are not part of the commercial forest base although these areas could be harvested at some point in the future. These areas typically have cultural value and comprise about five percent of the Reservation. There are 14 spotted owl activity centers on the reservation.

For the Klamath Tribes in Oregon, the only activity identified that may impact the fisher is bobcat trapping. According to Rick Ward (Klamath Tribe biologist), trapping activity is currently very low due to presently low pelt prices. However, as reported in the Klamath News, an official publication of the Klamath Tribe (2003), there is a current effort to return approximately 690,000 ac (2,792 $km^2$) of the former reservation from the Fremont-Winema National Forest to the Klamath Tribes. This includes areas where fisher have been documented. If the land ownership changes, that would likely alter management of fisher habitat.

The Coquille Tribe of Oregon manages their land according to the guidelines of the NWFP. The Coquille lands were formerly managed by the BLM. When the lands were transferred from the BLM to the Tribe, the Tribe agreed to manage their lands according to the guidelines in the NWFP and the Coos Bay BLM Resource Management Plan. Their land holdings in southwest Oregon are all in NWFP "matrix'' designation (*i.e.*, areas contemplated for timber harvest) which does not provide any benefits to fisher conservation.

There are 19 Tribes with forest lands within the range of the fisher in Washington State. The majority of those Tribes do not have any suitable fisher habitat or do not have sufficient acreage. The Tribal lands of the Makah, Quinault, and Yakama Indian Nations may have suitable fisher habitat, but only the Quinault and Yakama Tribes have management plans that protect enough habitat for the northern spotted owl (a late-successional associate) that the plans likely incidentally also provide habitat for fishers.

The Confederated Tribes and Bands of the Yakama Nation reservation is located in south central Washington State, east of the Cascade crest, and contains about 526,000 ac (2,129 $km^2$) of forests. In 1998, 144,559 ac (585 $km^2$) of reservation forest were typed as suitable habitat for spotted owls (Yakama Nation 2003). Of these, about 43 percent (62,266 ac; 252 $km^2$) are currently not managed for commercial timber production, while the remaining 57 percent will receive some level of stand management. Timber harvest is generally conducted using uneven-aged management prescriptions (King *et al.* 1997), in which up to 30 percent of the volume may be removed during an entry. Based on the Tribe's forest management practices and the distribution of spotted owl habitat, Yakama lands may widely provide suitable foraging habitat for fishers, and sufficient habitat elements including snags and downed logs to provide some denning/resting habitat, particularly in the areas reserved from harvest. Owl habitat may be a rough surrogate for fisher habitat, since both require late successional forests.

The North Boundary Area of the Quinault Tribe Reservation is contiguous with Forest Service Late Successional Reserves to the north and southeast, and National Park Service lands to the east, and is the only area on the reservation that has potential

habitat for the fisher. Negotiations are currently under way with the Tribe to protect habitat around occupied owl and murrelet sites, which may incidentally protect potential fisher habitat.

*State*

Washington

The Washington Department of Natural Resources (WDNR) manages the State lands in Washington. State lands occupy a substantial portion of the fisher's historic range in the State, consisting of roughly 1.6 million ac (6,475 $km^2$) of forest within the range of the northern spotted owl (primarily lands west of the crest of the Cascade Mountains). Because these lands generally occur at lower elevations than National Forest lands, a higher proportion is within the elevation range preferred by the fisher (Aubry and Houston 1992; WDNR 1997). Thus, State lands are important to the conservation of the fisher. However, over half of all WDNR forests are less than 60 years in age and less than 150,000 ac (607 $km^2$, about 9 percent) are over 150 years, indicating that most old growth on Washington State lands has been liquidated (WDNR 1997).

Several State Parks in Washington contain remnant stands of mature and late-successional forest and may have suitable habitat for the fisher. Like elsewhere, these parks are widely scattered and isolated by large areas that are unsuitable for fishers. There are approximately 18,858 ac (76 $km^2$) of mature or old-growth forests within State Parks in Washington. Unfortunately, many of the larger parks are on islands and would not contribute to the recovery of the fisher. A few state parks and forests, such as Mount Pilchuck State Forest, and Rockport, Ollalie, Hamilton Mountain/Beacon Rock, Twin Falls, and Wallace Falls State Parks have limited habitat which may provide some foraging opportunities for dispersing fishers and extend the habitat on Federal lands in the Cascades. Trapping of fishers has been prohibited in Washington since 1933, but fishers have been caught incidentally in traps set for other species, and the impact of incidental captures in Washington is unknown (Lewis and Stinson 1998).

In October 1998, the State of Washington listed the fisher as Endangered (WAC 232–12–297), which provides additional protections in the form of more stringent fines for poaching and a process for environmental analysis of projects affecting the species. There are no special regulations to protect habitat for the fisher or to conduct surveys for this species prior to obtaining forest activity permits. Although a few individuals may still reside in remote areas, the species is believed to be extirpated from Washington and the State is currently in the process of completing a feasibility report to determine suitable areas for reintroduction.

About 7 million ac (28,330 $km^2$) of non-Federal forest lands exist within the possible range of the fisher in the Olympic Peninsula and Cascades in Washington. A geographic information system (GIS) analysis of general habitat suitability typed about 2 percent (approximately 152,300 ac (616 $km^2$)) as suitable habitat for fisher. This analysis included mature/old-growth, northern spotted owl habitat, and habitat meeting other criteria as suitable fisher habitat. Because the remnant patches of mature forest are widely scattered and isolated, it is unlikely that there is sufficient habitat on non-Federal lands to support resident fishers. However, if proposed fisher reintroduction efforts occur and are successful, private lands may be important to maintain habitat in key linkage areas across the Puget Trough lowlands to provide connectivity between the Olympic Peninsula and the Cascades.

The primary regulatory mechanism on non-Federal forest lands in western Washington is the Washington State Forest Practice Rules, Title 222 of the Washington Administrative Code. These rules apply to all commercial timber growing, harvesting, or processing activities on non-Federal lands, and give direction on how to implement the Forest Practice Act (Title 76.09 Revised Code of Washington), and Stewardship of Non-Industrial Forests and Woodlands (Title 76.13 RCW). The rules are administered by the WDNR, and related habitat assessments and surveys are coordinated with the Washington Department of Fish and Wildlife (WDFW).

Washington's forest practice rules are more protective of riparian and aquatic habitats, and require more trees to be left than Oregon's forest practice rules. Clearcuts are limited to 120 ac (49 ha) in size with exceptions given up to 240 ac (97 ha). In all cutting units, three wildlife reserve trees (over 12 in (30)) in diameter), two green recruitment trees (over 10 in (25 cm) diameter, 30 ft (9 m) in height, and ⅓ of height in live crown) and two logs (small end diameter over 12 in (30 cm), over 20 ft (6 m) in length) must be retained per acre of harvest. These trees may be counted from those left in the "riparian management zones,'' which range in size from 80 to 200 ft (25 to 62 m) for fish-bearing streams, depending on the size of the stream, the class of site characteristics, and whether the harvest activity is east or west of the Cascade crest (Washington Administrative Code 222–30). Riparian management zones for non fish-bearing streams are 50 ft (15 m), applied to specified areas along the streams. Seventy acres (28 ha) of habitat must be protected around all known spotted owl activity centers during the nesting season, outside of which logging can occur. Washington's forest practices rules do not specifically preserve key components of fisher habitat.

Riparian buffers may provide some habitat for fishers, primarily along perennial fish-bearing streams where the riparian buffer requirements are widest. In western Washington—the majority of the State area addressed by the petition, the Forest Practice Rules require 90 to 200 ft (27 to 61 m) buffers on fish-bearing streams, depending on site class (site potential for tree growth). The riparian buffer of fish-bearing streams is divided into three zones, including a 50-ft (15-m) "core zone'' where no timber cutting is permitted. The remainder of the buffer is divided into an "inner zone'' where partial harvest is permitted consistent with achieving stand basal area requirements, and an outer zone where logging must generally leave at least 20 conifers per acre, of 12 inches DBH or greater. For parcels of 20 contiguous acres or less, landowners with total parcel ownership of less than 80 forested acres are exempt from the riparian buffer requirements described above; less stringent rules apply to those parcels.

While it has been noted that the Washington State Forest Practice Rules do not specifically address the fisher and its habitat requirements, some habitat components important to the fisher, like snags, canopy cover, *etc.*, are likely to be retained as a result of the rules.

Oregon

In Oregon, two final forest management plans for state forests in northwest and southwest Oregon were approved by the Oregon Board of Forestry in January 2001: the Northwest Oregon State Forests Plan and the Southwest Oregon State Forests Plan. The Elliott State Forest Management Plan was approved in 1994 and the Elliott State Forest Habitat Conservation Plan for northern spotted owls and marbled murrelets was approved in 1995, however, both the management plan and HCP are now being revised. Additionally, Oregon has proposed to develop the Western Oregon State

Forests Habitat Conservation Plan for threatened and endangered species and other species of concern on western Oregon state forests in 2004–2005.

The management plans for Oregon's State Forests generally appear to be of little benefit to the fisher. The 18,074 ac (73 km$^2$) of State forest lands in the Southwest Oregon State Forests Plan area consists of generally small parcels that range in size from 40 ac to 3,500 ac (0.16 km$^2$ to 14 km$^2$) and are widely scattered. There are no specific measures for or mention of the fisher in the plan. The Northwest Oregon State Forests Management Plan provides management direction for 615,680 ac (2,491 km$^2$) of state forest land, located in twelve northwest Oregon counties, but has no specific provisions for fishers. Both plans include provisions to protect some forest reserves, but these are not likely to benefit the fisher because of the fragmented nature of the lands. In Oregon, the fisher is designated a protected non-game species, and is listed as a "Sensitive Species—Critical Category.'' The Oregon Department of Fish and Wildlife (ODFW) does not allow take of fisher in Oregon, but some fishers may be injured and killed by traps set for other species. Training and testing is required of applicants for trapping licenses in order to minimize the potential take of non-target species such as fisher.

