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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–1299; Directorate Identifier 2011–NE–40–AD; Amendment 39–16878; AD 2011–25–02]

RIN 2120–AA64

Airworthiness Directives; BRP–Powertrain GmbH & Co. KG Reciprocating Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for BRP–Powertrain GmbH & Co. KG Rotax 912 F2, 912 F3, 912 F4, 912 S2, 912 S3, 912 S4, 914 F2, 914 F3, and 914 F4 reciprocating engines. This AD results from mandatory continuing airworthiness information (MCAI) issued by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

During a production process review, a deviation in the manufacturing process of certain part number (P/N) 888164 crankshafts has been detected, which may have resulted in a latent defect. This condition, if not corrected, could lead to crack formation on the power takeoff side of the crankshaft journal, possibly resulting in failure of the crankshaft support bearing, in-flight engine shutdown and forced landing, damage to the aeroplane and injury to the occupants.

We are issuing this AD to prevent in-flight failure of the engine and forced landing.

DATES: This AD becomes effective December 22, 2011.

We must receive comments on this AD by January 6, 2012.

The Director of the Federal Register approved the incorporation by reference of BRP–Powertrain GmbH & Co. KG, Rotax Aircraft Engines, Mandatory Alert Service Bulletins (ASB) Nos. ASB–912–059 and ASB 914–042 (combined in one document), dated November 15, 2011, listed in the AD as of December 22, 2011.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* (202) 493–2251.

For service information identified in this AD, contact BRP–Powertrain GmbH & Co. KG, Welser Strasse 32, A–4623 Gunskirchen, Austria, or go to: *http://www.rotax-aircraft-engines.com.* You may review copies of the referenced service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call (781) 238–7125.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (phone: (800) 647–5527) is the same as the Mail address provided in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Alan Strom, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; email: *alan.strom@faa.gov;* phone: (781) 238–7143; fax: (781) 238–7199.

SUPPLEMENTARY INFORMATION:

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD 2011–0222–E, dated November 15, 2011 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

During a production process review, a deviation in the manufacturing process of certain part number (P/N) 888164 crankshafts has been detected, which may have resulted in a latent defect. This condition, if not corrected, could lead to crack formation on the power takeoff side of the crankshaft journal, possibly resulting in failure of the crankshaft support bearing, in-flight engine shutdown and forced landing, damage to the aeroplane and injury to the occupants.

You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

We reviewed BRP–Powertrain GmbH & Co. KG, Rotax Aircraft Engines, Mandatory ASB Nos. ASB–912–059 and ASB 914–042 (combined in one document), dated November 15, 2011. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of this AD

This product has been approved by the aviation authority of Austria, and is approved for operation in the United States. Pursuant to our bilateral agreement with the European Community, EASA has notified us of the unsafe condition described in the MCAI and service information referenced above. We are issuing this AD because we evaluated all information provided by EASA and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Differences Between the AD and the MCAI or Service Information

None.

FAA's Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because of the short compliance

time of 4 operating hours, and the risk to single-engine airplanes affected. Therefore, we determined that notice and opportunity for public comment before issuing this AD are impracticable and that good cause exists for making this amendment effective in fewer than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not precede it by notice and opportunity for public comment. We invite you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2011–1299; Directorate Identifier 2011–NE–40–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this AD. Using the search function of the Web site, anyone can find and read the comments in any of our dockets, including, if provided, the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, *etc.*). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this AD:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

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

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2011–25–02 BRP-Powertrain GmbH & Co. KG (formerly BRP-Rotax GmbH & Co KG, Bombardier-Rotax GmbH & Co. KG, and Bombardier-Rotax GmbH): Amendment 39–16878; Docket No. FAA–2011–1299; Directorate Identifier 2011–NE–40–AD.

(a) Effective Date

This airworthiness directive (AD) becomes effective December 22, 2011.

(b) Affected ADs

None.

(c) Applicability

This AD applies to BRP-Powertrain GmbH & Co. KG Rotax 912 F2, 912 F3, 912 F4, 912 S2, 912 S3, 912 S4, 914 F2, 914 F3, and 914 F4 reciprocating engines, with the following part number (P/N) 888164 crankshafts installed.

TABLE 1—AFFECTED P/N 888164 CRANKSHAFT SERIAL NOS. (S/NS)

S/Ns 40232 through 40267 inclusive.
S/Ns 40293 through 40374 inclusive.
S/Ns 40408 through 40433 inclusive.
S/Ns 40435 through 40507 inclusive.

(d) Reason

This AD results from mandatory continuing airworthiness information (MCAI) issued by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

During a production process review, a deviation in the manufacturing process of certain part number (P/N) 888164 crankshafts has been detected, which may have resulted in a latent defect. This condition, if not corrected, could lead to crack formation on the power takeoff side of the crankshaft journal, possibly resulting in failure of the crankshaft support bearing, in-flight engine shutdown and forced landing, damage to the aeroplane and injury to the occupants.

We are issuing this AD to prevent in-flight failure of the engine and forced landing.

(e) Actions and Compliance

Unless already done, do the following actions.

(1) Within 4 flight hours after the effective date of this AD, clean and fluorescent-penetrant-inspect the crankshaft for cracks, in accordance with the Accomplishment Instructions paragraphs 3.1)4., 3.1)6., and Figure 1 of BRP–Powertrain GmbH & Co. KG, Rotax Aircraft Engines, Mandatory Alert Service Bulletins (ASB) Nos. ASB–912–059 and ASB 914–042 (combined in one document), dated November 15, 2011.

(2) If any crack is found, remove the crankshaft from service.

(f) Installation Prohibition

(1) After the effective date of this AD, do not install an engine having an affected P/N 888164 crankshaft installed, listed in Table 1 of this AD, on any airplane, unless the crankshaft has passed the inspection specified in paragraph (e)(1) of this AD.

(2) After the effective date of this AD, do not install an affected P/N 888164 crankshaft listed in Table 1 of this AD, in any engine, unless the crankshaft has passed the inspection specified in paragraph (e)(1) of this AD.

(g) FAA AD Differences

None.

(h) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request.

(i) Related Information

(1) Refer to MCAI European Aviation Safety Agency AD 2011–0222–E, dated November 15, 2011, for related information.

(2) Contact Alan Strom, Aerospace Engineer, Engine Certification Office, FAA,

Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; email: *alan.strom@faa.gov;* phone: (781) 238–7143; fax: (781) 238–7199, for more information about this AD.

(j) Material Incorporated by Reference

You must use BRP–Powertrain GmbH & Co. KG, Rotax Aircraft Engines, Mandatory Alert Service Bulletins Nos. ASB 912–059 and ASB 914–042 (combined in one document), dated November 15, 2011, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact BRP–Powertrain GmbH & Co. KG, Welser Strasse 32, A–4623 Gunskirchen, Austria, or go to: *http://www.rotax-aircraft-engines.com.*

(3) You may review copies of the service information at the FAA, New England Region, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call (781) 238–7125.

(4) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at an NARA facility, call (202) 741–6030, or go to *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Burlington, Massachusetts, on November 29, 2011.

Peter A. White,

Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2011–31501 Filed 12–6–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 110

[USCG–2011–0231]

RIN 1625–AA01

Anchorage Regulations; Wells, ME

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing three special anchorage areas in Wells Harbor, Wells, Maine. This action is necessary to facilitate safe navigation in that area and provide safe and secure anchorages for vessels not more than 20 meters in length. This action is intended to increase the safety of life and property in Wells Harbor, improve the safety of anchored vessels, and provide for the overall safe and efficient flow of vessel traffic and commerce.

DATES: This rule is effective January 6, 2012.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2011–0231 and are available online by going to *http://www.regulations.gov,* inserting USCG–2011–0231 in the ''Keyword'' box, and then clicking ''Search.'' This material is also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. John J. Mauro, Waterways Management Branch Chief, First Coast Guard District; telephone (617) 223–8355, email *John.J.Mauro@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On August 23, 2011, we published a notice of proposed rulemaking (NPRM) entitled ''Anchorage Regulations; Wells, Maine'' in the **Federal Register** (76 FR 52599). We received no comments on the proposed rule. A public meeting was not requested and none was held.

Basis and Purpose

The legal basis for this rule is 33 U.S.C. 471, 1221 through 1236, 2030, 2035, 2071; 33 CFR 1.05–1; and Department of Homeland Security Delegation No. 0170.1, which collectively authorize the Coast Guard to define anchorage grounds.

This rule is intended to reduce the risk of vessel collisions by creating three special anchorage areas in the western, central and eastern portions of Wells Harbor creating anchorage for approximately 150 vessels.

Background

This rule creates three new special anchorage areas in Wells, Maine. These three new special anchorage areas in Wells Harbor are described below. All coordinates are North American Datum 1983 (NAD 83).

Vessels not more than 20 meters in length are not required to sound signals as per Rule 35 of the Inland Navigation Rules (33 U.S.C. 2035) nor exhibit anchor lights or shapes as per Rule 30 of the Inland Navigation Rules (33 U.S.C. 2030) when at anchor in a special anchorage area. Mariners utilizing the anchorage areas are encouraged to contact local and state authorities, such as the local harbormaster, to ensure compliance with any additional applicable state and local laws. Such laws may involve, for example, compliance with direction from the local harbormaster when placing or using moorings within the anchorage.

Discussion of Comments and Changes

The Coast Guard received no comments on the proposed rulemaking. We have finalized the rule as proposed, without change.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Executive Order 12866 and Executive Order 13563

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, 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.

Although this regulation may have some impact on the public, the potential impact will be minimized for the following reasons: Normal surface navigation will not be affected as this area has been historically used as a mooring field by the Town of Wells and the number of vessels using the anchorage is limited due to depth (less than or equal to 18 feet).

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule will 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 could affect the following

entities, some of which might be small entities: The owners or operators of recreational and small fishing vessels intending to anchor in Wells Harbor. The rule will not have a significant economic impact on a substantial number of small entities for the following reasons: normal surface navigation will not be affected as this area has been historically used as a mooring field by the Town of Wells and the number of vessels using the anchorage is limited due to depth (less than or equal to 18 feet).

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), in the NPRM we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process.

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). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

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 (adjusted for inflation) 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 cause 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 would not create an environmental risk to health or risk to safety that might 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.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(f) of the Instruction because it involves the establishment of special anchorage grounds. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 110

Anchorage grounds.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 110 as follows:

PART 110—ANCHORAGE REGULATIONS

■ 1. The authority citation for part 110 continues to read as follows:

Authority: 33 U.S.C. 471; 1221 through 1236, 2030, 2035, 2071; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 110.9 to subpart A to read as follows:

§ 110.9 Wells Harbor, Maine.

(a) *Anchorage ''A''.* All of the waters enclosed by a line beginning at latitude 43°19′15.7″ N, longitude 070°33′42.1″ W; thence to latitude 43°19′15.7″ N, longitude 070°33′40.3″ W; thence to latitude 43°19′2.6″ N, longitude 070°33′45.7″ W; thence to latitude 43°19′3.7″ N, longitude 70°33′42.6″ W;

thence to the point of beginning. This area is approximately 5,800 sq. yards, encompassing the central portion of Wells Harbor.

(b) *Anchorage ''B''.* All of the waters enclosed by a line beginning at latitude 43°19′11.1″ N, longitude 070°33′49.8″ W; thence to latitude 43°19′10.5″ N, longitude 070°33′47.3″ W; thence to latitude 43°19′8.7″ N, longitude 070°33′50.6″ W; thence to latitude 43°19′8.3″ N, longitude 070°33′47.3 W; thence to the point of beginning. This area is approximately 25,000 sq. yards, encompassing the western portion of Wells Harbor.

(c) *Anchorage ''C''.* All of the waters enclosed by a line beginning at latitude 43°19′17.7″ N, longitude 070°33′34.0″ W; thence to latitude 43°19′18.4″ N, longitude 070°33′32.9″ W; thence to latitude 43°19′13.0″ N, longitude 070°33′26.2″ W; thence to latitude 43°19′13.8″ N, longitude 070°33′25.5″ W; thence to the point of beginning. This area is approximately 8,200 sq. yards, encompassing the eastern portion of Wells Harbor.

(d) *Regulations:* This area is principally for use by yachts and other recreational craft. Temporary floats or buoys for marking anchors or moorings in place are allowed in this area. Fixed mooring piles or stakes are not allowed. All moorings or anchors shall be placed well within the anchorage areas so that no portion of the hull or rigging will at any time extend outside of the anchorage.

Note to § 110.9: All anchoring in the areas is under the supervision of the Wells Harbor Master or other such authority as may be designated by the authorities of the Town of Wells, Maine. All coordinates referenced use datum: NAD 83.

Dated: November 21, 2011.

Daniel A. Neptun,

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

[FR Doc. 2011–31226 Filed 12–6–11; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2011–1090]

Drawbridge Operation Regulation; Willamette River, Portland, OR

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Thirteenth Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Morrison Bridge across the Willamette River, mile 12.8, at Portland, OR. The deviation is necessary to complete major rehabilitation of the bridge. This deviation allows single leaf operations during rehabilitation and requires a two hour advance notification for a single leaf opening.

DATES: This deviation is effective from 6 a.m. on December 1, 2011 through 6 p.m. on May 27, 2012.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2011–1090 and are available online by going to *http://www.regulations.gov,* inserting USCG–2011–1090 in the ''Keyword'' box and then clicking ''Search''. They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email the Bridge Administrator, Coast Guard Thirteenth District; telephone (206) 220–7282 email *randall.d. overton@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION: Multnomah County has requested to operate the Morrison Bascule Bridge with single leaf openings with two hours advance notice. Single leaf openings are required to facilitate major maintenance activity and deck rehabilitation on the bridge. The Morrison Bridge crosses the Willamette River at mile 12.8. The Morrison Bridge is charted on NOAA Chart 18526 with a vertical clearance of 69 ft above Columbia River Datum Mean Lower Low Water in the closed position. Under normal operations the bridge operates under 33 CFR 117.897 which requires a one hour notice for openings between 8 a.m. and 5 p.m. on weekdays and two hour notice for openings at all other times. This current deviation states the Morrison Bridge is allowed to operate with single leaf openings. The bridge will promptly open a single leaf when at least two hours of advanced notice is given. This deviation is effective from 6 a.m. on December 1, 2011 through 6 p.m. on May 27, 2012. This stretch of the Willamette River experiences moderate maritime traffic volumes including vessels ranging from small recreational craft to commercial tug and tow. During this maintenance period a debris containment system will be attached to the inoperable bascule leaf and will reduce the vertical clearance under the inoperable leaf up to 8 ft. Vessels which do not require a bridge opening may continue to transit beneath the bridge during this deviation period. An assist tug will be provided for larger vessels when maneuvering is constrained by the limited opening.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: November 23, 2011.

Randall D. Overton,

Bridge Administrator.

[FR Doc. 2011–31328 Filed 12–6–11; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2011–1037]

Drawbridge Operation Regulations; Hutchinson River, Bronx, NY

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Amtrak Pelham Bay Railroad Bridge at mile 0.5, across the Hutchinson River at the Bronx, New York. The deviation is necessary to facilitate scheduled maintenance at the bridge, pinion shaft bushing replacement. This deviation allows the bridge to remain in the closed position for four days.

DATES: This deviation is effective from 4 a.m. on December 2, 2011 through 4 a.m. on December 12, 2011.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2011–1037 and are available online at *http://www.regulations.gov,* inserting USCG–2011–1037 in the ''Keyword'' and then clicking ''Search''. They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE.,

Washington, DC, 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Judy Leung-Yee, Project Officer, First Coast Guard District, *judy.k.leung-yee@uscg.mil,* or telephone (212) 668–7165. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION: The Amtrak Pelham Bay Railroad Bridge, across the Hutchinson River at mile 0.5, at the Bronx, New York, has a vertical clearance in the closed position of 8 feet at mean high water and 15 feet at mean low water. The drawbridge operation regulations are listed at 33 CFR 117.5 and 33 CFR 117.793.

The waterway users are mostly commercial operators. The owner of the bridge, National Railroad Passenger Company (Amtrak), requested a temporary deviation from the regulations to facilitate scheduled maintenance, replace pinion shaft bushings, at the bridge.

Under this temporary deviation the Amtrak Pelham Bay Railroad Bridge may remain in the closed position from 10 p.m. on December 2, 2011 through 4 a.m. on December 5, 2011. In the event of inclement weather the bridge closure rain date will be from 10 p.m. on December 9, 2011 through 4 a.m. on December 12, 2011.

The commercial users were notified. No objections were received.

In accordance with 33 CFR 117.35(e), the bridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: November 16, 2011.

Gary Kassof,

Bridge Program Manager, First Coast Guard District.

[FR Doc. 2011–31329 Filed 12–6–11; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2011–1053]

Drawbridge Operation Regulation; Old Brazos River, Freeport, Brazoria County, TX

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Eighth Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Union Pacific Railroad Swing Span Bridge across the Old Brazos River, mile 4.4, at Freeport, Brazoria County, Texas. This deviation allows the bridge to remain closed to navigation for four days to replace lift cables.

DATES: This deviation is effective from 6 a.m. December 16 through 6 p.m. December 19, 2011.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2011–1053 and are available online by going to *http://www.regulations.gov,* inserting USCG–2011–1053 in the ''Keyword'' box and then clicking ''Search''. They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Jim Wetherington, Bridge Management Specialist, Eighth Coast Guard District, Bridge Administration Branch, telephone (504) 671–2128, *email: james.r.wetherington@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION: The Union Pacific Railroad Company has requested a temporary deviation from the published regulation for the Union Pacific Railroad Bridge across the Old Brazos River in 33 CFR 117.975 which states: The draw of the Union Pacific railroad bridge, mile 4.4 at Freeport, shall be maintained in the fully open position, except for the crossing of trains or for maintenance.

The requested deviation will allow the bridge to remain closed to marine traffic from 6 a.m. December 16 through 6 p.m. December 19, 2011. The clearance in the closed-to-navigation position is 10.67 feet above mean sea level (MSL).

This deviation will allow the lift span of the bridge to remain in the closed-to-navigation position in order for the cables to be replaced and re-tensioned. This work is necessary due to an ongoing bridge modification project, authorized by Coast Guard Bridge Permit Amendment P (7a–09–8) dated September 14, 2010. The project involves the replacement of the old swing span with the current vertical lift span.

Vessel traffic at the bridge site consists of commercial fishing vessels, commercial dive boats and recreational boats. There are no alternate routes. During the closure times, the process for tensioning the cables will allow the bridge to be able to open for emergencies and occasionally for the passage of vessels once the new cables are in place and being tensioned. Current waterway users above the bridge are aware of the closure and have not objected to this time period. Vessels that do not require an opening can pass at any time.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the designated time periods. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: November 21, 2011.

David M. Frank,

Bridge Administrator.

[FR Doc. 2011–31331 Filed 12–6–11; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2011–1071]

Drawbridge Operation Regulations; New Rochelle Harbor, New Rochelle, NY

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Glen Island Bridge, mile 0.8, across New Rochelle Harbor at New Rochelle, New York. The deviation is necessary to facilitate bridge rehabilitation repairs. This deviation allows the bridge to remain in the closed position to facilitate bridge rehabilitation.

DATES: This deviation is effective from December 5, 2011 through March 30, 2012.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2011–1071 and are available online at *http://www.regulations.gov,* inserting USCG–2011–1071 in the ''Keyword''

and then clicking ''Search''. They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Ms. Judy Leung-Yee, Project Officer, First Coast Guard District, *judy.k.leung-yee@uscg.mil,* or telephone (212) 668–7165. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

The Glen Island Bridge, across New Rochelle Harbor, mile 0.8, at New Rochelle, New York, has a vertical clearance in the closed position of 13 feet at mean high water and 20 feet at mean low water. The drawbridge operation regulations are listed at 33 CFR 117.802.

The waterway users are recreational vessels of various sizes. During the winter months the bridge rarely opens since the recreational vessels that transit this waterway are normally in winter storage.

The owner of the bridge, Westchester County, requested a temporary deviation from the regulations to help facilitate rehabilitation repairs at the bridge.

Under this temporary deviation the Glen Island Bridge may remain in the closed position from December 5, 2011 through March 30, 2012. Vessels that can pass under the bridge in the closed position may do so at any time.

The Coast Guard believes that this temporary deviation should meet the reasonable needs of navigation because the recreational users that normally use this bridge are recreational vessels that do not operate during the winter months when this deviation will be in effect.

In accordance with 33 CFR 117.35(e), the bridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: November 23, 2011.

Gary Kassof,

Bridge Program Manager, First Coast Guard District.

[FR Doc. 2011–31332 Filed 12–6–11; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2011–1073]

Drawbridge Operation Regulation; Atlantic Intracoastal Waterway (AIWW), Chesapeake, VA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Fifth Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the I64 Bridge across the Atlantic Intracoastal Waterway, South Branch of the Elizabeth River, mile 7.1, at Chesapeake, VA. The deviation is necessary for bridge rehabilitation and maintenance work. This deviation allows the bridge to remain in the closed-to-navigation position.

DATES: This deviation is effective from 7 a.m. on December 11, 2011 to 7 p.m. on December 18, 2011.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2011–1073 and are available online by going to *http://www.regulations.gov,* inserting USCG–2011–1073 in the ''Keyword'' box and then clicking ''Search''. They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lindsey Middleton, Bridge Management Specialist, Coast Guard; telephone (757) 398–6629, email *Lindsey.R.Middleton@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION: Virginia Department of Transportation (VDOT) has requested a temporary deviation from the current operating regulations of the I64 Bridge across the AIWW, South Branch of the Elizabeth River, mile 7.1 at Chesapeake, VA. The requested deviation is to accommodate the rehabilitation of the mechanical systems of the bridge and will allow the bridge to remain in the closed-to-navigation position throughout the week. The vertical clearance of this bridge is 65 feet at mean high water (MHW) in the closed-to-navigation position and unlimited in the open position. During this closure period, the vertical clearance in the closed position will remain at 65 feet at MHW and vessels able to pass under the bridge may do so at any time. The bridge will not be able to open for emergencies and there are no alternate routes available to vessels.

The current operating schedule for the bridge is set out in 33 CFR 117.997(e) which requires the bridge to open on signal if at least 24 hours notice is given.

VDOT has reached out to the main waterway user requiring bridge openings and schedules have been worked out accordingly. The majority of vessel traffic utilizing this waterway is tugs and tows. The Coast Guard will inform all other users of the waterway through our Local and Broadcast Notices to Mariners which will allow mariners to arrange their transits to minimize delay.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: November 22, 2011.

Waverly W. Gregory, Jr.,

Bridge Program Manager, by direction of the Commander, Fifth Coast Guard District.

[FR Doc. 2011–31330 Filed 12–6–11; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 155

[Docket No. USCG–2011–0576]

RIN 1625–AB75

Higher Volume Port Area—State of Washington

AGENCY: Coast Guard, DHS.

ACTION: Notice of intent.

SUMMARY: The Coast Guard announces that it intends to comply with recent legislation that would expand an existing higher volume port area (HVPA) for Puget Sound and the Strait of Juan de Fuca. The expansion would add Pacific Ocean waters, under U.S. jurisdiction and within a 50-mile arc measured from Cape Flattery, Washington, to the HVPA. Higher volume port areas require certain tankers to plan for faster response times following a spill of the tanker's cargo.

The expansion could require a tanker's owner or operator to review and modify the tanker's existing vessel response plan (VRP) accordingly, and to receive Coast Guard approval for the modified VRP by October 15, 2015.

ADDRESSES: The docket for this notice of intent is available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet by going to *http://www.regulations.gov,* inserting USCG–2011–0576 in the ''Keyword'' box, and then clicking ''Search.''

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of intent, call or email LT Evelynn Samms, U.S. Coast Guard Office of Vessel Activities; telephone (202) 372–1225, email *Evelynn.B.Samms@uscg.mil.* If you have questions on viewing the material in the docket, call Ms. Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION: A tanker is required by U.S. law and Coast Guard regulations to have a vessel response plan (VRP) if its cargo consists of petroleum or non-petroleum oil, animal fat, and/or vegetable oil. A VRP describes how the tanker prevents, mitigates, or responds to spills of its cargo. See 33 CFR 155.1010, 33 CFR 155.1110, and 33 CFR 155.1210. In describing how the tanker would respond to a spill, the VRP must demonstrate the tanker's ability to deploy specific response resources within one of three different timeframes (Tiers 1 through 3). 33 CFR 155.1020. Those response resources typically include the services of nearby response vessels under a contract between the tanker's owner or operator and an oil spill response organization that owns the response vessel. In 14 higher volume port areas (HVPAs) defined in 33 CFR 155.1020, the risk of a cargo spill is considered higher than normal because of a higher volume of shipping activity in these HVPAs. To offset the increased risk, these HVPAs require faster response times for each Tier.

The Coast Guard Authorization Act of 2010 (''the Act''), Pub. L. 111–281, 124 Stat. 2905, was enacted on October 15, 2010, and provides the authority for issuing this notice of intent. Section 710 of the Act requires the Coast Guard to undertake action that will lead to the expansion of the HVPA in the Strait of Juan de Fuca and Puget Sound, Washington. Expansion would be achieved by moving the seaward boundary of the HVPA, currently a 50-mile arc centered on the entrance to Port Angeles, Washington, westward to Cape Flattery, Washington. Moving the seaward boundary would add Pacific Ocean waters that are under U.S. jurisdiction and within a 50-mile arc measured from Cape Flattery to the Strait of Juan de Fuca and Puget Sound. We added an excerpt from navigation chart 18480, ''Approaches to Strait of Juan de Fuca—Destruction Island to Amphitrite Point,'' showing the revised HVPA, to the docket.

A currently valid VRP attests to a tanker's ability to comply with HVPA response time requirements within the more sheltered waters of the current HVPA, but the same tanker may need to revise its VRP to account for spill response in the open ocean waters of the future expanded HVPA. There may also be some tankers that do not operate within the current boundaries of the HVPA, but that do operate in the open ocean offshore of those boundaries, and these tankers may need to revise their VRPs to show how they will comply with HVPA requirements once those ocean waters become part of the HVPA.