The Oregon Department of Forestry (ODF) implements the Forest Practice Administrative Rules and Forest Practices Act (ODF 2000). Interim procedures (section 629–605–0180, Oregon Forest Practice Rules) exist for protecting sensitive resource sites on all State, county, and private lands in Oregon. These procedures apply only to threatened and endangered species, and to bird species listed as "sensitive'' in the rules, and currently do not apply to the fisher. Prior approval from the State Forester is also required before operating near or within critical wildlife habitat sites (629–605–0190), including habitat of species classified by ODFW as threatened or endangered, or any federally listed species, but fisher does not currently benefit from this status.

Although Oregon's rules governing forest management on State, county and private lands do not directly protect the fisher or its habitat, the rules may provide some fisher habitat elements. In clearcut harvest units that exceed 25 ac (10 ha), operations must retain two snags or two green trees, and two downed logs per acre. Green trees must be over 11 in (28 cm) DBH and 30 ft (9m) in height, and down logs must be over 6 feet long and 10 cubic feet in volume. Riparian management areas (RMAs) provide for vegetation retention along fish-bearing (Type F) and domestic-use streams without fish (Type D), in a band of 20 to 100 ft (6 to 30 m) width, depending on stream size and type. In general, RMAs for fish-bearing and domestic-use streams require no tree harvesting within 20 ft (6 m) of the stream, and, within the entire RMA, retention of a minimum basal area of conifer trees (40 trees per 1000 ft of stream for thinning operations). Along fish-bearing streams, the RMAs are intended to become similar to mature streamside stands, dominated by conifers; streams lacking fish will have sufficient streamside vegetation to support the functions and processes important to downstream fisheries, domestic water use, and wildlife habitat. Similar guidelines retain vegetation around wetlands, lakes, seeps and springs. No RMA is required for streams that do not provide for domestic water use or bear fish, for small wetlands, or for lakes 0.5 ac (.2 ha) or less.

California

The State of California manages relatively little forested lands. California has eight Demonstration State Forests totaling 71,000 ac (287 km$^2$), of which less than 20,000 ac (81 km$^2$) are within the current range of the fisher. These forests are managed primarily to achieve maximum sustained production of forest products, not for late-successional characteristics, and appear to provide little habitat for the fisher. California has about 270 State Park units and 1.3 million ac (5260 km$^2$), which are mostly outside the historic range of the fisher and appear to provide little habitat for fishers. The largest state park in the fisher's historic range, Humboldt Redwoods State Park, includes about 53,000 ac (214 km$^2$) in southern Humboldt County and has a Preliminary General Plan (June 2001) with a stated goal of protecting California species of concern. Although it does not include specific measures for fisher management, the general emphasis on retention of some habitat components (snags, canopy cover, *etc.*) will provide incidental benefits to the fisher.

The State of California classifies the fisher as a furbearing mammal that is protected from commercial harvest, which provides protection to the fisher in the form of minor fines for illegal trapping; trapping is discussed further under Factor B. The fisher is not listed under the California Endangered Species Act or as a State "fully protected'' species and thus does not receive protections available under those statutory provisions. The California Department of Fish and Game (CDFG) has identified the fisher as a Species of Special Concern (CDFG 1986). This status is applied to animals not listed under the Federal or the State endangered species acts, but judged vulnerable to extinction.

The California Environmental Quality Act (CEQA) requires disclosure of potential environmental impacts of public or private projects carried out or authorized by all non-Federal agencies in California. CEQA guidelines require a finding of significance if the project has the potential to "reduce the number or restrict the range of an endangered, rare or threatened species'' (CEQA Guidelines 15065). The lead agency can either require mitigation for unavoidable significant effects, or decide that overriding considerations make mitigation infeasible (CEQA 21002), although such overrides are rare. CEQA can provide protections for a species that, although not listed as threatened or endangered, meet one of several criteria for rarity (CEQA 15380).

Regulatory Mechanisms for Private and State Timberlands

In California, logging activities on commercial (private and State) forestlands are regulated through a process that is separate from but parallel to CEQA. Under CEQA provisions, the State has established an independent regulatory program to oversee timber management activities on commercial forestlands, under the Z'berg-Nejedly Forest Practice Act of 1973 and the California Forest Practice Rules (FPRs) (CDF 2003). The California FPRs are administered by the California Department of Forestry and Fire Protection (CDF), and apply to commercial harvesting operation for non-Federal, non-Tribal landowners of all sizes.

While the FPRs may incidentally protect some habitat or habitat elements used by the fisher, the rules do not require fisher surveys, protection of fisher or fisher den sites, or a mechanism for identifying individual or cumulative impacts to the fisher or its habitat.

The California FPRs provide specific, enforceable protections for species listed as threatened or endangered under CESA or the ESA, and for species identified by the California Board of Forestry as "sensitive species'' (CDF 2003); however, the fisher is not currently on any of these lists. The FPRs also include intent language about reducing significant impacts to non-listed species (FPR § 919.4, 939.4, 959.4) and maintaining functional wildlife habitat (FPR § 897(b)(1)), however,

implementation of these measures to provide protection to the fisher is not documented or tracked.

Some California FPR provisions could incidentally contribute to protection of important elements of fisher habitat, such as late seral forests and snags, downed wood, and large live trees containing the structural attributes that are used by fishers for resting and denning sites and contribute to the diversity and abundance of prey species. These are discussed below.

While the California FPRs generally require that snags within a logged area be retained to provide wildlife habitat, they also allow exceptions to this requirement. The FPRs do not require the retention of downed woody material, decadent or other large trees with structural features such as platforms, cavities, and basal hollows, which appear to be important components of fisher habitat. Some timber operations, such as salvage, fuelwood harvest, powerline right-of-way clearing, and fire hazard reduction are exempt from timber harvest plan preparation and submission requirements. In 2002, new rules were passed that prohibit the harvest of large old trees under exemptions, although harvest is still allowed in cases of safety, building construction, or when the tree is dead or will be dead within the year. Overall retention of habitat features important to fishers does occur to some degree but is specific to fishers.

California's FPRs provide for disclosure of impacts to late successional forest stands, in some cases. The rules require that information about late successional stands be included in a timber harvest plan when late successional stands over 20 ac (8 ha) in size are proposed for harvesting and such harvest will "significantly reduce the amount and distribution of late succession forest stands'' (FPR § 919.16, 939.16, 959.16). If the harvest is found to be "significant,'' FPR § 919.16 requires mitigation of impacts where it is feasible. In practice, such a finding during plan review can be challenged by the landowner.

The California FPRs require retention of trees within riparian buffers to maintain a minimum canopy cover, dependent on stream classification and slope. The rules currently mandate retention of large trees in watersheds identified as having "threatened or impaired'' values (watersheds with listed anadromous fish). For Class I (fish-bearing) streams, the 10 largest conifer trees per 330 ft (133 m) of stream channel must be retained along qualifying watercourses. These trees are retained within the first 50 ft (15 m) of permanent woody vegetation measured out from the stream channel; this provides about 26 trees per acre within that zone. The threatened and impaired provision applies to many streams within the fisher's range in northern California, but not to most of the Sierra Nevada nor to most of the upper Trinity River basin (where fishers still occur), and is set to expire in 3 years. Where applied, the threatened and impaired rules should result in the retention of some large trees of value to fishers, but the value may be limited, as it applies to only a small part of any affected watershed and in a fragmentary pattern. Averaged over the landscape, the measure provides on average less than one retained tree per forested acre in qualifying watersheds, based on an evaluation of a sample of timber harvest plans (Scott Osborn, CDFG, pers. comm. 2003). Over time, the retained trees may develop late seral and decadent characteristics, but this is likely to take place over time scales of decades and centuries.

Outside of "threatened and impaired'' watersheds, watercourse protection measures are limited. Class I streams must retain at least 50 percent of the overstory and 50 percent of the understory. No minimum canopy closure requirements are specified for Class II and Class III streams. Harvest plans are required to leave 50 percent of the existing total canopy including understory, and provide no protection for large trees or other late-seral habitat elements.

Regulations Providing Protections for Other Listed Species

Regulatory protections for habitat of the federally-listed northern spotted owl, marbled murrelet, and anadromous salmonids may provide some elements that benefit the fisher, but because these protections are not implemented consistent with specific life history requirements of the fisher (wide ranging, avoids open areas, *etc.*), these measures may be of limited conservation value for fishers. For example, fishers are likely to require larger habitat blocks in contiguous spacing (Lewis and Stinson 1998). Finally, a large part of the current and historic west coast range of the fisher is outside the range of the listed owl, murrelet and salmonids.

Regulatory Mechanisms for Private and State Timberlands

In California, logging activities on commercial (private and State) forestlands are regulated through a process that is separate from but parallel to CEQA. Under CEQA provisions, the State has established an independent regulatory program to oversee timber management activities on commercial forestlands, under the Z'berg-Nejedly Forest Practice Act of 1973 and the California Forest Practice Rules (FPRs) (CDF 2003). The California FPRs are administered by the California Department of Forestry and Fire Protection (CDF), and apply to commercial harvesting operation for non-Federal, non-Tribal landowners of all sizes.

Based on the best available information on fisher habitat, fishers can use areas of younger (non-old-growth) forest, but the presence of late seral elements within those forests is important in providing resting/denning sites and adding to increased foraging opportunities and prey base.