The Act further requires that, if a VRP needs to be revised in light of the boundary change, the Coast Guard must approve the revision not later than October 15, 2015. Our purpose in issuing this document is to announce our intent to comply with the Act. The HVPA has not yet been expanded; therefore, we cannot require tanker owners and operators to revise VRPs in preparation for expansion at this time. However, if you would be affected by the future expansion of the HVPA and would need a VRP covering the expanded area, we advise you to begin developing a VRP now so that you can submit it in time for Coast Guard review and approval before the mandatory October 15, 2015, deadline.

Dated: November 23, 2011.

Paul F. Thomas,

Captain, U.S. Coast Guard, Acting Director of Prevention Policy.

[FR Doc. 2011–31218 Filed 12–6–11; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA–HQ–OPPT–2011–0109; FRL–8892–2]

RIN 2070–AB27

Revocation of the Significant New Use Rule on a Certain Chemical Substance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is revoking a significant new use rule (SNUR) promulgated under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for the chemical substance identified generically as substituted ethoxyethylamine phosphonate, which was covered by premanufacture notice (PMN) P–95–1950. EPA issued a SNUR designating certain activities as significant new uses based on the concern criteria. Subsequently, EPA received and reviewed new information and test data for the chemical substance. Based on the new information and test data, the Agency no longer finds that the activities not described in PMN P–95–1950 constitute significant new uses.

DATES: This final rule is effective February 6, 2012.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPPT–2011–0109. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave. NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are

processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; *telephone number:* (202) 564–9232; *email address: moss.kenneth@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; *telephone num*ber: (202) 554–1404; *email address: TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Does this action apply to me?

You may be potentially affected by this action if you manufacture, import, process, or use the chemical substance contained in this revocation. Potentially affected entities may include, but are not limited to:

- Manufacturers, importers, or processors of the subject chemical substance (NAICS codes 325 and 324110), *e.g.,* chemical manufacturing and petroleum refineries.

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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in § 721.5. 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**.

II. Background

A. What action is the agency taking?

In the **Federal Register** of May 11, 2011 (76 FR 27294) (FRL–8871–3), the Agency proposed revocation of the SNUR at 40 CFR 721.6078 for the chemical substance identified generically as substituted ethoxyethylamine phosphonate (PMN P–95–1950). The comment period for the proposed rule closed on June 10, 2011; EPA received no comments on the action.

Based on the results of submitted aquatic toxicity testing for the chemical substance, EPA has determined that the substance has inherently low toxicity, mitigating concerns for toxicity to aquatic organisms. Therefore, EPA rescinds its determination that releases to water resulting in stream concentrations that exceed 30 parts per billion (ppb) may cause significant adverse environmental effects. Based on available information, the substance no longer meets the concern criteria at § 721.170(b)(4)(ii). Therefore, EPA is revoking the SNUR for this chemical substance pursuant to § 721.185(a)(4).

B. What is the agency's authority for taking this action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a ''significant new use.'' EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture, import, or process the chemical substance for that use. The mechanism for reporting under this requirement is established under § 721.5.

Upon conclusion of the review for PMN P–95–1950, based on the concern criteria in § 721.170(b)(4)(ii), EPA determined that there was a concern for potential environmental effects of the substance and promulgated a SNUR for this chemical substance.

Under § 721.185, EPA may at any time revoke a SNUR for a chemical substance which has been added to subpart E of 40 CFR part 721 if EPA makes one of the determinations set forth in § 721.185 (a)(1) through (a)(6). Revocation may occur on EPA's initiative or in response to a written request. EPA has determined that the criteria set forth in § 721.185(a)(4) have been satisfied for the chemical substance. Therefore, EPA is hereby revoking the SNUR provisions for this chemical substance. When this final revocation becomes effective, EPA will no longer require notice of intent to manufacture, import, or process this substance for any significant new uses. In addition, export notification under TSCA section 12(b) and 40 CFR part 707, subpart D triggered by the SNUR would no longer be required.

III. Statutory and Executive Order Reviews

This rule revokes or eliminates an existing regulatory requirement and does not contain any new or amended requirements. As such, the Agency has determined that this SNUR revocation would not have any adverse impacts, economic or otherwise.

The Office of Management and Budget (OMB) has exempted these types of regulatory actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This rule does not contain any information collections subject to approval under the Paperwork Reduction Act (PRA), (44 U.S.C. 3501 *et seq.*). Since this rule eliminates a reporting requirement, the Agency certifies pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), that this SNUR revocation would not have a significant economic impact on a substantial number of small entities.

For the same reasons, this action does not require any action under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). This rule has neither Federalism implications, because it would not have substantial direct effects 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), nor tribal implications, because it would not have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes, as specified in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000).

This action is not subject to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined under Executive Order 12866, and it does not address environmental health or safety risks disproportionately affecting children. It 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. Because this action does not involve any technical standards, 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), does not apply to this action. This action does not involve special considerations of environmental justice related issues as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

IV. 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 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

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: November 29, 2011.

Wendy C. Hamnett,

Director, Office of Pollution Prevention and Toxics.

Therefore, 40 CFR parts 9 and 721 are amended as follows:

PART 9—[AMENDED]

1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.,* 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.,* 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345(d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.,* 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

■ 2. The table in § 9.1 is amended by removing under the undesignated center heading ''Significant New Uses of Chemical Substances'' § 721.6078.

PART 721—[AMENDED]

■ 3. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

§ 721.6078 [Removed]

■ 4. Remove § 721.6078.

[FR Doc. 2011–31393 Filed 12–6–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R05–OAR–2008–0395; FRL–9499–6]

Approval and Promulgation of Air Quality Implementation Plans; Indiana; Redesignation of Lake and Porter Counties to Attainment of the Fine Particulate Matter Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is taking several related actions affecting Lake and Porter Counties and the State of Indiana for the 1997 annual fine particulate matter ($PM_{2.5}$) National Ambient Air Quality Standard (NAAQS or standard). EPA is approving a request from the State of Indiana for the redesignation of Lake and Porter Counties to attainment of the 1997 annual $PM_{2.5}$ standard. EPA is approving, as a revision to the Indiana State Implementation Plan (SIP), the State's plan for maintaining the 1997 annual $PM_{2.5}$ standard in the Chicago-Gary-Lake County, Illinois-Indiana (IL-IN) $PM_{2.5}$ nonattainment area (Greater Chicago nonattainment area) through 2025. EPA is also approving Indiana's 2025 Nitrogen Oxides (NO_X) and $PM_{2.5}$ Motor Vehicle Emission Budgets (MVEBs). Finally, EPA is approving Indiana's 2005 NO_X, primary $PM_{2.5}$, and sulfur dioxide (SO_2) emissions inventories for Lake and Porter Counties.

DATES: This final rule is effective February 6, 2012.

ADDRESSES: EPA has established a docket for this action: Docket ID No. EPA–R05–OAR–2008–0395. All documents in the docket are listed on the *http://www.regulations.gov* web site. Although listed in the index, some information is not publicly available, i.e., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically at *http://www.regulations.gov* or in hard copy at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. We recommend that you telephone Edward Doty, Environmental Scientist, at (312) 886–6057, before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Edward Doty, Environmental Scientist, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6057, *doty.edward@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA. This supplementary information section is arranged as follows:

Table of Contents

I. What is the background for this rule?
II. What comments did we receive on the proposed rule?
III. What actions is EPA taking?
IV. Statutory and and Executive Order Reviews

I. What is the background for this rule?

On July 18, 1997 (62 FR 38652), EPA promulgated an annual $PM_{2.5}$ standard at a level of 15 micrograms per cubic meter (μg/m³) of ambient air, based on the three-year average of the annual mean $PM_{2.5}$ concentration at any monitor (1997 annual $PM_{2.5}$ standard). On October 17, 2006 (71 FR 61144), EPA retained the annual $PM_{2.5}$ standard at 15 μg/m³ (2006 annual $PM_{2.5}$ standard). However, in response to legal challenges of the 2006 annual $PM_{2.5}$ standard, the United States Court of Appeals for the District of Columbia Circuit (DC Circuit) remanded the 2006 annual $PM_{2.5}$ standard to EPA for further consideration. EPA has retained and continues to enforce the 1997 annual $PM_{2.5}$ standard.

On January 5, 2005 (70 FR 944), EPA published air quality area designations for the 1997 annual $PM_{2.5}$ standard based on air quality data for calendar 2001–2003. In that rulemaking, EPA designated the Greater Chicago area, which includes Lake and Porter Counties in Indiana, as nonattainment for the 1997 annual $PM_{2.5}$ standard.

On April 3, 2008, the Indiana Department of Environmental Management (IDEM) submitted a request for EPA approval of a redesignation of Lake and Porter Counties to attainment of the 1997 annual $PM_{2.5}$ standard. This

redesignation request is based on 2004–2007 monitoring data showing attainment of the 1997 annual $PM_{2.5}$ standard. On March 6, 2009, IDEM submitted a technical addendum to the April 3, 2008, $PM_{2.5}$ redesignation request to show that the Greater Chicago nonattainment area continued to attain the 1997 annual $PM_{2.5}$ standard through 2008.

On November 27, 2009 (74 FR 62243), EPA made a final determination that the Greater Chicago nonattainment area was attaining the 1997 annual $PM_{2.5}$ standard.

On May 26, 2011, IDEM submitted a revised $PM_{2.5}$ maintenance plan to EPA demonstrating maintenance of the 1997 annual $PM_{2.5}$ standard in Lake and Porter Counties through 2025. In this submittal, the State included additional air quality data showing continued attainment of the 1997 annual $PM_{2.5}$ standard in the Greater Chicago area during 2008–2010.

On September 27, 2011 (76 FR 59600), EPA issued a notice of rulemaking proposing to approve Indiana's request to redesignate Lake and Porter Counties to attainment of the 1997 annual $PM_{2.5}$ standard. This notice of rulemaking also proposed to approve Indiana's $PM_{2.5}$ maintenance plan for Lake and Porter Counties, as revised in Indiana's May 26, 2011, submittal, 2005 NO_X, SO_2, and primary $PM_{2.5}$ emission inventories for Lake and Porter Counties, and 2025 NO_X and $PM_{2.5}$ MVEBs for Lake and Porter Counties.

The primary background for today's actions is contained in EPA's September 27, 2011, proposal to approve Indiana's redesignation request, and in EPA's November 27, 2009, final determination that the Greater Chicago area has attained the 1997 annual $PM_{2.5}$ standard. In particular, the September 27, 2011, proposed rulemaking provides a detailed discussion of how Indiana's $PM_{2.5}$ redesignation request and maintenance plan meet the Clean Air Act (CAA) requirements for redesignation to attainment for the 1997 annual $PM_{2.5}$ standard.

II. What comments did we receive on the proposed rule?

The public comment period for the proposed rule ended on October 27, 2011. No comments were received regarding the September 27, 2011, proposed rule.

III. What actions is EPA taking?

After reviewing Indiana's redesignation request, EPA has determined that it meets the criteria set forth in section 107(d)(3)(E) of the CAA. Therefore, EPA is approving the redesignation of Lake and Porter Counties to attainment for the 1997 annual $PM_{2.5}$ standard. EPA is also approving Indiana's $PM_{2.5}$ maintenance plan for Lake and Porter Counties as a revision of the Indiana SIP based on Indiana's demonstration that the plan meets the requirements of section 175A of the CAA. In addition, EPA is approving the 2005 NO_X, SO_2, and $PM_{2.5}$ emission inventories for Lake and Porter Counties as meeting the requirement for emission inventories contained in section 172(c)(3) of the CAA. Finally, EPA also finds adequate and is approving the State's 2025 NO_X and $PM_{2.5}$ MVEBs for Lake and Porter Counties for purposes of future transportation conformity analyses and demonstrations.

IV. Statutory and Executive Order Reviews

Under the CAA, redesignation of an area to attainment and the accompanying approval of a maintenance plan under section 107(d)(3)(E) are actions that affect the status of a geographical area and do not impose any additional regulatory requirements on sources beyond those imposed by State law. A redesignation to attainment does not in and of itself create any new requirements, but rather results in the applicability of requirements contained in the CAA for areas that have been redesignated to attainment. Moreover, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve State choices, provided that they meet the criteria of the CAA. Accordingly, these actions merely do not impose additional requirements beyond those imposed by State law and the CAA. For that reason, these actions:

- Are not ''significant regulatory actions'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Do not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Are certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Do not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Do not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Are not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Are not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Are not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and,
- Do not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

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 action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 6, 2012. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Particulate matter, Sulfur dioxide.

40 CFR Part 81

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

Dated: November 22, 2011.

Susan Hedman,

Regional Administrator, Region 5.

Parts 52 and 81, chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

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

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

Subpart P—Indiana

■ 2. Section 52.776 is amended by adding paragraphs (v)(4) and (w)(4) to read as follows:

§ 52.776 Control strategy: Particulate matter.

* * * * *

(v) * * *

(4) The Chicago-Gary-Lake County, IL-IN nonattainment area (Lake and Porter Counties), as submitted on April 3, 2008, and supplemented on March 6, 2009. The maintenance plan establishes 2025 motor vehicle emissions budgets for Lake and Porter Counties of 2,915.19 tons per year for NO_X and 132.70 tons per year for primary $PM_{2.5}$.

(w) * * *

(4) Indiana's 2005 NO_X, primary $PM_{2.5}$, and SO_2 emissions inventory satisfies the emission inventory requirements of section 172(c)(3) of the Clean Air Act for Lake and Porter Counties.