The California FPRs provide specific, enforceable protections for species listed as threatened or endangered under CESA or the ESA, and for species identified by the California Board of Forestry as "sensitive species'' (CDF 2003); however, the fisher is not currently on any of these lists. The FPRs also include intent language about reducing significant impacts to non-listed species (FPR § 919.4, 939.4, 959.4) and maintaining functional wildlife habitat (FPR § 897(b)(1)). However, this language has not been effective in securing protections for the species, due to the lack of specific enforceable measures in the rules. Moreover, FPR language (§ 1037.5(f)) makes it difficult for CDF to adopt mitigation measures above those specified in the California FPRs, unless the landowner agrees to them. In comments to CDF on timber harvest plans in northwestern California, CDFG has raised concerns regarding adverse effects on fishers and other species associated with the loss of late seral habitat elements and has recommended retention of such elements. These efforts have generally not been successful in effecting mitigation measures for the fisher and other late-seral species (Ken Moore, CDFG, Yreka, pers. comm., 2003; Scott Osborn, CDFG, pers. comm., 2003).

Some California FPR provisions could incidentally contribute to protection of important elements of fisher habitat, such as late seral forests and snags, downed wood, and large live trees containing the structural attributes that are used by fishers for resting and denning sites and contribute to the diversity and abundance of prey species. These are discussed below.

While the California FPRs generally require that all snags within a logged area be retained to provide wildlife habitat, they also allow broad

discretionary exceptions to this requirement, which greatly reduce the effectiveness of the snag retention requirement. The FPRs do not require the retention of downed woody material, making retention of these structural elements voluntary. Similarly, the California FPRs do not contain enforceable and/or effective measures for protection of decadent or other large trees with structural features such as platforms, cavities, and basal hollows, which appear to be important components of fisher habitat. Some timber operations, such as salvage, fuelwood harvest, powerline right-of-way clearing, and fire hazard reduction are exempt from timber harvest plan preparation and submission requirements. CDF considers applications for exemptions as ministerial in nature, and therefore exemptions receive minimal review by CDF. In 2002, new rules were passed that prohibit the harvest of large old trees under exemptions, although harvest is still allowed in cases of safety, building construction, or when the tree is dead or will be dead within the year.

California's FPRs provide for disclosure of impacts to late successional forest stands, in some cases. The rules require that information about late successional stands be included in a timber harvest plan when late successional stands over 20 ac (8 ha) in size are proposed for harvesting and such harvest will "significantly reduce the amount and distribution of late succession forest stands'' (FPR § 919.16, 939.16, 959.16). If the harvest is found to be "significant,'' FPR § 919.16 requires mitigation of impacts where it is feasible. In practice, such a finding during plan review is very rare and likely to be challenged by the landowner. Also, few proposed harvests trigger the late successional analysis because very little forest on commercial timberlands meets the definition of late successional forest, due to past logging history (Curt Babcock, CDFG, pers. comm. 2003).

The California FPRs require retention of trees within riparian buffers to maintain a minimum canopy cover, dependent on stream classification and slope. The FPR prescriptions are not designed or intended to protect late seral habitat, but this may occur at times. The rules currently mandate retention of large trees in watersheds identified as having "threatened or impaired'' values (watersheds with listed anadromous fish). For Class I (fish-bearing) streams, the 10 largest conifer trees per 330 ft (133 m) of stream channel must be retained along qualifying watercourses. These trees are retained within the first 50 ft (15 m) of permanent woody vegetation measured out from the stream channel; this provides about 26 trees per acre within that zone. There are no additional protection measures required for non-fish-bearing streams (classes II and III) within "threatened or impaired'' watersheds. The threatened and impaired provision applies to many streams within the fisher's range in northern California, but not to most of the Sierra Nevada nor to most of the upper Trinity River basin (where fishers still occur), and is set to expire in 3 years. Where applied, the threatened and impaired rules should result in the retention of some large trees of value to fishers, although the protective value is limited, as it applies to only a small part of any affected watershed and in a fragmentary pattern. Averaged over the landscape, the measure provides on average less than one retained tree per forested acre in qualifying watersheds, based on an evaluation of a sample of timber harvest plans (Scott Osborn, CDFG, pers. comm. 2003), and on Arcata FWO calculations on watercourse density on commercial timberland ownerships in northwestern California. Also, in many watersheds, few large trees remain along watercourses, thus most of the trees retained under this measure are likely to be of a size and age that provide little current value as late seral elements commonly used by fishers. Over time, the retained trees may develop late seral and decadent characteristics, but this is likely to take place over time scales of decades and centuries.

Outside of "threatened and impaired'' watersheds, watercourse protection measures are limited. Class I streams must retain at least 50 percent of the overstory and 50 percent of the understory. No minimum canopy closure requirements are specified for Class II and Class III streams. Harvest plans are required to leave 50 percent of the existing total canopy including understory, and provide no protection for large trees or other late-seral habitat elements.

*Habitat Conservation Plans (HCPs)*

Some non-Federal lands are managed under HCPs with strategies that conserve habitat. These HCPs may provide some incidental benefit to fishers and some have fisher-specific protection measures. Habitat conservation plans cover large areas within the historic range of the fisher, particularly in western Washington and northwestern California. Although the fisher is a covered species in seven HCPs within Washington and California, the species is currently known to be present only on lands under two California HCPs. In most HCPs, the areas where late successional habitat will be protected or allowed to develop are mostly in riparian buffers and smaller blocks of remnant old forest. The HCP conservation strategies generally do not provide the large blocks of forest with late seral structure that appear to be important for sustaining resident fisher populations, particularly for providing denning and resting sites.

In conclusion, the primary threats are the loss and fragmentation of habitat and further decline and isolation of the remaining small populations. Any of the key elements of fisher habitat (*see* Habitat section) may be affected by Federal and State management activities. Reduction of any of these elements could pose a risk to the fishers. Activities under Federal regulatory control that result in fisher habitat fragmentation or population isolation pose a risk to the persistence of fishers. A large proportion of forests within the range of the West Coast DPS for the fisher are managed under the NWFP or SNFPA. These regional planning efforts provide for retention and recruitment of older forests, and provide for spatial distribution of this type of habitat that will benefit late successional forest dependent species such as the fisher. The adequacy of these plans, however is uncertain, as evidenced in the FEMAT's own assessment of fisher viability under the NWFP.

Proposed changes to both the NWFP and SNFPA are in progress, which could weaken habitat measures that benefit the fisher. Even with these plans in place, timber harvest, fuels reduction treatments, and road construction may continue to result in the loss of habitat and habitat connectivity in areas, resulting in a negative impact on fisher distribution, abundance and recovery/recolonization potential.

The same potential risks apply to non-Federal forested lands as discussed for lands under Federal regulatory control. Protections provided under state regulation of forest practices are less than provided on Federal lands, where the NWFP and SNFPA provide greater consideration of late-successional forest and dependent species, and of forest management at larger geographic scales. Existing regulatory processes for non-Federal, non-Tribal timberlands in California and Washington do not include specific measures for management and conservation of fishers or fisher habitat. Regulations regarding late successional forest rarely provide protection of these forests on

commercial timberlands. This is largely because the regulations lack specific and enforceable conservation measures for these forests, and for most unlisted wildlife species, including the fisher. While the State regulatory process for these lands in all three States incidentally protects some fisher habitat via the Forest Practice Rules, the benefits are limited and do not include strategies which target either the fisher or key fisher habitat requirements. Existing habitat conservation plans for non-Federal timberlands provide some additional benefits to the fisher. These plans are focused on providing some level of protection for the habitat of spotted owls, marbled murrelets, and listed salmonids, which can protect important habitat elements for the fisher where habitat overlaps. However, many of these plans only protect occupied habitat, and harvest deferrals may be lifted if the mature stands no longer support listed species. Thus, benefits to the fisher from these HCPs may be ephemeral, especially in the case of listed species decline, like that of the spotted owl population occurring in Washington. HCPs only apply to a small part of the fisher's currently occupied range on non-Federal lands in California and Oregon, and the adequacy of the measures in these plans is uncertain. Because of the loss and fragmentation of low-elevation habitat, large geographic areas that were once occupied have become unsuitable, which poses a significant challenge for fisher genetic exchange across isolated patches of habitat.

In addition to the inadequacy of regulations to address fisher habitat requirements, current trapping regulations in Washington, Oregon, and California, while prohibiting intentional trapping of fishers, do not provide accurate reporting of the numbers of incidental captures of fishers, and appear inadequate to control such incidental trapping where fishers are present. Any source of additional mortality in small fisher populations could prevent recovery or reoccupation of suitable habitat (Lewis and Stinson 1998; Lewis and Zielinksi 1996).

It is uncertain whether current regulations will be effective in reducing the level of threat to the fisher. We therefore believe that existing regulatory mechanisms are not sufficient to protect the DPS as a whole from the acknowledged habitat pressures discussed under Factors A and E.

*Factor E. Other natural or manmade factors affecting the continued existence of the species.* Fisher populations in the West Coast DPS are small and isolated and may be threatened by numerous factors including inbreeding depression and unpredictable variation (stochasticity) in demographic or environmental characteristics. Other natural or anthropogenically-influenced factors, including urban development, barriers to dispersal, contaminants, pest control programs, non-target poisoning, stand-replacing fire, timber harvest, accidental trapping in manmade structures, decrease in prey base, and climate change may cause additional fisher declines. Because of small population size, accidental death is a threat.