PART 81—[AMENDED]

■ 3. The authority citation for part 81 continues to read as follow:

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

■ 4. Section 81.315 is amended by revising the entry for Chicago-Gary-Lake County, IL-IN in the table entitled ''Indiana $PM_{2.5}$ (Annual NAAQS)'' to read as follows:

§ 81.315 Indiana.

* * * * *

INDIANA—$PM_{2.5}$

[Annual NAAQS]

Designated area	Designation [1]	
	Date [2]	Type
* * *	* * *	*
Chicago-Gary-Lake County, IL-IN: Lake County Porter County	February 6, 2012	Attainment.
* * *	* * *	*

[1] Includes Indian Country located in each county or area, except as otherwise specified.
[2] This date is 90 days after January 5, 2005, unless otherwise noted.

* * * * *

[FR Doc. 2011–31131 Filed 12–6–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–1026; FRL–9325–2]

Saflufenacil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of saflufenacil in or on Banana; Coffee, green bean; and Mango. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 7, 2011. Objections and requests for hearings must be received on or before February 6, 2012, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–1026. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Kathryn Montague, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; *telephone number:* (703) 305–1243; *email address: montague.kathryn@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 those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).

• Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide 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 electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2010–1026 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before February 6, 2012. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–1026, by one of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

• *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of February 4, 2011 (76 FR 6465) (FRL–8858–7), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0E7806) by BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709–3528. The petition requested that 40 CFR 180.649 be amended by establishing tolerances for residues of the herbicide saflufenacil, including its metabolites and degradates, in or on Banana, whole fruit; Coffee, green bean; and Mango, fruit at 0.03 parts per million (ppm). Compliance with the tolerance levels is to be determined by measuring only the sum of saflufenacil, 2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl]-4-fluoro-*N*-[[methyl(1-methylethyl)amino]sulfonyl]benzamide, and its metabolites *N*-[2-chloro-5-(2,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2*H*)-pyrimidinyl)-4-fluorobenzoyl]-*N'*-isopropylsulfamide and *N*-[4-chloro-2-fluoro-5-({[(isopropylamino)sulfonyl]amino}carbonyl)phenyl]urea, calculated as the stoichiometric equivalent of saflufenacil, in or on the commodities. That notice referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, *http://www.regulations.gov.* Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has modified the commodity terms for Banana and Mango. The reason for this change is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

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. * * *

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in 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 for saflufenacil including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with saflufenacil follows.

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.

Saflufenacil has low acute toxicity via the oral, dermal, and inhalation routes of exposure. It is slightly irritating to the eye but is neither a dermal irritant nor sensitizer.

Short-term, subchronic, and chronic toxicity studies in rats, mice, and dogs identified the hematopoietic system as the target organ of saflufenacil. Protoporphyrinogen oxidase inhibition in the mammalian species may result in disruption of heme synthesis which in turn causes anemia. In these studies, decreased hematological parameters (red blood cells (RBC), hematocrit (Ht), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), and mean corpuscular hemoglobin concentration (MCHC)) were seen at about the same dose level across species, except in the case of the dog, where the effects were seen at a slightly higher dose. These effects occurred around the same dose level from the

short- through long-term exposures without increasing in severity. Effects were also seen in the liver (increased weight, centrilobular fatty change, and lymphoid infiltrate) in mice, the spleen (increased spleen weight and extramedullary hematopoiesis) in rats, and in both these organs (increased iron storage in the liver and extramedullary hematopoiesis in the spleen) in dogs. No dermal toxicity was seen at the limit dose in a 28-day dermal toxicity study in rats.

Carcinogenicity studies in rats and mice showed no evidence of increased incidence of tumors at the tested doses. Saflufenacil is weakly clastogenic in the *in vitro* chromosomal aberration assay in V79 cells in the presence of S9 activation; however, the response was not evident in the absence of S9 activation. It is neither mutagenic in bacterial cells nor clastogenic in rodents *in vivo.* Saflufenacil is classified as ''not likely to be carcinogenic to humans.''

Increased fetal and offspring susceptibility to saflufenacil were observed in the developmental toxicity studies in the rat and rabbit and in the 2-generation reproduction study in the rat. Developmental effects such as decreased fetal body weights and increased skeletal variations occurred at doses that were not maternally toxic in the developmental study in rats, indicating increased quantitative susceptibility. In rabbits, developmental effects such as increased liver porphyrins were observed at doses that were not maternally toxic, indicating increased quantitative susceptibility. In the 2-generation reproduction study in rats, offspring effects such as increased number of stillborn pups, decreased viability and lactation indices, decreased pre-weaning body weight and/or body-weight gain, and changes in hematological parameters were observed at a dose resulting in less severe maternal toxicity (decreased food intake, body weight/weight gain and changes in hematological parameters and organ weights indicative of anemia), indicating increased qualitative susceptibility.

There was no evidence of neurotoxicity or neuropathology in the toxicity database for saflufenacil. In the acute neurotoxicity study, a decrease in motor activity was observed on the first day of dosing at the limit dose in males only. The finding was not accompanied by any other neuropathological changes and was considered a reflection of a mild and transient general systemic toxicity and not a substance-specific neurotoxic effect. In the subchronic neurotoxicity study, systemic toxicity (anemia), but no evidence of neurotoxicity, was seen in males and females.

There is no evidence of immunotoxity in the saflufenacil database. The increase in spleen weight seen only in rats in the 90-day oral toxicity study is attributable to an increased clearance of defective RBCs (*i.e.,* defective hemoglobin synthesis) and is thus an indication of toxicity to the hematopoietic system rather than to the immune system. In a 28-day immunotoxicity study in rats, saflufenacil failed to induce toxicity specific to the immune system at the highest dose tested, indicating that saflufenacil does not directly target the immune system at the dose levels being used for risk assessment.

Specific information on the studies received and the nature of the adverse effects caused by saflufenacil as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document *Saflufenacil. Human-Health Risk Assessment for Proposed Tolerances for Residues in/on Imported Coffee, Banana, and Mango* at page 19 in docket ID number EPA–HQ–OPP–2010–1026.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors (U/SF) are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for saflufenacil used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of May 11, 2011 (76 FR 27256) (FRL–8872–7).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to saflufenacil, EPA considered exposure under the petitioned-for tolerances as well as all existing saflufenacil tolerances in 40 CFR 180.649. EPA assessed dietary exposures from saflufenacil in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for saflufenacil. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). The unrefined assessment assumed 100% crop treated (CT), Dietary Exposure Evaluation Model (DEEM)™ 7.81 default concentration factors, and tolerance-level residues for all commodities, except cottonseed; sunflower subgroup 20B; soybean, seed; vegetable, legume, subgroup 6C, pea and bean (except soybean); and rapeseed subgroup 20A, for which the tolerance levels were multiplied by a correction factor to account for a metabolite of concern which is not included in the tolerance expression.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. Chronic dietary exposure was assessed using the same food residue assumptions as in the acute dietary exposure assessment discussed in unit III.C.1.i.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that saflufenacil does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for saflufenacil in drinking water. These

simulation models take into account data on the physical, chemical, and fate/transport characteristics of saflufenacil. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the First Index Reservoir Screening Tool (FIRST) and Pesticide Root Zone Model/Ground Water (PRZM/GW) models, the estimated drinking water concentrations (EDWCs) of saflufenacil for acute exposures are estimated to be 37.3 parts per billion (ppb) for surface water and 180 ppb for ground water. EDWCs for chronic exposures for non-cancer assessments are estimated to be 23.8 ppb for surface water and 173 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 180 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 173 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Saflufenacil is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found saflufenacil to share a common mechanism of toxicity with any other substances, and saflufenacil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that saflufenacil does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10×) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10×, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The pre- and postnatal toxicity database for saflufenacil includes rat and rabbit developmental toxicity studies, a 2-generation reproduction toxicity study in rats, acute and subchronic neurotoxicity studies in rats, and a 28-day immunotoxicity study in rats. As discussed in Unit III.A. there was evidence of quantitative susceptibility of fetuses to saflufenacil exposure in the developmental toxicity studies in rats and rabbits and evidence of qualitative susceptibility of offspring in the rat reproduction study.

An analysis was performed to determine the degree of concern for the effects observed in the developmental and reproduction toxicity studies when considered in the context of all available toxicity data, and to identify any residual uncertainties after establishing toxicity endpoints and traditional uncertainty factors (UFs) to be used in the risk assessment of saflufenacil. The degree of concern is low and there are no residual uncertainties for the increased susceptibility since:

i. Clear NOAELs/LOAELs were established for the developmental effects seen in rats and rabbits as well as for the offspring effects seen in the 2-generation reproduction study;

ii. Dose-response relationships for the effects of concern are well characterized;

iii. None of the effects in the developmental or reproduction studies were attributable to a single exposure and, therefore, are not of concern for acute risk assessment; and

iv. The dose used to evaluate chronic dietary risks is lower than the NOAELS for fetal/offspring effects in the developmental and reproduction studies and is, therefore, protective of the developmental and offspring effects observed in these studies.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

i. The toxicity database for saflufenacil is complete.

ii. There is no indication that saflufenacil is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. Although there is evidence of increased quantitative and qualitative susceptibility of offspring in the developmental and reproduction studies for saflufenacil, the degree of concern is low and the Agency did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of saflufenacil.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to saflufenacil in drinking water. These assessments will not underestimate the exposure and risks posed by saflufenacil.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to saflufenacil will occupy <1% of the aPAD for the general U.S. population and all population subgroups including infants and children.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to saflufenacil from food and water will utilize 31% of the cPAD for infants less than 1 year

old, the population group receiving the greatest exposure. There are no residential uses for saflufenacil.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

A short-term adverse effect was identified; however, saflufenacil is not registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for saflufenacil.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however, saflufenacil is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for saflufenacil.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, saflufenacil is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to saflufenacil residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography/mass spectroscopy/mass spectroscopy (LC–MS/MS)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; *telephone number:* (410) 305–2905; *email address: residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for saflufenacil.

C. Response to Comments

An anonymous citizen objected to the presence of any pesticide residues on food. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned completely. However, the existing legal framework provided by section 408 of FFDCA contemplates that tolerances greater than zero may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework.

D. Revisions to Petitioned-For Tolerances

EPA has revised the proposed commodity terms as follows to agree with the Agency's Food and Feed Commodity Vocabulary: ''Banana, whole fruit'' was changed to ''Banana;'' ''Mango, fruit'' was changed to ''Mango''.

V. Conclusion

Therefore, tolerances are established for residues of saflufenacil, including its metabolites and degradates, as set forth in the regulatory text.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances 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 final rule has been exempted from review under Executive Order 12866, this final 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.,* 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).

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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10,

1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

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).

VII. 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 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: November 21, 2011.

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 180.649 is amended by alphabetically adding the following commodities to the table in paragraph (a)(1) to read as follows:

§ 180.649 Saflufenacil; tolerances for residues.

(a) *General.* (1) * * *

Commodity	Parts per million
* * * * *	
Banana [1]	0.03
Coffee, green bean [1]	0.03
* * * * *	
Mango [1]	0.03
* * * * *	

[1] No U.S. registration as of December 7, 2011.

* * * * *

[FR Doc. 2011–31394 Filed 12–6–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0845; FRL–8885–8]

Isoxaflutole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of isoxaflutole in or on Soybean, seed and Grain, aspirated fractions. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 7, 2011. Objections and requests for hearings must be received on or before February 6, 2012, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0845. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Kathryn V. Montague, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; *telephone number:* (703) 305–1243; *email address: montague.kathryn@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 those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide 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 electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those

objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2010–0845 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before February 6, 2012. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–0845, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of December 15, 2010 (75 FR 78240) (FRL–8853–1), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F7750) by Bayer CropScience, 2 T.W. Alexander Dr., Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.537 be amended by establishing tolerances for combined residues of the herbicide isoxaflutole, 5-cyclopropyl-4-(2-methylsulfonyl-4-trifluoromethylbenzoyl) isoxazole and its metabolite 1-(2-methylsulfonyl-4-trifluoromethylphenyl)-2-cyano-3-cyclopropyl propane-1,3-dione, (RPA 202248), calculated as the parent compound, in or on soybean at 0.05 parts per million (ppm), and soybean, aspirated grain fractions at 0.25 ppm. That notice referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition and the preferred crop terminology, EPA has made two changes to the requested tolerances. First, EPA has changed the commodity descriptions for the tolerances to soybean, seed and grain, aspirated fractions. Second, EPA is raising the grain, aspirated fractions tolerance from 0.25 ppm to 0.30 ppm.

III. Aggregate Risk Assessment and Determination of Safety

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 * * *.''

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in 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 for isoxaflutole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with isoxaflutole follows.

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.

Isoxaflutole exhibited low acute toxicity via oral, dermal, and inhalation routes of exposure and it is not a dermal sensitizer. In long-term studies via the oral route, isoxaflutole caused ocular toxicity in rats, hepatotoxicity (including liver tumor formation) and thyroid tumors in rats and mice, and hematotoxicity (toxicity to blood) in dogs and mice at high doses. The liver and ocular toxicities observed in rats were consistent with the mode of action of isoxaflutole in mammals (*i.e.,* inhibition of the hepatic enzyme 4-hydroxyphenylpyruvate dioxygenase (HPPD)) that leads to a buildup of tyrosine in the blood and the eye.