*Other Causes of Mortality*

There have been several incidents of fishers being found dead in open water tanks. The remains of eight fishers were discovered in an abandoned water tank near a logging road in the northwestern California Coast Ranges (Folliard 1997). The tank had been used to store water for transferring into tank trucks to spread on roads for dust abatement during summer months. The fishers had entered the cylindrical 13-foot-long, 7.5-foot-deep tank from a lidless, 1.5-foot opening in the top. Fisher remains were the only species found inside. It was apparent from the carcasses' different stages of decay that the fishers had been trapped over a period of several years. In another instance of a manmade structure trapping fishers, Truex *et al.* (1998) reported that a 5-year-old female fisher died in the southern Sierra Nevada study area due to a combination of starvation and exposure after becoming entrapped in an uncovered, empty water storage tank. This source of mortality is cause for concern.

*Population Size and Isolation*

Preliminary analyses indicate West Coast fisher populations, particularly in the southern Sierra, may be at significant risk of extinction because of small population size and factors consequent to small population size such as isolation, low reproductive capacity, demographic and environmental stochasticity. A scarcity of sightings in Washington, Oregon, and the northern and central Sierra Nevada of California suggests that fisher is extirpated from most of its historical range in Washington, Oregon, and California (Zielinski *et al.* 1997b; Carroll *et al.* 1999; Aubry *et al.* 2000). The southern Sierra Nevada and northern California/Oregon Siskiyou populations are the only naturally-occurring, known breeding populations of fishers in the Pacific region from southern British Columbia to California that we have been able to identify (Zielinski *et al.* 1997b).

The current rarity of fishers in Washington brings their continued existence there into question. Eleven years ago, Thomas *et al.* (1993) stated that existing fisher populations in northern Oregon and Washington were at a medium to high risk of extirpation on National Forest lands within the next 50 years. According to FEMAT (1993), it was unknown whether the individual fishers that may exist in Washington could repopulate the State in the future. Recovery of the fisher in Washington will probably not occur without reintroductions (Lewis and Stinson 1998). Immigration of fishers into Washington from British Columbia, Idaho, or Montana is unlikely to provide significant demographic support to Washington's fisher population; fisher populations in adjacent parts of Idaho and British Columbia are small, the number of dispersing individuals is probably very low (Heinemeyer 1993), and the geographical separation is large. Reintroductions have apparently been successful in some, but not all other parts of the fisher's national range.

The introduced population in the southern Cascades of Oregon is small and isolated. It stems from the release of 28 fishers from British Columbia between 1961 and 1980, and an additional release of 13 fishers from Minnesota in 1981 (Aubry *et al.* 2002; Drew *et al.* 2003). Aubry *et al.* (in press 2003) concluded, "The high degree of relatedness among fishers in the southern Cascade Range (R = .56) is consistent with the hypothesis that this population is small and isolated.'' This reintroduced population is separated from the northwestern California/southwestern Oregon population by large expanses of non-forested areas, an interstate highway (Interstate 5), recreational developments, and densely populated areas. The isolation of these populations from each other in Oregon is further demonstrated by evidence indicating that there has been no genetic exchange between fishers in the northern Siskiyou Mountains and those in the southern Cascade Range (Aubry *et al.* in press 2003). Small size and isolation make the Oregon populations vulnerable to extirpation.

Because of the apparent loss of viable fisher populations from most of Oregon and Washington, and the northern contraction in the British Columbia populations, fishers in California are reproductively isolated from fishers in the rest of North America. This isolation precludes both immigration and associated genetic interchange, increasing the vulnerability of the California/southern Oregon populations to the adverse effects of deterministic

and stochastic factors. Wisely *et al.* (in litt. 2003) documented that fishers in northern California already have lower genetic diversity than other populations in North America. Drew *et al.* (2003) cite evidence of genetic divergence between the California and British Columbia fisher populations; since becoming isolated, the California populations have lost a genetic haplotype still found in British Columbia fishers. The genetic divergence of California populations from each other and from British Columbia fishers could be associated with adaptation to local conditions, but is more likely the result of reduction of population numbers with habitat loss (Drew *et al.* 2003). Isolation makes it unlikely that in the event of population decline, immigration from other populations could temporarily augment the population, rescuing it from extinction.

Genetic studies using mitochondrial and nuclear DNA sequencing indicate that California populations, in particular, differ strongly in haplotype frequencies from each other and from all other populations (Drew *et al.* 2003). These results are consistent with the conclusions of Aubry and Lewis (2003) that native populations in California and the reintroduced population in southwestern Oregon have become isolated from the main body of the species' range due to the apparent extirpation of fishers in Washington and northern Oregon. According to Drew *et al.* (2003), their findings suggest that gene flow once occurred between fisher populations in British Columbia and those in the Pacific states, but extant populations in these regions are now genetically isolated. The southern Sierra Nevada population is geographically isolated from others by approximately 420 km (260 mi) (Zielinski *et al.* 1995, 1997b). There is a low probability that it could be rescued through migration of individuals from other populations were it to decline, since the distance to the nearest population is almost four times the species' maximum dispersal distance of 66 mi (107 km) as reported by York (1996). The unexpected magnitude of Pacific states fishers' genetic structure and lack of gene flow indicates that intermediate distances may represent evolutionarily important barriers to movement that can facilitate rapid genetic divergence (Wisely *et al.* in litt. 2003). Truex *et al.* (1998) concluded that, "Recolonization of the central and northern Sierra Nevada may be the only way to prevent fisher extinction in the isolated southern Sierra Nevada population.''

Indications that extant fisher populations are small in size include the apparent reduction in the range of the fisher on the west coast, the lack of detections or sightings over much of its historical distribution, and the apparently high degree of genetic relatedness within some populations. Small fisher population sizes are cause for concern, particularly considering that the West Coast populations are isolated from the larger continental populations and may have high female mortality (Truex *et al.* 1998). Small populations are at risk of extinction solely from demographic and environmental stochasticity, independent of deterministic factors such as anthropogenic habitat loss (Lande and Barrowclough 1987; Lande 1993). Random fluctuations in gender ratio, fecundity, mortality, droughts, cold weather, heavy snow years and other temporal environmental changes can lead to declines that, in small populations, result in rapid extinction. These factors present threats to the long-term survival of isolated populations such as the southern Sierra Nevada population (Lamberson *et al.* 2000). Catastrophes, such as stand-replacing fire or severe storms, magnify risk of extinction further (Shaffer 1987; Lande 1993).

According to Heinemeyer and Jones (1994), the greatest long-term risk to the fisher in the western United States is probably population extinction due to isolation of small populations. Fishers are known to be solitary and territorial with large home ranges. This results in low population densities as the population requires a large amount of quality habitat for survival and proliferation. Additionally, fishers are long-lived, have low reproductive rates, and small dispersal distances. Given the apparent reluctance of fishers to cross open areas (Coulter 1966; Kelly 1977; Powell 1977; Buck *et al.* 1994; Jones and Garton 1994), it is more difficult for fishers to locate and occupy distant, but suitable, habitat. These factors together imply that fishers are highly prone to localized extirpation, their colonizing ability is somewhat limited, and their populations are slow to recover from deleterious impacts. Isolated populations are therefore unlikely to persist.

Some fisher populations in northeastern North America have shown patterns of rapid density fluctuation consistent with those following cycles in prey numbers (deVos 1952; Rand 1944), or with changes expected for animals whose density-dependent feedback comes through changes in mortality rather than in reproduction, allowing them to recover into areas from which they had been extirpated. Western populations, however, do not appear to be recovering from early overtrapping and habitat degradation. Powell and Zielinski (1994) state:

> This pattern of rapid population increase has not been observed in western populations, many of which have failed to recover despite decades of protection from trapping (*e.g.*, northern Sierra Nevada, Olympic Peninsula), reintroductions (*e.g.*, Oregon), or both. Therefore, one or more major life requisites must be missing. Suitable habitat may be limited, colonization of suitable habitat may be limited due to habitat fragmentation, or some other factor or combination of factors may be involved.

Low fecundity retards the recovery of populations from declines, further increasing their vulnerability. As stated above, fishers have very low reproductive capacity. After 2 years of age, they generally produce only one to four kits per year, and only a portion of all females breed (Powell 1993; Truex *et al.* 1998; Lamberson *et al.* 2000). Truex *et al.* (1998) documented that of the females in the southern Sierra Nevada study area (one of three study areas that they analyzed in California), about 50 to 60 percent successfully gave birth to young. In the study area they analyzed on the North Coast, however, 73 percent of females gave birth to young in 1995, but only 14 percent (one of seven) did so in 1996, indicating fisher reproductive rates may fluctuate widely. Low survival rates for kits, coupled with low reproductive rates, would result in very low reproductive success rates. In their study on the west slope of the Cascade Range in southern Oregon, Aubry *et al.* (2002) radio-collared 13 females and monitored two to four adult females each year from 1995 to 2001. Although their data are preliminary at this point, they found that the average annual reproductive success was only 44 percent.

Female survival has been shown to be the most important single demographic parameter determining fisher population stability (Truex *et al.* 1998; Lamberson *et al.* 2000). Truex *et al.* (1998) documented a low annual survival rate, pooled across years, of 61.2 percent of adult female fishers in the southern Sierra Nevada from 1994 to 1996, 72.9 percent for females and 85.5 percent for males in their eastern Klamath study area, and 83.8 percent for both females and males in their North Coast study area. Addressing the southern Sierra Nevada population, Truex *et al.* (1998) conclude that, "High annual mortality rates raise concerns about the long-term viability of this population.'' Lamberson *et al.* (2000) used a model (deterministic, Leslie stage-based matrix) to gauge risk of

extinction for the southern Sierra Nevada population of the fisher and found that the population has a very high likelihood of extinction given reasonable assumptions with respect to demographic parameters. They concluded, "In our model population, growth only occurs when parameter combinations are extremely optimistic and likely unrealistic: if female survival and fecundity are high, other parameters can be relaxed to medium or low values. If female survival and fecundity are medium and all other parameters high, a steady decline toward extinction occurs.''