Developmental toxicity was observed in rats and rabbits primarily as growth retardations, including delays in skeletal ossification, effects that have been observed with other HPPD inhibitors (*e.g.,* pyrasulfotole). There was no evidence of reproductive toxicity in the 2-generation reproductive toxicity study in rats; however, both adults and offspring exhibited ocular and liver toxicities as seen in long-term studies.

In the acute and subchronic neurotoxicity studies in rats, mild changes in functional-observation battery (FOB) parameters (grip strength and/or landing foot splay) were observed in adult animals. However, similar effects were not observed either in pregnant animals or in offspring in a developmental neurotoxicity (DNT) study in rats. In both maternal animals and offspring, changes in body weight and/or food consumption were the primary effects seen in the DNT study and at the same dose tested. Decreased brain weights were observed in offspring on post-natal day (PND) 11 at the high dose only, but not at a later time point, an indicator of a developmental delay and/or a secondary effect of the decreased body weight. Although morphometric analyses were not performed in the study, there were no effects on pup swimming ability, learning, memory, motor activity, or auditory startle response at any dose, nor was there any evidence of neuropathology in the study at any dose. As a result, the missing morphometric measurements, while required, are unlikely to affect the tentative lowest-observed adverse-effect level (LOAEL) of the study (highest dose tested).

Isoxaflutole was negative in a variety of genotoxicity screening assays. In carcinogenicity studies, isoxaflutole

induced liver and thyroid tumors in rats and liver tumors in mice. Isoxaflutole was classified as ''likely to be a human carcinogen.'' The method of quantification was linear cancer slope factor (Q_1*).

Specific information on the studies received and the nature of the adverse effects caused by isoxaflutole as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document ''Isoxaflutole. Section 3 Registration for Use on Soybeans. Human-Health Risk Assessment,'' p. 13 in docket ID number EPA–HQ–OPP–2010–0845.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for isoxaflutole used for human risk assessment is shown in the Table of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ISOXAFLUTOLE FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Females 13–49 years of age).	LOAEL = 5 milligrams/kilograms/day (mg/kg/day) UF_A = 10x UF_H = 10x FQPA SF = 3 (includes UF_L)	Acute RfD = aPAD = 0.02 mg/kg/day.	Prenatal developmental toxicity (rabbit) LOAEL = 5 mg/kg/day based on mg/kg/day based on increased incidence of fetuses with 27th pre-sacral vertebrae.
Acute dietary (General population including infants and children).	NOAEL = 125 mg/kg UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = aPAD = 1.25 mg/kg	Acute neurotoxicity (rat) LOAEL = 500 mg/kg based on significant decreases in hind limb grip strength and landing foot splay on day 15.
Chronic dietary (All populations)	NOAEL= 2 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = cPAD = 0.02 mg/kg/day.	Combined chronic toxicity/carcinogenicity (rat) LOAEL = 20 mg/kg/day based on liver, thyroid, ocular, and nervous system toxicity (M) and liver toxicity (F).
Cancer (Oral, dermal, inhalation) ..	Classification: ''Likely to be Carcinogenic to Humans''. Q_1* (mg/kg/day)$^{-1}$ of 1.14 x 10^{-2} from the male CD–1 mouse liver for the linear low-dose extrapolation based on statistically significant increases in liver tumors in both sexes of mice and rats.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of data or other data deficiency. FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to isoxaflutole, EPA considered exposure under the petitioned-for tolerances as well as all existing isoxaflutole tolerances in 40 CFR 180.537. EPA assessed dietary exposures from isoxaflutole in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for isoxaflutole. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed that 100% of the crop was treated and that for all commodities residues were at tolerance levels.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA assumed that 100% of the crop was treated and that for all commodities residues were at tolerance levels.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. If quantitative cancer risk assessment is appropriate, cancer risk may be quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or non-linear approach is used and a cancer RfD is calculated based on an earlier non-cancer key event. If carcinogenic mode of action data are not available, or if the mode of action data

determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that isoxaflutole should be classified as ''Likely to be Carcinogenic to Humans'' and a linear approach has been used to quantify cancer risk.

In conducting the cancer dietary exposure assessment EPA used the same food consumption data from the USDA and assumptions for residue levels in food as the Chronic Exposure in Unit III. C. 1. ii., of this unit.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for isoxaflutole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of isoxaflutole. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of isoxaflutole and metabolite RPA 202248 are estimated to be 8.68 parts per billion (ppb) for surface water and 0.255 ppb for ground water for acute exposures, 1.26 ppb for surface water and 0.255 ppb for ground water for chronic exposures for non-cancer assessments, and 0.53 ppb for surface water and 0.255 ppb for ground water for cancer assessments.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 8.68 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 1.26 ppb was used to assess the contribution to drinking water. For cancer dietary risk assessment, the water concentration of value 0.53 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Isoxaflutole is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Pyrasulfotole, mesotrione, isoxaflutole, and topramezone belong to a class of herbicides that inhibit the liver enzyme HPPD, which is involved in the catabolism (metabolic breakdown) of tyrosine (an amino acid derived from proteins in the diet). Inhibition of HPPD can result in elevated tyrosine levels in the blood, a condition called tyrosinemia. HPPD inhibiting herbicides have been found to cause a number of toxicities in laboratory animal studies including ocular, developmental, liver and kidney effects. Of these toxicities, the ocular effect (corneal opacity) is highly correlated with the elevated blood tyrosine levels. In fact, rats dosed with tyrosine alone show ocular opacities similar to those seen with HPPD inhibitors. Although the other toxicities may be associated with chemically induced tyrosinemia, other mechanisms may also be involved.

There are marked differences among species in the ocular toxicity associated with inhibition of HPPD. Ocular effects following treatment with HPPD inhibitor herbicides are seen in the rat but not in the mouse. Monkeys also seem to be recalcitrant to the ocular toxicity induced by HPPD inhibition. The explanation of this species-specific response in ocular opacity is related to the species differences in the clearance of tyrosine. A metabolic pathway exists to remove tyrosine from the blood that involves a liver enzyme called tyrosine aminotransferase (TAT). In contrast to rats where ocular toxicity is observed following exposure to HPPD-inhibiting herbicides, mice and humans are unlikely to achieve the levels of plasma tyrosine necessary to produce ocular opacities because the activity of TAT in these species is much greater compared to rats. Thus, humans and mice have a highly effective metabolic process for handling excess tyrosine.

HPPD inhibitors (*e.g.,* nitisinone) are used as an effective therapeutic agent to treat patients suffering from rare genetic diseases of tyrosine catabolism. Treatment starts in childhood but is often sustained throughout patient's lifetime. The human experience indicates that a therapeutic dose (1 mg/kg/day dose) of nitisinone has an excellent safety record in infants, children, and adults and that serious adverse health outcomes have not been observed in a population followed for approximately a decade. Rarely, ocular effects are seen in patients with high plasma tyrosine levels; however, these effects are transient and can be readily reversed upon adherence to a restricted protein diet. This indicates that an HPPD inhibitor in and of itself cannot easily overwhelm the tyrosine-clearance mechanism in humans.

Therefore, due to an efficient metabolic process to handle excess tyrosine, exposure to environmental residues of HPPD inhibiting herbicides is unlikely to result in high blood levels of tyrosine and ocular toxicity in humans; and EPA has concluded that a cumulative risk assessment with other HPPD inhibitors is unnecessary.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Developmental toxicity was observed in rats and rabbits as growth retardations including delays in skeletal ossification; effects that have been observed with other HPPD inhibitors (*e.g.,* pyrasulfotole). There was evidence of increased susceptibility in the rabbit study in the form of increased incidence of fetuses with 27th pre-sacral vertebrae at a dose much lower than those causing maternal deficits in body weight and food consumption. Neither the rat developmental study nor the rat 2-generation reproductive toxicity studies revealed any evidence of increased susceptibility. However, both adults and offspring in the 2-generation reproductive toxicity study exhibited ocular and liver toxicities seen in long-term studies.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x for all exposure scenarios, except acute dietary for females 13–49 years of age for which an FQPA SF is retained but reduced to 3X.

That decision is based on the following findings:

i. The toxicity database for isoxaflutole is complete.

ii. There are not residual concerns regarding neurotoxicity, including developmental neurotoxicity, based on the results of acute, subchronic, and developmental neurotoxicity studies.

iii. There is no evidence that isoxaflutole results in increased susceptibility following *in utero* exposure in a rat developmental study or in young rats in the 2-generation reproduction study. However, there was evidence of increased susceptibility following *in utero* exposure in a rabbit developmental study and a NOAEL for developmental effects was not identified in that study. To address the concern for increased *in utero* susceptibility and the lack of a NOAEL in the rabbit study, this study was selected for the acute dietary endpoint for females of 13–49 years of age and a 3X FQPA SF was retained for that population subgroup. Use of a 3X FQPA SF applied to the LOAEL yielded a point of departure that is comparable to the point of departure for the chronic dietary exposure scenario and the offspring effects in the rat 2-generation reproductive toxicity study. Therefore, all dietary exposure scenarios are considered protective of developmental effects.

iv. There are no residual uncertainties identified in the exposure databases. EPA made the very conservative, health-protective assumption that all commodities for which tolerances exist or are proposed contain residues at the tolerance level. Additionally, EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to isoxaflutole in drinking water. These assessments will not underestimate the exposure and risks posed by isoxaflutole.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to isoxaflutole will occupy 2.4% of the aPAD for females 13 to 49 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to isoxaflutole from food and water will utilize 1% of the cPAD for all infants (<1 year old) the population group receiving the greatest exposure. There are no residential uses for isoxaflutole.

3. *Short-term risk.* A short-term adverse effect was identified; however, isoxaflutole is not registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for isoxaflutole.

4. *Intermediate-term risk.* An intermediate-term adverse effect was identified; however, isoxaflutole is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for isoxaflutole.

5. *Aggregate cancer risk for U.S. population.* The aggregate cancer risk assessment for the general population takes into account exposure estimates from dietary consumption of isoxaflutole from food and drinking water sources. Average food plus water source dietary exposure was used. Estimated cancer risk for the U.S. population includes infants and children. The aggregate cancer risk estimate for isoxaflutole is 8×10^{-7}. This risk estimate is based, in part, on the conservative assumption that 100% of all crops for which isoxaflutole is registered or proposed for registration are treated. Additional refinement using percent crop treated estimates would result in a lower estimate of cancer risk.

EPA generally considers cancer risks in the range of one in one million (1×10^{-6}) or less to be negligible. Accordingly, EPA has concluded the cancer risk for all existing isoxaflutole uses and the uses associated with the tolerances established in this action is negligible.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to isoxaflutole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography with tandem mass spectrometry (LC/MS/MS) method (IS–004–P10–02)) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; *telephone number:* (410) 305–2905; *email address: residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for isoxaflutole.

V. Conclusion

Therefore, tolerances are established for residues of isoxaflutole, (5-cyclopropyl-4-isoxazolyl) [2-(methylsulfonyl)-4-(trifluoromethyl)phenyl] methanone and its metabolite 1-(2-methylsulfonyl-4-trifluoromethylphenyl)-2-cyano-3-cyclopropyl propane-1,3-dione, in or on

soybean, seed and grain, aspirated fractions at 0.05 ppm and 0.30 ppm, respectively.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances 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 final rule has been exempted from review under Executive Order 12866, this final 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) or Executive Order 13045, entitled *Protection of Children From Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.,* 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).

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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

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).

VII. 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 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: November 21, 2011.

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 180.537 is amended in paragraph (a) by revising the introductory text and alphabetically adding the following commodities to the table to read as follows:

§ 180.537 Isoxaflutole; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide, isoxaflutole, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of isoxaflutole ((5-cyclopropyl-4-isoxazolyl) [2-(methylsulfonyl)-4-(trifluoromethyl)phenyl] methanone) and its metabolite 1-(2-methylsulfonyl-4-trifluoromethylphenyl)-2-cyano-3-cyclopropyl propan-1,3-dione (RPA 202248), calculated as the stoichiometric equivalent of isoxaflutole, in or on the commodity:

Commodity	Parts per million
* * * * *	
Grain, aspirated fractions	0.30
Soybean, seed	0.05

* * * * *

[FR Doc. 2011–31397 Filed 12–6–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–2000–0003; FRL–9500–9]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Deletion of the Palmer Barge Line Superfund Site

AGENCY: Environmental Protection Agency.

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) Region 6 is publishing a direct final Notice of Deletion of the Palmer Barge Line (PBL) Superfund Site located in Port Arthur, Texas (Jefferson County), from the National Priorities List (NPL). The NPL, promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). This direct final deletion is being published by EPA with the concurrence of the State of Texas, through the Texas Commission on Environmental Quality, because EPA has determined that all appropriate response actions at these identified parcels under CERCLA, other than operation, maintenance, and Five-Year Reviews, have been completed. However, this deletion does not preclude future actions under Superfund.

DATES: This direct final deletion is effective February 6, 2012 unless EPA receives adverse comments by January 6, 2012. If adverse comments are received, EPA will publish a timely withdrawal of the direct final deletion

in the **Federal Register** informing the public that the deletion will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–SFUND–2000–0003, by one of the following methods:

- *http://www.regulations.gov:* Follow Internet on-line instructions for submitting comments.
- *Email:* Rafael Casanova, *casanova.rafael@epa.gov.*
- *Fax:* (214) 665–6660.
- *Mail:* Rafael A. Casanova; U.S. Environmental Protection Agency, Region 6; Superfund Division (6SF–RA); 1445 Ross Avenue, Suite 1200; Dallas, Texas 75202–2733.
- *Hand delivery:* U.S. Environmental Protection Agency, Region 6; 1445 Ross Avenue, Suite 700; Dallas, Texas 75202–2733; Contact: Rafael A. Casanova (214) 665–7437. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–AFUND–2000–0003. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or email. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *http://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at:

1. U.S. Environmental Protection Agency, Region 6; 1445 Ross Avenue, Suite 700; Dallas, Texas 75202–2733; Hours of operation: Monday thru Friday, 9 a.m. to 12 p.m. and 1 p.m. to 4 p.m. Contact: Rafael A. Casanova (214) 665–7437.
2. Port Arthur Public Library; 4615 9th Avenue; Port Arthur, Texas 77642–5799; Hours of operation: Monday thru Thursday, 9 a.m. to 9 p.m.; Friday, 9 a.m. to 6 p.m.; Saturday, 9 a.m. to 5 p.m.; and Sunday, 2 p.m. to 5 p.m.

FOR FURTHER INFORMATION CONTACT: Rafael A. Casanova, Remedial Project Manager; U.S. Environmental Protection Agency, Region 6; Superfund Division (6SF–RA); 1445 Ross Avenue, Suite 1200; Dallas, Texas 75202–2733; *telephone number:* (214) 665–7437; *email: casanova.rafael@epa.gov.*

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. NPL Deletion Criteria
III. Deletion Procedures
IV. Basis for Site Deletion
V. Deletion Action

I. Introduction

EPA Region 6 is publishing this direct final Notice of Deletion for the Palmer Barge Line (PBL) Superfund Site (Site), from the National Priorities List (NPL). The NPL constitutes Appendix B of 40 CFR Part 300 which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) of 1980, as amended. EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Sites on the NPL may be the subject of remedial actions financed by the Hazardous Substance Superfund (Fund). As described in 300.425(e)(3) of the NCP, a site deleted from the NPL remains eligible for Fund-financed remedial action if future conditions warrant such actions.

Because EPA considers this action to be noncontroversial and routine, this action will be effective February 6, 2012 unless EPA receives adverse comments by January 6, 2012. Along with this direct final Notice of Deletion, EPA is co-publishing a Notice of Intent for Deletion in the ''Proposed Rules'' section of the **Federal Register**. If adverse comments are received within the 30-day public comment period on this deletion action, EPA will publish a timely withdrawal of this direct final Notice of Deletion before the effective date of the deletion and the deletion will not take effect. EPA will, as appropriate, prepare a response to comments and continue with the deletion process on the basis of the Notice of Intent for Deletion and the comments already received. There will be no additional opportunity to comment.

Section II of this document explains the criteria for deleting sites from the NPL. Section III discusses procedures that EPA is using for this action. Section IV discusses the PBL Superfund Site and demonstrates how it meets the deletion criteria. Section V discusses EPA's action to delete the Site from the NPL unless adverse comments are received during the public comment period.

II. NPL Deletion Criteria

The NCP establishes the criteria that EPA uses to delete sites from the NPL. In accordance with 40 CFR 300.425(e), sites may be deleted from the NPL where no further response is appropriate. In making such a determination pursuant to 40 CFR 300.425(e), EPA will consider, in consultation with the State, whether any of the following criteria have been met:

i. Responsible parties or other persons have implemented all appropriate response actions required;

ii. All appropriate Fund-financed response under CERCLA has been implemented, and no further response action by responsible parties is appropriate; or

iii. The remedial investigation has shown that the release poses no significant threat to public health or the environment and, therefore, the taking of remedial measures is not appropriate.

Pursuant to CERCLA section 121(c) and the NCP, EPA conducts five-year reviews to ensure the continued protectiveness of remedial actions where hazardous substances, pollutants, or contaminants remain at a site above levels that allow for unlimited use and unrestricted exposure. EPA conducts such five-year reviews even if a site is deleted from the NPL. EPA may initiate further action to ensure continued protectiveness at a deleted site if new

information becomes available that indicates it is appropriate. Whenever there is a significant release from a site deleted from the NPL, the deleted site may be restored to the NPL without application of the hazard ranking system.

III. Deletion Procedures

The following procedures apply to all areas and media within the PBL Superfund Site:

1. EPA has consulted with the state of Texas prior to developing this direct final Notice of Deletion and the Notice of Intent for Deletion co-published in the ''Proposed Rules'' section of the **Federal Register**.

2. EPA has provided the state 30 working days for review of this notice and the parallel Notice of Intent for Deletion prior to their publication today, and the state, through the Texas Commission on Environmental Quality, has concurred on this deletion of the Site from the NPL.

3. Concurrently with the publication of this direct final Notice of Deletion, a notice of the availability of the parallel Notice of Intent for Deletion is being published in a major local newspaper, The Port Arthur News. The newspaper announces the 30-day public comment period concerning the Notice of Intent for Deletion of the Site from the NPL.

4. The EPA placed copies of documents supporting the deletion in the deletion docket and made these items available for public inspection and copying at the Site information repositories identified above.

5. If adverse comments are received within the 30-day public comment period on this deletion action, EPA will publish a timely notice of withdrawal of this direct final Notice of Deletion before its effective date and will prepare a response to comments and continue with the deletion process on the basis of the Notice of Intent for Deletion and the comments already received.

Deletion of a site from the NPL does not itself create, alter, or revoke any individual's rights or obligations. Deletion of a site from the NPL does not in any way alter EPA's right to take enforcement actions, as appropriate. The NPL is designed primarily for informational purposes and to assist EPA management. Section 300.425(e)(3) of the NCP states that the deletion of a site from the NPL does not preclude eligibility for further response actions, should future conditions warrant such actions.

IV. Basis for Site Deletion

The following information provides EPA's rationale for deleting the PBL Superfund Site from the NPL. A map of the Site, including the aerial extent of the Site proposed for deletion, is available in the deletion docket:

Site Location and History

The PBL Superfund Site (Site, CERCLIS ID—TXD068104561), a former barge-cleaning operation, encompasses approximately 17 acres and is located approximately 4.5 miles east-northeast of the City of Port Arthur on Old Yacht Club Road on Pleasure Islet. Pleasure Islet is a peninsula located approximately 0.5 miles southwest of the mouth of the Neches River. The Site is bordered by vacant property to the north, by Old Yacht Club Road to the west, by the State Marine of Port Arthur Superfund Site to the south, and Sabine Lake to the east.

Pleasure Islet is a manmade landmass consisting of dredge spoils generated during the construction and maintenance of the Sabine-Neches canal, also called the Intercoastal Waterway. The canal was constructed between 1898 and approximately 1920 in the vicinity of Sabine Lake and the Neches River, between the current Site location and the mainland. Between 1955 and 1957, a portion of the canal along the western side of Pleasure Islet was abandoned, and a new canal was cut along the eastern and southern sides of Pleasure Islet. Pleasure Islet was created when a land bridge was constructed across the abandoned portions of the canal, between the northern tip of Pleasure Island and the mainland. Vehicle access to the Site is limited to a single dirt road starting at the western Site border along Old Yacht Club Road.

The Site, along with the adjacent properties to the north and south, were used as a Municipal Landfill for the City of Port Arthur from 1956 to 1987. Although disposal at the landfill has long since ceased and the landfill contents have been covered with dredged sediments, the contents are still present on the Site in the subsurface soils.

In April 1982, John Palmer, President of Palmer Barge Line Inc. purchased approximately 17 acres from the City of Port Arthur, for the purpose of servicing and maintaining barges and marine vessels. The company ceased operations on the property in July 1997.

During operation, the typical activities performed at the Site included cleaning, degassing, maintenance, and inspection of barges and other marine equipment. Cleaning operations included the removal of sludge and other residual material by pressure steaming the vessel holds, engines and boilers. Engines were degreased and accumulations of sludges were removed. Degassing activities involved the removal of explosive vapors from vessel holds using nitrogen or boiler exhaust. Maintenance and inspection activities included the replacement and/or repair of valves, engine repairs, and line leak repairs followed by pressure tests. A flare was located on-site to burn excess gases and liquids produced during facility operations.

The surface water migration pathway was scored as part of the Hazard Ranking System Documentation Record. The EPA determined that the Site warranted further investigation to assess the nature and extent of the human health and environmental risks associated with the Site's previous barge-cleaning and inspection activities. The Site was proposed to be included on the NPL on May 11, 2000, (65 FR 30489) and made final on July 27, 2000, (65 FR 46096).

EPA conducted a Time Critical Removal Action in August 2000 that addressed the source materials stored on-site. Removal activities included waste removal, water treatment, oil/water separation, and sludge stabilization. Approximately 250,000 gallons of water were treated on-site; 500 cubic yards of sludge were stabilized; and 100,000 gallons of oil/styrene were separated and removed from the Site.

The investigations of the Site included the wastewater aboveground storage tank (AST), boiler house ASTs, open top slop tanks area, horizontal ASTs, twelve ASTs area, flare area, area east of flare in the center of the Site, ground water, and sediments of Sabine Lake.

Remedial Investigation and Feasibility Study

On September 30, 2002, the EPA issued an Administrative Order on Consent (AOC) to the potentially responsible parties (PRPs) to conduct a Remedial Investigation and Feasibility Study (RI/FS). The objectives of the RI/FS were to characterize the nature and extent of constituents of concern in soil, ground water, and surface water and sediments of Sabine Lake.

Constituents detected in soil samples included metals, semivolatile organic compounds (SVOCs), volatile organic compounds (VOCs), polychlorinated biphenyls (PCBs), and pesticides. Several samples containing above background concentrations of metals and SVOCs were from samples collected in soil that contained municipal waste, indicating that some constituents

present may not be due to activities from the barge cleaning operation.

There is no current or anticipated future use of the shallow groundwater at the Site. The shallow groundwater at the Site is not considered a potential drinking water source. The shallow groundwater resulted from the dredging activities that formed the isle where the former PBL Superfund Site is located. Ground water samples collected from permanent ground water monitoring wells installed downgradient of the Site did not contain significant concentrations of these Site-related constituents above risk-based levels.

Constituents detected in the sediments of Sabine Lake included polycyclic aromatic hydrocarbons and metals. Many of the constituents found in the soil at the Site were not detected in sediment samples. Surface water samples contained only metals at low concentrations.

The human health risk assessment concluded that contaminants were present in Site soils and sediments that presented an unacceptable risk to on-site workers and off-site recreational anglers. The screening level ecological risk assessment concluded that site contaminants did not present an unacceptable risk to ecological receptors.

A total of four alternatives were developed for the Site during the Feasibility Study. The EPA chose excavation and off-site disposal as the Selected Remedy for the contaminated soils at the Site.

Selected Remedy

Based on the results of the Baseline Human Health Risk Assessment (BHHRA) and Screening Level Ecological Risk Assessment (SLERA), the EPA's Selected Remedy for the PBL Superfund Site, identified in the September 2005 Record of Decision, was ''Excavation and Off-Site Disposal.'' The Selected Remedy consisted of the following components:

- Excavation of approximately 1,204 cubic yards of the upper two feet of soil that exceed human health and ecological risk-based levels at each of the response areas.
- Confirmation sampling for constituents of potential concern at each of the response areas.
- Backfilling of excavated areas with clean soil.
- Off-site disposal of the excavated soils at a permitted disposal facility.
- Implementation of institutional controls to restrict future land use only for industrial purposes. The ICs shall be a restrictive covenant by the property owner recorded in the real property records of Jefferson County, Texas.
- Abandonment of five existing ground water monitoring wells.
- Wastewater AST sludge removal and decontamination and off-site disposal.

Remedial Action Objectives

The Remedial Action Objectives (RAOs) for the Site are based on the following:

- The reasonable anticipated land use scenario is based on the future redevelopment of the Site for industrial or commercial use, consistent with current Site use and surrounding land use.
- Potential ecological risks were considered for Site soils to prevent exposure to ecological receptors and prevent surface runoff of contaminants to Sabine Lake sediments.

The RAOs for the Site were:

- Prevent direct contact, ingestion, and inhalation of surface soils that exceed human health risk-based levels, based on an industrial worker scenario, for the chemicals of concern (COCs).
- Prevent off-site migration of COCs to Sabine Lake sediments that exceed human health and ecological risk-based levels for the COCs.
- Prevent exposure to Site soils that may pose a risk to ecological receptors.

Response Actions

On May 7, 2007, the EPA issued a Unilateral Administrative Order (UAO) for Remedial Design and Remedial Action to the PRPs. The UAO became effective on June 6, 2007. The Final Remedial Design/Remedial Action Work Plan was approved by the EPA on August 2, 2007. A total of 181 tons of contaminated soils were excavated and disposed at a permitted disposal facility. Each response area was then backfilled with clean soil. The Record of Decision (ROD) required the collection of confirmation samples, including analyses for the constituents of potential concern, at each of the response areas. Analytical results were used to determine horizontal limits of impacted media in each of the response areas. If constituents were found to contain concentrations in excess of the remediation goals (RG), step-out samples were analyzed for those constituents. Additional step-out samples were collected and analyzed when the step-out samples exceeded the RG. This process continued until sample results for perimeter samples were below the RG, indicating horizontal delineation had been achieved according to the requirements of the ROD. Additionally, approximately 78,340 pounds of oil were skimmed from the 10,000-barrel AST and recycled for fuel blending, and approximately 854,886 pounds of the remaining sludge material within the AST were incinerated. As required by the 2005 ROD, five permanent ground water monitoring wells were plugged and abandoned.