As with any small, isolated population, risks of extinction are enhanced by stochastic factors (Lamberson *et al.* 2000). Demographic stochasticity, the chance events associated with annual survival and reproduction, and environmental stochasticity, temporal fluctuations in environmental conditions, tend to reduce population persistence (Shaffer 1981; Boyce 1992). Habitat specificity coupled with human-induced habitat fragmentation may also contribute to the exceptionally low levels of gene flow (migrants per generation) estimated among populations of fishers (Wisely *et al.* in litt. 2003). Wisely *et al.* (in litt. 2003) found that populations of the fisher exhibit high genetic structure (FST = 0.45, SE = 0.07) and limited gene flow (Nm < 1) within their 994 mi (1,600 km) long peninsular distribution down through Washington, Oregon, and California. They state concerns about the future viability of the western fisher: * * * we found that * * * genetic diversity decreases from the base [British Columbia] to the tip [southern Sierra Nevada] of the peninsula, and that populations do not show an equilibrium pattern of isolation-by-distance. Genetic structure was greater at the periphery than at the core of the distribution and our data fit a one-dimensional model of stepping-stone range expansion. Multiple lines of paleontological and genetic evidence suggest that the fisher recently (<5000 ybp) expanded into the mountain forests of the Pacific coast. The reduced dimensionality of the distribution of the fisher in the West appears to have contributed to the high levels of structure and decreasing diversity from north to south. These effects were likely exacerbated by human-caused changes to the environment. The low genetic diversity and high genetic structure of populations in the southern Sierra Nevada suggest that populations in this part of the geographic range are vulnerable to extinction.

It is difficult for subpopulations to rescue each other when distributed in such a narrow, linear fashion north-south peninsular distribution. Even isolated from other threats, the north-south peninsular distribution of fishers in the Sierra Nevada is a risk factor for the southern Sierra Nevada population. Being at the southernmost extent of the genus' distribution, the population already exists at the edge of environmental tolerances. The loss of remaining genetic diversity may lead to inbreeding and inbreeding depression. Given the recent evidence for elevated extinction rates of inbred populations, inbreeding may be a greater general threat to population persistence than is generally recognized (Vucetich and Waite 1999).

Combinations of factors can interact to produce significant cumulative risk. Lamberson *et al.* (2000) give the following example: if demographic stochasticity results in lower than average recruitment of female kits into a population for three consecutive years, and this is followed by two heavy-snow winters and one large fire, the population may quickly become in jeopardy of local extinction. Wisely and others (in litt. 2003) "have demonstrated isolation among populations with limited exchange suggesting that populations on the Pacific coast have little demographic buffer from variation in the population growth rate. Immediate conservation action may be needed to limit further erosion of the unique genetic architecture found in this one-dimensional metapopulation.''

In summary, unregulated trapping for furs began in the 1700s; predator bounties began in the 1800s and extended to 1960; extensive, lethal predator control programs were used until the mid-1970s. These factors have likely impacted fishers for nearly two centuries and were exacerbated by loss and fragmentation of habitat from urban growth and development, forest management activities, and road construction. The remaining two populations are threatened with extirpation due to their size and isolation. There is substantial information indicating that the interaction of all the factors above may cause the populations of fishers in their west coast range to become significantly at risk of extirpation.

## Conservation Activities

This fiscal year, the Pacific Region (Region 5) of the U.S. Forest Service is due to complete a conservation assessment for the fisher in the Sierra Nevada Mountains. This effort is part of the Sierra Nevada Framework planning document and is a collaborative effort including scientists from the State and Federal agencies. The assessment may be used to develop a conservation strategy for the Sierra Nevada fisher populations in California.

The timber industry and their representatives, including Sierra Pacific Industries, Simpson Timber Company and the California Forestry Association have indicated willingness to develop a conservation strategy to, if appropriate, conduct a reintroduction and/or relocation strategy in California. Their participation could include funding, staffing, and assistance with analysis and planning.

The State of Washington has completed a reintroduction feasibility study and has identified several sites in the Washington Cascades and the Olympic peninsula where sufficient potential habitat exists to support a fisher population. Reintroduction efforts and evaluation by the State are ongoing and would potentially compliment efforts to establish additional populations throughout the range of the fisher.

## Finding

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats faced by this species. We reviewed the petition, available published and unpublished scientific and commercial information, and information submitted to us during the public comment period following our 90-day petition finding. This finding reflects and incorporates information we received during the public comment period and responds to significant issues. We also consulted with recognized fisher experts and Federal and State resource agencies. On the basis of this review, we find that the West Coast population of the fisher constitutes a valid DPS, which is both discrete and significant under our DPS policy, and that listing the fisher in its west coast range is warranted but precluded by pending proposals for other species with higher listing priorities.

In making this finding, we recognize that there have been declines in the distribution and abundance of the fisher in its west coast range, primarily attributed to historical overtrapping and habitat alteration. Much of the fisher's historical habitat and range has been lost. There is substantial information indicating that the habitat of fishers continues to be threatened with further loss and fragmentation resulting in a negative impact on fisher distribution and abundance. Mortalities and injuries

from incidental captures of fishers may be frequent enough to prevent local recovery of populations, or prevent the re-occupation of suitable habitat. Removing important habitat elements such as cover could allow predation to become a significant threat. Other factors considered to be threats to the fisher include mortality from vehicle collisions, a decrease in the prey base, and increased human disturbance. Fisher populations are low or absent throughout most of their historical range in Washington, Oregon, and California. Because of small population sizes and isolation, fisher populations on the West Coast may be in danger of extirpation.

Federal, State, and private land management activities may affect key elements of fisher habitat; reduction of any of these key habitat elements could pose a risk to the fisher. Current regulations provide insufficient certainty that conservation efforts will be implemented or that they will be effective in reducing the level of threat to the fisher. We, therefore, believe that existing regulatory mechanisms are not sufficient to protect the DPS as a whole from habitat pressures.

We conclude that the overall magnitude of threats to the West Coast DPS of the fisher is high, and that the overall immediacy of these threats is non-imminent. Pursuant to our Listing Priority System (64 FR 7114), a DPS of a species for which threats are high and non-imminent is assigned a Listing Priority Number of 6. The threats occur across the range of the DPS resulting in a negative impact on fisher distribution and abundance. The threats are non-imminent as the greatest long-term risks to the fisher in its west coast range are the subsequent ramifications of the isolation of few, small populations. While we conclude that listing the West Coast DPS of the fisher is warranted, an immediate proposal to list is precluded by other higher priority listing actions. During Fiscal Year 2004 we must spend nearly all of our Listing Program funding to comply with listing actions required by court orders and judicially approved settlement agreements, which are now our highest priority actions. To the extent that we have discretionary funds, we will give priority to using them to address emergency listings and listing actions for other species with a higher priority. We expect that our discretionary listing activity in Fiscal Year 2004 will focus on addressing our highest priority listing actions.

There are currently efforts underway to implement a conservation strategy to reintroduce the fisher into its former range along the Pacific Coast. Additional populations of fishers will reduce the probability that a stochastic event would result in extirpation of these species. We will evaluate a completed conservation strategy in accordance with our Policy on Evaluating Conservation Efforts (68 FR 15100, March 28 2003) to determine whether it sufficiently removes threats to the fisher so that it no longer meets the definition of threatened under the Act.

We will add the West Coast DPS of the fisher to the list of candidate species upon publication of this notice of 12-month finding. We request that you submit any new information, whenever it becomes available, for this species concerning status and threats. This information will help us monitor and encourage the conservation of this species. Should an emergency situation develop with this or any of the candidate species, we will act to provide immediate protection, if warranted.

We intend that any proposed listing action for the West Coast DPS of the fisher will be as accurate as possible. Therefore, we will continue to accept additional information and comments from all concerned governmental agencies, the scientific community, industry, or any other interested party concerning this finding.

## References Cited

A complete list of all references cited is available on request from the Sacramento Fish and Wildlife Office (see **ADDRESSES** section, above).

## Author(s)

The primary author of this document is the Sacramento Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT** section).

## Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: April 2, 2004.

**Steve Williams,**

*Director, Fish and Wildlife Service.*

[FR Doc. 04–7941 Filed 4–7–04; 8:45 am]

**BILLING CODE 4310–55–P**

Federal Register

Thursday,
April 8, 2004

# Part VI

# Department of Homeland Security

## Coast Guard

## 33 CFR Part 165

## Security Zones: St. Simons Sound and the Atlantic Ocean, GA; Security Zones and Regulated Navigation Areas: Savannah River, GA; Proposed Rules

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 165**

**[COTP Savannah–04–041]**

**RIN 1625–AA00**

## Security Zone, St. Simons Sound and the Atlantic Ocean, GA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard proposes to establish temporary security zones, from June 5, 2004, through June 11, 2004, for the G–8 Summit to be held in Sea Island, Georgia. These proposed security zones are required to provide for the security of the public, the G–8 Summit and its participants, and the safety of the waterways due to the potential for hostile and violent acts from demonstrators protesting the G–8 conference. The proposed rule would prohibit the entry of all vessels and persons into the waters in the vicinity of Sea Island, Jekyll Island, and all waters of the Atlantic Ocean from the baseline of Sea Island and Jekyll islands extending seaward to a distance of 3 nautical miles, as well as waters on the Hampton River, Jones Creek, Lanier Island, St. Simons Sound, and the security zones prohibit entering closer than 100-yards to certain bridges within these same areas.

**DATES:** Comments and related material must reach the Coast Guard on or before May 10, 2004. The proposed security zones would be effective from 8 a.m. on June 5, 2004, until 4 p.m. on June 11, 2004.

**ADDRESSES:** You may mail comments and the related material to Marine Safety Office Savannah, 100 W. Oglethorpe Ave., Suite 1017, Savannah, Georgia 31401. Marine Safety Office Savannah maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at Marine Safety Office Savannah between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** LTJG Anthony Quirino, Coast Guard Marine Safety Office Savannah, (912) 652–4353, ext 235.

**SUPPLEMENTARY INFORMATION:**

### Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking [COTP Savannah 04–041], indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to know that your submission reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule due to the comments received.

### Public Meeting

We do not now plan to hold a public meeting. Persons may submit a request for a public meeting by submitting a written request to Marine Safety Office Savannah at the address listed in the **ADDRESSES** section of this notice of proposed rulemaking. This request should describe the benefits of a public meeting. If we determine that a public meeting would aid this rulemaking, we will hold one at a time and place announced by a separate notice in the **Federal Register**.

### Background and Purpose

The G8 (Group of 8) is an informal group of eight countries—Canada, France, Germany, Italy, Japan, Russia, the United Kingdom and the United States—whose leaders meet to discuss broad economic and foreign policies. The 30th G–8 Summit will be held in Sea Island, Georgia, from June 8 through June 10, 2004.

Cities that have recently hosted conferences or summits similar to the G–8 Summit have experienced significant property damage, and their law enforcement officers and public citizens have sustained personal injuries from a segment of protestors engaged in violent demonstrations against those summits and their agendas. Examples include the September 2003 World Trade Organization (WTO) Ministerial in Cancun, Mexico; the 2003 G–8 Summit in Calgary, Canada, the 2001 G–8 Summit in Genoa, Italy; and the 1999 World Trade Organization in Seattle, Washington. These conferences and summits experienced an influx of protestors, and in particular protest groups opposing international trade who have a propensity for violence and a desire to engage in hostile acts against, among others, summit attendees, conference venues, the general public, business and municipal buildings, and law enforcement officials. Information and intelligence indicates that there is a high potential for similar acts to be attempted during the upcoming June G–8 Summit in Savannah, Georgia.

This history has heightened the need for the development and implementation of various security measures in the vicinity of St. Simons Sound. In particular, there is a need for additional security around venue areas established for the dignitaries and official parties attending the G–8 Summit, bridges, and waterways used by commercial shipping. The Coast Guard has determined from information provided by local, State, and Federal law enforcement officials that vessels or persons in close proximity to the G–8 Summit may launch hostile or violent acts from the waterways adjacent to the Summit and from the waterways adjacent to where Summit attendees are staying. The potential for these acts poses a security threat to the public, the G–8 Summit and its participants, and the flow of commerce on the navigable waterways.

The proposed security zones would mitigate these threats and are necessary to protect the public, the G–8 Summit attendees, law enforcement officers, and the flow of commerce on the waterways from persons attempting hostile and violent acts. Please note that elsewhere in today's **Federal Register**, we have published another proposed rule, entitled "Security Zones and Regulated Navigation Areas; Savannah River, GA,'' [COTP Savannah–04–040] that is also intended to provide security of the public, the G–8 Summit and its participants, and the safety of the waterways during this same period—June 5, 2004, until 4 p.m. on June 11, 2004.

### Discussion of Proposed Rule

The proposed security zones prohibit all vessels and persons from entering the waters encompassed by the following points unless they obtain permission in advance from the Captain of the Port of Savannah to transit the zones: All waters of St. Simons Sound and the Atlantic Ocean, from surface to bottom, encompassed by a line commencing from the north east point of Little St. Simons Island at 31°15′24″ N, 081°16′55″ W; thence, easterly seaward into the waters of the Atlantic Ocean out to a distance of 3 nautical miles at 31°15′24″ N, 081°11′55″ W; thence southerly following the contour of the coastline at a distance of 3 nautical miles to 31°00′44″ N,

081°19′35″ W; thence westerly to the southern tip of Jekyll Island at 31°00′44″ N, 081°26′03″ W; thence north westerly to the south side of the Sidney Lanier bridge at 31°06′48″ N, 081°29′40″ W; thence continuing north easterly to the northern tip of Lanier Island at 31°11′06″ N, 081°25′17″ W; thence continuing north easterly to the Hampton River at 31°17′36″ N, 081°20′33″ W; thence back to the original point.

Additionally, the following bridges would have security zones, to the extent they are not already within the St. Simons sound security zone, encompassing all waters within 100-yards of the bridge:

| Roadway | Bridge | Located at |
|---|---|---|
| Jekyll Island Causeway | Cedar Creek | 31°05.318′ N, 081°28.780′ W. |
| Jekyll Island Causeway | Jekyll Creek | 31°02.808′ N, 081°25.347′ W. |
| Highway 17 | Sidney Lanier | 31°06.982′ N, 081°29.094′ W. |
| Saint Simons Causeway | Terry Creek | 31°09.697′ N, 081°28.137′ W. |
| Saint Simons Causeway | Back River | 31°09.868′ N, 081°26.766′ W. |
| Saint Simons Causeway | Little River | 31°10.120′ N, 081°26.200′ W. |
| Saint Simons Causeway | MacKay River | 31°10.276′ N, 081°25.494′ W. |
| Saint Simons Causeway | Frederica River | 31°10.050′ N, 081°24.782′ W. |

Although the G–8 Summit is scheduled to take place from June 8 through June 10, 2004, it is necessary to make the security zones effective from June 5 through June 11, 2004 to provide security for arriving and departing G–8 summit attendees and allow law enforcement officials time to stand up and stand down from patrolling the security zones.

The Captain of the Port may, if security conditions allow, permit vessels to transit through the security zones under the escort of law enforcement officials. However, southbound vessels transiting the Intracoastal waterway should plan on exiting at Altamaha Sound to the Atlantic Ocean and proceed southbound seaward of 3 nautical miles and outside the 3 nautical mile limit of the security zone to the entrance of St. Andrew Sound, and then travel westward to rejoin the Intracoastal waterway and continue their southbound voyage. Conversely, northbound vessels transiting the Intracoastal waterway should generally plan to exit the Intracoastal waterway east from St. Andrew Sound to the Atlantic Ocean, and proceed northbound seaward of 3 nautical miles and the 3 nautical mile limit of the security zone to the entrance of Altamaha Sound, and then travel west to rejoin the Intracoastal waterway to continue their northbound voyage.

Entry into or remaining within the security zones is prohibited unless authorized by the Coast Guard Captain of the Port, Savannah, Georgia or that officer's designated representatives. Persons desiring to enter or transit the areas encompassed by the security zone may contact the Coast Guard on VHF Channel Marine 16 or at (912) 652–4353 to seek permission to enter or transit the area. If permission is granted, all persons and vessels must comply with the instructions of the Captain of the Port or that officer's designated representatives.

## Regulatory Evaluation

This proposed rule is not a "significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not "significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS).

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary.

## Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term "small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

This proposed rule would affect the following entities, some of which might be small entities: the owners or operators of vessels intending to transit or anchor in a portion of St. Simons Sound, the Intracoastal Waterway and the Atlantic Ocean covered by this proposed security zone. Owners of such small entities are encouraged to contact the Captain of the Port to seek permission to transit these security zones.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **FOR FURTHER INFORMATION CONTACT**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

## Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

## Collection of Information

This proposed rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

## Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this proposed rule under that Order and have determined that it does not have implications for federalism.

## Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of

their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

**Taking of Private Property**

This proposed rule would not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

**Civil Justice Reform**

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

**Protection of Children**

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This proposed rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

**Indian Tribal Governments**

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does 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.

**Energy Effects**

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action'' under that order because it is not a "significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

**Environment**

We have analyzed this proposed rule under Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this proposed rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation.

**List of Subjects in 33 CFR Part 165**

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

## PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1226, 1231; 50 U.S.C. 191, 195; 46 U.S.C. Chapter 701; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

2. From 8 a.m. on June 5, 2004, until 4 p.m. on June 11, 2004, add a new temporary § 165.T07–041 to read as follows:

**§ 165.T07–041 Temporary Security Zones, St. Simons Sound, GA**

(a) *Locations.* The following areas are security zones:

(1) *Security zone; St. Simons Sound and the Atlantic Ocean.* All waters of St. Simons Sound and the Atlantic Ocean, from surface to bottom, encompassed by a line commencing from the north east point of Little St. Simons Island at 31°15′24″ N, 081°16′55″ W; thence, easterly seaward into the waters of the Atlantic Ocean out to a distance of 3 nautical miles at 31°15′24″ N, 081°11′55″ W; thence southerly following the contour of the coastline at a distance of 3 nautical miles to 31°00′44″ N, 081°19′35″ W; thence westerly to the southern tip of Jekyll Island at 31°00′44″ N, 081°26′03″ W; thence north westerly to the south side of the Sidney Lanier bridge at 31°06′48″ N, 081°29′40″ W; thence continuing north easterly to the northern tip of Lanier Island at 31°11′06″ N, 081°25′17″ W; thence continuing north easterly to the Hampton River at 31°17′36″ N, 081°20′33″ W; thence back to the original point. All coordinates are based upon North American Datum 83 (NAD 83).