An institutional control (IC) in the form of Restrictive Covenant by the property owner, to the benefit of the State of Texas and the United States Government, was filed in the appropriate property records at the County Clerk's office in Jefferson County on March 25, 2011. This IC ensures that future site use remains commercial/industrial.

Cleanup Goals

The EPA chose a 1.0×10^{-5} target cleanup goal based on exposure to COCs that exceeded those levels at surface soils. The COCs and the selected soil cleanup goals achieved for the Human Health Risk Areas were:

- Aldrin—1.1 milligrams/kilogram (mg/kg).
- Benzo(a)pyrene—2.3 mg/kg.
- Benzo(a)anthracene—23.0 mg/kg.
- Dieldrin—1.2 mg/kg.
- Heptachlor Epoxide—2.1 mg/kg.
- Naphthalene—210.0 mg/kg.
- Pentachlorophenol—100.0 mg/kg.
- Lead—800.0 mg/kg.

The COCs and the selected soil cleanup goals achieved for ecological receptors were:

- 4,4′-DDD—0.0864 mg/kg.
- 4,4′-DDE—0.0864 mg/kg.
- 4,4′-DDT—0.0865 mg/kg.
- Butyl benzyl phthalate—5.37 mg/kg.
- Lead, total—497.0 mg/kg.
- Methoxychlor—0.09 mg/kg.

Operation and Maintenance

Operation and maintenance activities include monitoring effectiveness of institutional controls to ensure land use remains industrial/commercial.

Five-Year Reviews

Since the Selected Remedy would result in hazardous substances remaining on-site above levels that allow for unlimited use and unrestricted exposure, a Five-Year Review will be conducted no less often than every five years from initiation of the Remedial Action to ensure that the remedy is, or will continue to be, protective of human health and the environment. The first five-year Review will be conducted before September 4, 2012.

Community Involvement

Public participation activities have been satisfied as required in CERCLA

Section 113(k), 42 U.S.C. 9613(k) and CERCLA Section 117, 42 U.S.C. 9617. Documents in the deletion docket which the EPA relied on for recommendation for the deletion from the NPL are available to the public in the information repositories, and a notice of availability of the Notice of Intent for Deletion has been published in The Port Arthur News to satisfy public participation procedures required by 40 CFR 300.425(e)(4).

Determination That the Criteria for Deletion Have Been Met

In accordance with 40 CFR 300.425(e), sites may be deleted from the NPL where no further response is appropriate. The EPA has determined that the criteria for deletion have been met. The EPA has implemented all appropriate response actions required and no further response action by responsible parties is appropriate. EPA received a letter, dated May 26, 2011, from the State of Texas, through the Texas Commission on Environmental Quality, concurring on the deletion of PBL Superfund Site from the NPL.

V. Deletion Action

The EPA, with concurrence of the State of Texas, through the Texas Commission on Environmental Quality, has determined that all appropriate response actions under CERCLA, other than operation, maintenance, monitoring, and Five-Year Reviews, have been completed. Therefore, EPA is deleting the PBL Superfund Site from the NPL.

Because EPA considers this action to be noncontroversial and routine, EPA is taking it without prior publication. This action will be effective February 6, 2012 unless EPA receives adverse comments by January 6, 2012. If adverse comments are received within the 30-day public comment period, EPA will publish a timely withdrawal of this direct final notice of deletion before the effective date of the deletion and it will not take effect. EPA will prepare a response to comments and continue with the deletion process on the basis of the notice of intent to delete and the comments already received. There will be no additional opportunity to comment.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: November 14, 2011.

Al Armendariz,

Regional Administrator, Region 6.

For the reasons set out in this document, 40 CFR part 300 is amended as follows:

PART 300—[AMENDED]

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923; 3 CFR, 1987 Comp., p. 193.

Appendix B—[Amended]

■ 2. Table 1 of Appendix B to Part 300 is amended by removing the entry ''Palmer Barge Line, Port Arthur'' under TX.

[FR Doc. 2011–31268 Filed 12–6–11; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 202, 204, 205, 206, 207, 209, 211, 212, 213, 214, 215, 216, 217, 219, 225, 227, 234, 237, 243, 252, and Appendix A to Chapter 2

Defense Federal Acquisition Regulation Supplement; Technical Amendments

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is making technical amendments to the Defense Federal Acquisition Regulation Supplement (DFARS) to provide needed editorial changes and guidance to contracting officers.

DATES: *Effective Date:* December 7, 2011.

FOR FURTHER INFORMATION CONTACT: Ms. Mary Overstreet, Defense Acquisition Regulations System, OUSD(AT&L)DPAP(DARS), Room 3B855, 3060 Defense Pentagon, Washington, DC 20301–3060. Telephone (703) 602–0311; facsimile (703) 602–0350.

SUPPLEMENTARY INFORMATION: This final rule amends the DFARS as follows:

1. Updates the definition of ''Contracting activity'' at 202.101.

2. Directs contracting officers to additional procedures and guidance by adding references to the DFARS PGI at 204.402, 204.403, 205.207(a)(i) and (d)(iii), 215.407–2, 219.202–1, 219.301–2, 219.301–3, 237.102–75, and 237.102–76.

3. Corrects references in 206.203(b), 207.471(b), 209.105–1(2), 209.403, 209.406–1(a)(i)(A), 211.002, 212.503(a)(x), 212.504(a)(xvi), 213.301(2), 214.404–1, 216.603–4(b)(3), 225.7501(a)(2)(i), 227.304–1, 234.003, 234.201(4), and 243.204–71(b).

4. Adds a paragraph at 217.171(d) reflecting a statutory threshold for multiyear contracts for services that was inadvertently omitted from a final rule published at 76 FR 58152 on September 20, 2011. This coverage was previously included at DFARS 217.171(a)(6).

5. Revises the subpart 217.5 heading to align with the Federal Acquisition Regulation (FAR), redesignates 217.500(b) as 217.500(a), and redesignates 217.504 as 217.503 and adds a FAR reference.

6. Makes minor editorial corrections at 225.403(c) and 227.7203–15(c)(1) through (4).

7. Makes minor corrections to clause dates, format, addresses, and references in the clauses at 252.203–7003, 252.211–7003, 252.212–7001, 252.227–7015, 252.229–7006, 252.229–7008, and 252.235–7002.

8. Adds an editorial footnote to the charter for the Armed Services Board of Contract Appeals in Appendix A to cross reference to a revised statutory citation.

List of Subjects in 48 CFR Parts 202, 204, 205, 206, 207, 209, 211, 212, 213, 214, 215, 216, 217, 219, 225, 227, 234, 237, 243, 252, and Appendix A to Chapter 2

Government procurement.

Mary Overstreet,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 202, 204, 205, 206, 207, 209, 211, 212, 213, 214, 215, 216, 217, 219, 225, 227, 234, 237, 243, 252, and Appendix A to Chapter 2 are amended as follows:

■ 1. The authority citation for 48 CFR parts 202, 204, 205, 206, 207, 209, 211, 212, 213, 214, 215, 216, 217, 219, 225, 227, 234, 237, 243, 252 and Appendix A to Chapter 2 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 202—DEFINITIONS OF WORDS AND TERMS

202.101 [Amended]

■ 2. Section 202.101 is amended by—

■ a. Amending the Department of Defense list by removing the ''Counterintelligence Field Activity'';

■ b. Amending the Department of Defense list by removing ''Washington Headquarters Services, Acquisition and Procurement Office'' and adding in its place ''Washington Headquarters Services, Acquisition Directorate'';

■ c. Amending the Navy list by removing ''Office of the Deputy Assistant Secretary of the Navy (Acquisition & Logistics Management)'' and adding in its place ''Office of the Deputy Assistant Secretary of the Navy (Acquisition & Procurement)''; and

■ d. Removing the Defense Business Transformation Agency Contracting Office.

PART 204—ADMINISTRATIVE MATTERS

204.402 [Amended]

■ 3. Section 204.402 is amended by adding the parenthetical phrase ''(see PGI 204.402)'' at the end of the sentence.

■ 4. Section 204.403 is added to read as follows:

204.403 Responsibilities of contracting officers.

Contracting officers shall ensure that solicitations comply with PGI 204.403.

PART 205—PUBLICIZING CONTRACT ACTIONS

■ 5. Section 205.207 is amended by—

■ a. Adding a new paragraph (a)(i); and

■ b. Adding a new paragraph (d)(iii).

The additions read as follows:

205.207 Preparation and transmittal of synopses.

(a)(i) For numbering synopsis notices, follow the procedures at PGI 205.207(a)(i).

(d)(i) * * *

(iii) For special notices for small business events, follow the procedures at PGI 205.207(d)(ii).

PART 206—COMPETITION REQUIREMENTS

206.203 [Amended]

■ 6. Section 206.203 is amended by removing ''(see 226.7003)'' and adding in its place ''(see 226.370)''.

PART 207—ACQUISITION PLANNING

207.471 [Amended]

■ 7. Section 207.471(b) is amended by removing ''Chapter 7, Section 070207'' and adding in its place ''Chapter 6, section 060206''.

PART 209—CONTRACTOR QUALIFICATIONS

209–105–1 [Amended]

■ 8. Section 209.105–1(2) is amended by removing ''(see PGI 212.403(c) and PGI 249.470)'' and adding in its place ''(see subpart 42.15)''.

209.403 [Amended]

■ 9. Section 209.403(1) is amended by removing ''Navy'' and adding in its place ''Navy/Marine Corps''.

209.406–1 [Amended]

■ 10. Section 209.406–1(a)(i)(A) is amended by removing ''Subpart 203.70'' and adding in its place ''FAR subpart 3.10''.

PART 211—DESCRIBING AGENCY NEEDS

211–002 [Amended]

■ 11. Section 211.002 is amended by—

■ a. Removing ''DoDD 5000.1,'' and adding in its place ''DoDD 5000.01,''; and

■ b. Removing ''DoDI 5000.2,'' and adding in its place ''DoDI 5000.02,''.

PART 212—ACQUISITION OF COMMERCIAL ITEMS

212.503 [Amended]

■ 12. Section 212.503(a)(x) is amended by removing ''see 225.7019–2(b) (Section 8064 of Pub. L. 106–259)'' and adding in its place ''see 225.7009–3 (section 8065 of Pub. L. 107–117)''.

212.504 [Amended]

■ 13. Section 212.504(a)(xvi) is amended by removing ''see 225.7009–2(b) (Section 9064 of Pub. L. 106–259)'' and adding in its place ''see 225.7009–3 (section 8065 of Pub. L. 107–117)''.

PART 213—SIMPLIFIED ACQUISITION PROCEDURES

213.301 [Amended]

■ 14. Section 213.301(2) is amended by removing ''201.603–3(b)'' and adding in its place ''201.603–3(a)''.

PART 214—SEALED BIDDING

214.404–1 [Amended]

■ 15. Section 214.404–1 is amended by removing ''(FAR 14.404–1(c) and (e)'' and adding in its place ''FAR 14.404–1(c) and (e)(1)''.

PART 215—CONTRACTING BY NEGOTIATION

■ 16. Section 215.407–2(a) is added to read as follows:

215.407–2 Make-or-buy programs.

(a) *General.* See PGI 215.407–2 for guidance on factors to consider when deciding whether to request a make-or-buy plan and for factors to consider when evaluating make-or-buy plan submissions.

* * * * *

PART 216—TYPES OF CONTRACTS

216.603–4 [Amended]

■ 17. Section 216.603–4(b)(3) is amended by removing ''217.7405(b)'' and replacing it with ''217.7406(b)''.

PART 217—SPECIAL CONTRACTING METHODS

■ 18. Section 217.171(d) is added to read as follows:

217.171 Multiyear contracts for services.

* * * * *

(d) The head of an agency may not initiate a multiyear contract for services if the value of the multiyear contract exceeds $625.5 million unless a law specifically provides authority for the contract (10 U.S.C. 2306(c)).

Subpart 217.5—Interagency Acquisitions

■ 19. Subpart 217.5 heading is revised as set forth above.

217.500 [Amended]

■ 20. In section 217.500, paragraph (b) is redesignated as paragraph (a).

217.504 [Redesignated as 217.503]

■ 21. Section 217.504 is redesignated as section 217.503 and revised to read as follows:

217.503 Ordering procedures.

(a) When the requesting agency is within DoD, a copy of the executed determination and findings required by FAR 17.502–2 shall be furnished to the servicing agency as an attachment to the order. When a DoD contracting office is acting as the servicing agency, a copy of the executed determination and findings shall be obtained from the requesting agency and placed in the contract file for the Economy Act order.

PART 219—SMALL BUSINESS PROGRAMS

■ 22. Section 219.202–1 is added to read as follows:

219.202–1 Encouraging small business participation in acquisitions.