(2) *Security zone, Bridges.* All waters from surface to bottom within 100-yards of the following bridges:

| Roadway | Bridge | Located at |
|---|---|---|
| (i) Jekyll Island Causeway | Cedar Creek | 31°05.318′ N, 081°28.780′ W. |
| (ii) Jekyll Island Causeway | Jekyll Creek | 31°02.808′ N, 081°25.347′ W. |
| (iii) Highway 17 | Sidney Lanier | 31°06.982′ N, 081°29.094′ W. |
| (iv) Saint Simons Causeway | Terry Creek | 31°09.697′ N, 081°28.137′ W. |
| (v) Saint Simons Causeway | Back River | 31°09.868′ N, 081°26.766′ W. |
| (vi) Saint Simons Causeway | Little River | 31°10.120′ N, 081°26.200′ W. |
| (vii) Saint Simons Causeway | MacKay River | 31°10.276′ N, 081°25.494′ W. |
| (viii) Saint Simons Causeway | Frederica River | 31°10.050′ N, 081°24.782′ W. |
| (ix) All coordinates are based upon North American Datum 83 (NAD 83). | | |

(b) *Definitions.* As used in this section, *designated representatives* means Coast Guard Patrol Commanders including Coast Guard coxswains, petty officers and other officers operating Coast Guard vessels, and Federal, State, and local officers designated by or assisting the Captain of the Port of Savannah (COTP) to restrict vessels and persons from entering the security zones.

(c) *Regulations.* Entry into or transiting within the security zones is prohibited unless authorized by the

Coast Guard Captain of the Port, Savannah, Georgia or that officer's designated representatives. Vessels docked, moored, or anchored in one of the security zones when they become effective must remain in place unless ordered by or given permission from the COTP to do otherwise. Persons desiring to enter or transit the areas encompassed by the security zones may contact the Coast Guard on VHF Channel Marine 16 or at (912) 652–4353 to seek permission to enter or transit the zones. If permission is granted, all persons and vessels must comply with the instructions of the Captain of the Port or that officer's designated representatives.

Dated: March 30, 2004.

**Harvey E. Johnson, Jr.,**

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

[FR Doc. 04–7994 Filed 4–7–04; 8:45 am]

**BILLING CODE 4910–15–P**

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## DEPARTMENT OF HOMELAND SECURITY

## Coast Guard

## 33 CFR Part 165

**[COTP Savannah–04–040]**

**RIN 1625–AA00**

## Security Zones and Regulated Navigation Areas; Savannah River, GA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard proposes to establish temporary security zones and a temporary regulated navigation area, from June 5, 2004, through June 11, 2004, for the G–8 Summit to be held in Sea Island, Georgia. These proposed rules are required to provide for the security of the public, the G–8 Summit and its participants, and the safety of the waterways due to the potential for hostile and violent acts from demonstrators protesting the G–8. The proposed temporary security zones would prohibit the entry of all vessels into all waters of the Savannah River from Port Wentworth south to the boundary of the proposed temporary regulated navigation area that is located in the vicinity of the south east tip of Elba Island at the western portion of the Lower Flats Range. The proposed temporary regulated navigation area would control the movement of all vessels operating on the Intracoastal Waterway in the vicinity of Fields Cut and south through Elba Island Cut to St. Augustine Creek.

**DATES:** Comments and related material must reach the Coast Guard on or before May 10, 2004.

**ADDRESSES:** You may mail comments and the related material to Marine Safety Office Savannah, 100 W. Oglethorpe Ave., Suite 1017, Savannah, Georgia 31401. Marine Safety Office Savannah maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at Marine Safety Office Savannah between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** LTJG Anthony Quirino, Coast Guard Marine Safety Office Savannah, (912) 652–4353, ext 235.

**SUPPLEMENTARY INFORMATION:**

### Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking [COTP Savannah 04–040], indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 81/2 by 11 inches, suitable for copying. If you would like to know that your submission reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

### Public Meeting

We do not now plan to hold a public meeting. Persons may submit a request for a public meeting by submitting a written request to Marine Safety Office Savannah at the address listed in the **ADDRESSES** section of this notice of proposed rulemaking. This request should describe the benefits of a public meeting. If we determine that a public meeting would aid this rulemaking, we will hold one at a time and place announced by a separate notice in the **Federal Register**.

### Background and Purpose

The G8 (Group of 8) is an informal group of eight countries—Canada, France, Germany, Italy, Japan, Russia, the United Kingdom and the United States—whose leaders meet to discuss broad economic and foreign policies. The 30th G–8 summit will be held in Sea Island, Georgia, from June 8 through June 10, 2004.

Cities that have recently hosted conferences or summits similar to the G–8 Summit have experienced significant challenges to public safety, property damage, and their law enforcement officers and public citizens have sustained personal injuries from a small, but determined segment of protestors engaged in violent demonstration against those summits and their agendas. Examples include the September 2003 World Trade Organization (WTO) Ministerial in Cancun, Mexico; the 2003 G–8 Summit in Calgary, Canada, the 2001 G–8 Summit in Genoa, Italy; and the 1999 World Trade Organization in Seattle, Washington. These conferences and summits experienced an influx of protestors, and in particular protest groups opposing international trade who have a propensity for violence and a desire to engage in hostile acts against, among others, summit attendees, conference venues, the general public, business and municipal buildings, and law enforcement officials. Information and intelligence indicates that there is a high potential for similar acts to be attempted during the upcoming June G–8 Summit in Savannah, Georgia.

This history has heightened the need for the development and implementation of various security measures in the vicinity of the Savannah River, particularly around venue areas established for the dignitaries and official parties attending the G–8 Summit, critical port facilities and infrastructure, bridges, and the navigable waterways. The Coast Guard has determined from information provided by local, state, and federal law enforcement officials that vessels or persons in close proximity to the G–8 Summit may launch hostile or violent acts from the waterways adjacent to the Summit and from the waterways adjacent to where Summit attendees are staying. The potential for these acts poses a threat to public safety and security, the G–8 Summit and its participants, and the flow of commerce on the navigable waterways.

The proposed temporary security zones and proposed temporary regulated navigation area are being established to mitigate these threats and are necessary to protect public safety, the G–8 conference and attendees, law enforcement officers, the Port of Savannah and commerce within the port from persons attempting hostile and violent acts.

Please note that elsewhere in today's **Federal Register**, we have published another proposed rule also intended to provide security of the public, the G–8 Summit and its participants, and the safety of the waterways during the same time as this proposed rule. That other proposed rule is COTP Savannah–04–041, entitled "Security Zone, St. Simons Sound and the Atlantic Ocean, GA.''

**Discussion of Rule**

The proposed temporary security zones would prohibit all vessels and persons from entering the waters encompassed by the following areas unless they first obtain permission from the Captain of the Port of Savannah or his designated representatives by calling on VHF Channel Marine 16 or at (912) 652–4353:

(1) *Savannah River.* An imaginary line starting at Channel Light 22, (Light List Volume III, Number 5090), at the intersection of the Middle River and the Savannah River and crossing due West over the Savannah River to Port Wentworth at approximate point 32°08′47″ N, 081°06′36″ W; then all waters of the Savannah River from shore to shore and surface to bottom south and east of this imaginary line downriver to an imaginary line starting at the south east tip of Elba Island at approximate point 32°04′19″ N, 080°58′27″ W and extending due north across the Savannah River and through Red Buoy #36 to approximate point 32°04′40″ N, 080°58′19″ W.

(2) *Back River.* The proposed security zone also includes all waters of the Back River south and east of the Highway 17 bridge from shore to shore and surface to bottom easterly to where the Back River meets the Savannah River.

(3) *South Channel Elba Island.* The proposed security zone also includes all waters of the South Channel south of Elba Island, from shore to shore and surface to bottom, from the intersection of the Savannah River and the South Channel and continuing south easterly to an imaginary line starting at the south east tip of Elba Island at approximate point 32°04′19″ N, 080°58′27″ W and extending south westerly following the northern edge of Elba Island Cut channel to the north east tip of McQueen Island at approximate position 32°04′08″ N, 080°58′55″ W.

(4) *Intracoastal Waterway Alternate Route.* The proposed security zone also includes all waters of the Intracoastal Waterway Alternate Route from shore to shore and surface to bottom from St. Augustine Creek Day Beacon A18 (Light List, Vol. III, no. 35960) to Day Beacon A12 (Light List, Vol. III, no. 35945).

The proposed temporary RNA would require all vessels to obtain permission from the Captain of the Port of Savannah or his designated representatives via VHF Channel Marine 16, before entering or transiting the RNA and would require all vessels to proceed continuously and at a slow speed while transiting within the RNA. Specific security concerns may cause the Captain of the Port to delay the grant of permission to enter or transit the RNA. All vessels within the proposed temporary RNA are subject to control by the Captain of the Port of Savannah and his designated representatives—normally Coast Guard and law enforcement patrol craft in the area. The proposed temporary RNA includes all waters encompassed by the following areas:

(1) *Savannah River, Lower Flats Range.* An imaginary line starting at the south east tip of Elba Island at approximate point 32°04′19″ N, 080°58′27″ W and extending due north across the Savannah River and through Red Buoy #36 to approximate point 32°04′40″ N, 080°58′19″ W and all waters of the Savannah River southeast of that line, from shore to shore and surface to bottom in the vicinity of Lower Flats Range, to an imaginary line starting at the western tip of Jones Island at the intersection of the Intracoastal Waterway and extending southwesterly across the Savannah River intersecting through Green buoy "35'' to Bird Island at approximate point 32°04′15″ N, 080°58′00″ W.

(2) *Intracoastal Waterway.* All waters of the Intracoastal Waterway from shore to shore and surface to bottom from Fields Cut Buoy 48 (Light List, Vol. III, no. 35865) at Wright River to Elba Island Cut Light 10 (Light List, Vol. III no. 35900) at St. Augustine Creek.

The proposed temporary RNA is necessary to ensure the safety of the public, critical port facilities and infrastructure, the G–8 Summit and the navigable waters of the United States.

Information and past experience indicate the G–8 demonstrators may attempt to interfere with commercial shipping, both underway and while moored. Attempts may include unauthorized boardings of vessels while underway or moored in an effort to interrupt commerce and port operations. Additionally, demonstrators may attempt unauthorized entry into or upon commercial and government facilities located along the Savannah River for these same reasons. The proposed temporary RNA, by regulating the movement of vessels by requiring vessels to obtain permission prior to entering or transiting the zone and imposing a slow speed zone will assist law enforcement officers in ensuring the safety and security of the Port of Savannah, critical port facilities and infrastructure, the G–8 Summit and the navigable waters of the United States.

The temporary RNA requires all vessels within the regulated navigation area to proceed continuously and at a slow speed. Slow speed is defined as the speed at which a vessel proceeds when it is fully off plane, completely settled into the water and not creating an excessive wake. In no instance shall slow speed be interpreted as a speed less than that required to maintain steerageway. Requiring vessels within the temporary RNA to transit at a slow speed will allow law enforcement officers to identify, respond to, stop, and query vessels that are suspected of presenting a threat to the public, the Port of Savannah, and the G–8 Summit. Specifically, the slow speed requirement will allow the Coast Guard to adequately protect against threats of hostile and violent acts carried out by smaller vessels against commercial vessels or critical port facilities and infrastructure. The slow speed requirement enhances the ability of the Captain of the Port and his designated representatives to control the movement of vessels with the proposed temporary RNA which will further provide for the safety of the public, the Port of Savannah and the G–8 Summit.

Nothing in the RNA alleviates vessels or operators from complying with all state and local laws.

**Regulatory Evaluation**

This proposed rule is not a "significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not "significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS).

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary.

**Small Entities**

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term "small entities'' comprises small businesses, not-for-profit

organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

This proposed rule would affect the following entities, some of which might be small entities: the owners or operators of vessels intending to transit or anchor in portions of the Savannah River and the Intracoastal Waterway covered by these proposed security zones and regulated navigation areas.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

**Assistance for Small Entities**

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed under the **FOR FURTHER INFORMATION CONTACT** section.

**Collection of Information**

This proposed rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

**Federalism**

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this proposed rule under that Order and have determined that it does not have implications for federalism.

**Unfunded Mandates Reform Act**

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this proposed rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

**Taking of Private Property**

This proposed rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

**Civil Justice Reform**

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

**Protection of Children**

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

**Indian Tribal Governments**

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does 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. We invite your comments on how this proposed rule might impact tribal governments, even if that impact may not constitute a "tribal implication'' under the Order.

**Energy Effects**

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action'' under that order because it is not a "significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

**Environment**

We have analyzed this proposed rule under Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation.

**List of Subjects in 33 CFR Part 165**

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 part 165 as follows:

## PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1226, 1231; 50 U.S.C. 191, 195; 46 U.S.C. Chapter 701; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1

2. From 8 a.m. on June 5, 2004, until 4 p.m. on June 11, 2004 add a new temporary § 165.T07–040 to read as follows:

### § 165.T07–040 Temporary Security Zone and Temporary Regulated Navigation Areas, Savannah River, GA

(a) *Locations.*

(1) *Security Zone, Savannah River.* An imaginary line starting at Channel Light 22, (Light List Volume III, Number 5090), at the intersection of the Middle River and the Savannah River and crossing due West over the Savannah River to Port Wentworth at approximate point 32°08′47″ N, 081°06′36″ W; then all waters of the Savannah River from shore to shore and surface to bottom south and east of this imaginary line downriver to an imaginary line starting at the southeast tip of Elba Island at approximate point 32°04′19″ N, 080°58′27″ W and extending due north across the Savannah River and through Red Buoy #36 to approximate point 32°04′40″ N, 080°58′19″ W. All coordinates are based upon North American Datum 83 (NAD 83).

(2) *Security Zone, Back River.* All waters of the Back River south and east

of the Highway 17 bridge from shore to shore and surface to bottom easterly to where the Back River meets the Savannah River.

(3) *Security Zone, South Channel Elba Island.* All waters of the South Channel south of Elba Island, from shore to shore and surface to bottom, from the intersection of the Savannah River and the South Channel and continuing southeasterly to an imaginary line starting at the southeast tip of Elba Island at approximate point 32°04′19″ N, 080°58′27″ W and extending southwesterly following the northern edge of Elba Island Cut channel to the northeast tip of McQueen Island at approximate position 32°04′08″ N, 080°58′55″ W. All coordinates are based upon North American Datum 83 (NAD 83).

(4) *Security Zone, Intracoastal Waterway Alternate Route.* All waters of the Intracoastal Waterway Alternate Route from shore to shore and surface to bottom from St. Augustine Creek Day Beacon A18 (Light List, Vol. III, no. 35960) to Day Beacon A12 (Light List, Vol. III, no. 35945).

(5) *Regulated navigation area; Savannah River, Lower Flats Range.* An imaginary line starting at the southeast tip of Elba Island at approximate point 32°04′19″ N, 080°58′27″ W and extending due north across the Savannah River and through Red Buoy #36 to approximate point 32°04′40″ N, 080°58′19″ W and all waters of the Savannah River southeast of that line, from shore to shore and surface to bottom in the vicinity of Lower Flats Range, to an imaginary line starting at the western tip of Jones Island at the intersection of the Intracoastal Waterway and extending southwesterly across the Savannah River intersecting through Green buoy "35'' to Bird Island at approximate point 32°04′15″ N, 080°58′00″ W. All coordinates are based upon North American Datum 83 (NAD 83).

(6) *Regulated navigation area; Intracoastal Waterway Fields Cut.* All waters of the Intracoastal Waterway from shore to shore and surface to bottom from Fields Cut Buoy 48 (Light List, Vol. III, no. 35865) at Wright River to Elba Island Cut Light 10 (Light List, Vol. III no. 35900) at St. Augustine Creek. All coordinates are based upon North American Datum 83 (NAD 83).

(b) *Definitions.* The following definitions apply to this section:

*Designated Representatives* means Coast Guard Patrol Commanders including Coast Guard coxswains, petty officers and other officers operating Coast Guard vessels, and Federal, State, and local officers designated by or assisting the Captain of the Port of Savannah, to regulate the movement of vessels within the RNA and restrict vessels and persons from entering the security zones.

*Slow speed* means the speed at which a vessel proceeds when it is fully off plane, completely settled in the water and not creating excessive wake. Due to the different speeds at which vessels of different sizes and configurations may travel while in compliance with this definition, no specific speed is assigned to slow speed. In no instance should slow speed be interpreted as a speed less than that required to maintain steerageway. A vessel is not proceeding at slow speed if it is:

(1) On a plane;

(2) In the process of coming up onto or coming off a plane; or

(3) Creating an excessive wake.

(c) *Regulations.* (1) *Security Zones.* The regulations in this paragraph apply to the zones in paragraphs (a)(1) through (a)(4) of this section. Entry into or transiting within the security zones is prohibited unless authorized by the Coast Guard Captain of the Port, Savannah, Georgia or that officer's designated representatives. Vessels moored, docked or anchored in the security zones when they become effective must remain in place unless ordered by or given permission from the COTP to do otherwise. Persons desiring to enter or transit the areas encompassed by the security zones may contact the Coast Guard on VHF Channel Marine 16 or at (912) 652–4353 to seek permission to enter or transit the area. If permission is granted, all persons and vessels must comply with the instructions of the Captain of the Port or that officer's designated representatives.

(2) *Regulated Navigation Areas.* The regulations in this paragraph apply to the areas in paragraph (a)(5) and (a)(6) of this section.

(i) All vessels entering and transiting through the regulated navigation area shall proceed continuously and at a slow speed. In no instance should slow speed be interpreted as a speed less than that required to maintain steerageway. Nothing in this rule alleviates vessels or operators from complying with all state and local laws in the area.

(ii) All vessels shall comply with orders from the Coast Guard Captain of the Port of Savannah or that officer's designated representatives, regulating their speed, course, direction and movements within the RNA. All vessels shall obtain the permission of the Captain of the Port prior to entering or transiting via VHF Channel 16.

(d) *Effective period:* This section is effective from 8 a.m. on June 5, 2004, until 4 p.m. on June 11, 2004.

Dated: March 30, 2004.

**Harvey E. Johnson, Jr.,**

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

[FR Doc. 04–7995 Filed 4–7–04; 8:45 am]

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## 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/public_laws/public_laws.html*.

The text of laws is not published in the **Federal Register** but may be ordered in "slip law" (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO Access at *http://www.gpoaccess.gov/plaws/index.html*. Some laws may not yet be available.

**H.R. 254/P.L. 108–215**

To authorize the President of the United States to agree to certain amendments to the Agreement between the Government of the United States of America and the Government of the United Mexican States concerning the establishment of a Border Environment Cooperation Commission and a North American Development Bank, and for other purposes. (Apr. 5, 2004; 118 Stat. 579)

**H.R. 3926/P.L. 108–216**

Organ Donation and Recovery Improvement Act (Apr. 5, 2004; 118 Stat. 584)

**H.R. 4062/P.L. 108–217**

To provide for an additional temporary extension of programs under the Small Business Act and the Small Business Investment Act of 1958 through June 4, 2004, and for other purposes. (Apr. 5, 2004; 118 Stat. 591)

**Last List April 5, 2004**

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