See PGI 205.207(d)(iii) for information on how to advertise a small business event on the Government point of entry.

■ 23. Section 219.301–2 is added to read as follows:

219.301–2 Rerepresentation by a contractor that represented itself as a small business concern.

Follow the procedures at PGI 204.606(4)(vii) for reporting modifications for rerepresentation actions.

■ 24. Section 219.301–3 is added to read as follows:

219.301–3 Rerepresentation by a contractor that represented itself as other than a small business concern.

Follow the procedures at PGI 204.606(4)(vii) for reporting modifications for rerepresentation actions.

PART 225—FOREIGN ACQUISITION

225.403 [Amended]

■ 25. Section 225.403(c) is amended—

■ a. In paragraph (i)(B), by removing ''; or'' and adding in its place '';'';

■ b. In paragraph (ii)(B), by removing ''.'' and adding in its place ''; or''.

■ 26. Section 225.7501(a)(2)(i) is amended by removing ''225.104(a)(iii)'' and adding in its place ''225.104(a)''.

PART 227—PATENTS, DATA, AND COPYRIGHTS

227.304–1 [Amended]

■ 27. Section 227.304–1 is amended by removing the parenthetical phrase ''(FAR 27.304–1(e)(2)(ii))''.

227.7203–15 [Amended]

■ 28. Section 227.7203–15(c) is amended—

■ a. In paragraph (1), by removing ''252.227.7014'' and adding in its place ''252.227–7014;

■ b. In paragraph (2), by removing ''252.227.7019'' and adding in its place ''252.227–7019'';

■ c. In paragraph (3), by removing ''252.227.7025'' and adding in its place ''252.227–7025''; and

■ d. In paragraph (4), by removing 252.227.7028'' and adding in its place ''252.227–7028''.

PART 234—MAJOR SYSTEM ACQUISITION

234.003 [Amended]

■ 29. Section 234.003 is amended by—

■ (a) Removing ''DoDD 5000.1'' and adding in its place ''DoDD 5000.01''; and

■ (b) Removing ''DoDI 5000.2'' and adding in its place ''DoDI 5000.02''.

234.201 [Amended]

■ 30. Section 234.201(4) is amended by removing ''PGI 234.201(4)'' and adding in its place ''PGI 234.201(3)''.

PART 237—SERVICE CONTRACTING

■ 31. Section 237.102–75 is added to read as follows:

237.102–75 Guidebook for the acquisition of services.

See PGI 237.102–75 for the ''Guidebook for the Acquisition of Services.''

■ 32. Section 237.102–76 is added to read as follows:

237.102–76 Review criteria for the acquisition of services.

See PGI 237.102–76 for tenets and review criteria to be used when conducting preaward and postaward reviews for the acquisition of services.

PART 243—CONTRACT MODIFICATIONS

243.204–71 [Amended]

■ 33. Section 243.204–71(b) is amended by removing ''PGI 243.204–70(b)'' and adding in its place ''PGI 243.204–71(b)''.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 34. Section 252.203–7003 is revised to read as follows:

252.203–7003, Agency Office of the Inspector General.

As prescribed in 203.1004(a), use the following clause:

AGENCY OFFICE OF THE INSPECTOR GENERAL (DEC 2011)

The agency office of the Inspector General referenced in paragraphs (c) and (d) of FAR clause 52.203–13, Contractor Code of Business Ethics and Conduct, is the DoD Office of Inspector General at the following address:

Department of Defense Office of Inspector General, Investigative Policy and Oversight, 4800 Mark Center Drive, Suite 11H25, Alexandria, VA 22350–1500, For FedEx or UPS packages, use this zip code: 22311, Toll Free Telephone: (866) 429–8011. (End of clause)

252.211–7003 [Amended]

■ 35. Section 252.211–7003, Alternate I is amended by—

■ a. Amending the clause date by removing ''(AUG 2008)'' and adding in its place ''(DEC 2011)''.

■ b. Amending the introductory text by removing ''211.274–4(c)'' and adding in its place ''211.274–6(a)(4)''.

252.212–7001 [Amended]

■ 36. Section 252.212–7001 is amended by—

■ a. Amending the introductory text by removing ''and 227.7103–6(a) and (e)'';

■ b. Amending the clause date by removing ''(OCT 2011)'' and adding in its place ''(DEC 2011)'';

■ c. Amending paragraph (b)(1) by removing ''(JAN 2009)'' and adding in its place ''(SEP 2011)'';

■ d. Amending paragraph (b)(4) by removing ''(OCT 2010)'' and adding in its place ''(SEP 2011)'';

■ e. Redesignating paragraph (b)(16) as (b)(17 and paragraph (b)(17) as (b)(16);

■ f. Amending paragraph (b)(20) by removing ''(MAR 2011)'' and adding in its place ''(DEC 2011)''; and

■ g. Amending paragraph (c)(3) by removing ''(SEP 2011)'' and adding in its place ''(DEC 2011).

252.227–7015 [Amended]

■ 37. Section 252.227–7015 is amended by—

■ a. Amending the introductory text by removing ''227.7102–3(a)(1)'' and adding in its place ''227.7102–4(a)(1)'';

■ b. Amending the clause date by removing ''(SEP 2011)'' and adding in its place ''(DEC 2011)'';

■ c. Amending the Alternate I clause date by removing ''(MAR 2011)'' and adding in its place ''(DEC 2011)''; and

■ d. Amending the Alternate I introductory text by removing ''227.7102–3(a)(2)'' and adding in its place ''227.7102–4(a)(2)''.

■ 38. Section 252.229–7006 is revised to read as follows:

252.229–7006 Value Added Tax Exclusion (United Kingdom)

As prescribed in 229.402–70(f), use the follow clause:

VALUE ADDED TAX EXCLUSION (UNITED KINGDOM) (DEC 2011)

The supplies or services identified in this contract are to be delivered at a price exclusive of value added tax under arrangements between the appropriate United States authorities and Her Majesty's Revenue and Customs (HMRC) (Reference HMRC Notice 431, entitled ''Relief from Customs Duty and/or Value Added Tax on United States Government Expenditures in the United Kingdom''). By executing this contract, the Contracting Officer certifies that these supplies or services are being purchased for United States Government official purposes only. (End of clause)

■ 39. Section 252.229–7008 is revised to read as follows:

252.229–7008 Relief from Import Duty (United Kingdom)

As prescribed in 229.402–70(h), use the following clause:

RELIEF FROM IMPORT DUTY (UNITED KINGDOM) (DEC 2011)

Any import dutiable articles, components, or raw materials supplied to the United States Government under this contract shall be exclusive of any United Kingdom import duties. Any imported items supplied for which import duty already has been paid will be supplied at a price exclusive of the amount of import duty paid. The Contractor is advised to contact Her Majesty's Revenue and Customs (HMRC) to obtain a refund upon completion of the contract (Reference HMRC Notice No. 431, entitled ''Relief from Customs Duty and/or Value Added Tax on United States Government Expenditures in the United Kingdom''). (End of clause)

252.235–7002 [Amended]

■ 40. Section 252.235–7002 is amended by—

■ a. Amending the clause date by removing ''(DEC 1991)'' and adding in its place ''(DEC 2011)''; and

■ b. Amending paragraph (a) by removing ''7 U.S.C. 2316'' and adding in its place ''7 U.S.C. 2136''.

■ Appendix A to Chapter 2—[Amended]

■ 41. Appendix A to Chapter 2, Part 1—Charter, paragraph 1 is amended by removing ''(41 U.S.C. Sect 601, et seq.)'' and adding in its place ''(41 U.S.C. Section 7101–7109)''.

[FR Doc. 2011–31324 Filed 12–6–11; 8:45 am]

BILLING CODE 5001–06–P

Proposed Rules

Federal Register
Vol. 76, No. 235
Wednesday, December 7, 2011

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.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

[Docket No. PRM–50–94; NRC–2010–0004]

Petition for Rulemaking Submitted by Sherwood Martinelli

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; denial.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or the Commission) is denying a petition for rulemaking (PRM) submitted by Mr. Sherwood Martinelli (the petitioner) (PRM–50–94). The petitioner requests that the NRC amend its regulations as they relate to decommissioning and decommissioning funding. Specifically, the petitioner requests that the NRC revise its reporting requirements, restrict funding mechanisms, require deposits within 90 days to cover shortfalls regardless of cause, amend the definition of the safe storage (SAFSTOR) decommissioning option, and eliminate the ENTOMB decommissioning option.

DATES: The docket for the petition for rulemaking, PRM–50–94, is closed on December 7, 2011.

ADDRESSES: You can access publicly available documents related to this petition for rulemaking using the following methods:

- *NRC's Public Document Room (PDR):* The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, O–1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* Publicly available documents created or received at the NRC are available online at the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* From this page, the public can gain entry into ADAMS, which provides text and image files of NRC's public documents. If you do not have access to ADAMS, or if there are problems in accessing the documents located in ADAMS, contact the NRC PDR reference staff at 1–(800) 397–4209, (301) 415–4737, or by email to *pdr.resource@nrc.gov.*
- *Federal rulemaking Web site:* Public comments and supporting materials related to this petition for rulemaking can be found at *http://www.regulations.gov* by searching on Docket ID: NRC–2010–0004. Address questions about NRC dockets to Carol Gallagher, telephone (301) 492–3668; email *Carol.Gallagher@nrc.gov.*

FOR FURTHER INFORMATION CONTACT: Aaron L. Szabo, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555; *telephone:* (301) 415–1985 or *email: Aaron.Szabo@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background
II. Avoiding Legacy Sites
  a. Revise Reporting Requirements
  b. Restrict Funding Mechanisms and Increase Financial Assurance
III. Changes to SAFSTOR and ENTOMB Decommissioning Options
IV. Public Comments on the Petition
V. Reason for Denial

I. Background

On December 23, 2009, the NRC received a petition for rulemaking filed by Mr. Sherwood Martinelli (ADAMS Accession No. ML093620175). The petitioner requests that the NRC amend its regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) part 50, ''Domestic Licensing of Production and Utilization Facilities,'' to require yearly reporting by licensees on the status of the financial mechanisms used to ensure funding for the decommissioning of nuclear power plants, and biannual reporting if the license is within 5 years of expiration. The petitioner further requests that the NRC require additional deposits to the funding accounts within 90 days from the time a shortage is noted in the annual reports. The petitioner requests that the regulations be revised to require that licensees create a financial mechanism, such as a trust fund with a host State, controlled and managed by that State, to ensure that there is sufficient funding to pay for the ultimate decommissioning of the facility. The petitioner also requests that the NRC amend its regulations to clarify that a licensee's choice of alternative decommissioning strategy must result in the return of the site to unrestricted use within 60 years, and that the NRC eliminate the ENTOMB strategy as an option. On February 26, 2010 (75 FR 8843), the NRC published a **Federal Register** Notice (FRN) announcing the receipt and docketing of the petition for rulemaking as PRM–50–94 and requesting public comment from interested parties. The comment period closed on May 12, 2010.

The petitioner also makes two claims in PRM–50–94 that are not being addressed in the PRM process under 10 CFR 2.802, ''Petition for rulemaking:'' (1) Entergy Nuclear Operations, Inc. (Entergy) is violating NRC rules and regulations by allowing Indian Point Nuclear Generating Unit No. 1 (IP1) to remain in SAFSTOR, is wrongfully and illegally depending on parts of IP1 to help run Indian Point Nuclear Generating Units No. 2 and 3 (IP2 and IP3), and is using the reactor of IP1 as an illegal storage/dumping ground for radiological waste streams from the continued operations of IP2 and IP3; and (2) the NRC has negligently allowed certain licensees to violate the current regulations on funding and the filing of reports.

The petitioner's first claim contains general assertions of violations but does not ask for enforcement-related action; therefore the NRC did not consider this under the 10 CFR 2.206 process. Further, the petitioner's claim was not considered within the allegation process because NRC regulations do not disallow a unit from remaining in SAFSTOR and IP2 and IP3 are allowed to utilize structures, systems and components of IP1 in accordance with their 10 CFR Part 50 licenses. The NRC's recognition of this situation is evidenced by the Staff's statement in NUREG–1437, Supplement 38, ''General Environmental Impact Statement for License Renewal of Nuclear Plants Regarding Indian Point Nuclear Generating Unit Nos. 2 and 3,'' (ADAMS Accession No. ML103350405) that ''radioactive waste storage and process facilities located in IP1 provide additional waste processing services for IP2.'' The NRC has no regulations forbidding the storage of radioactive waste at a 10 CFR part 50 licensee's facility, although these licensees must obtain NRC approval for onsite storage of radioactive waste. The NRC's regulations at 10 CFR part 20, ''Standards for Protection against

Radiation,'' state the general requirements for ensuring that radioactive waste is stored safely and securely. Also, the NRC routinely inspects licensees to ensure radioactive waste is maintained safely and securely under the Reactor Oversight Process. To address the petitioner's second claim, this petition has been forwarded to the NRC's Office of the Inspector General for a determination of whether the claim qualifies as an allegation of wrongdoing.

II. Avoiding Legacy Sites

a. Revise Reporting Requirements

The petitioner requests that the NRC amend its requirements pertaining to the frequency of reporting the status of decommissioning funding from once every 2 years to once every year, and from annual to biannual reporting if the license is within 5 years of expiration. Although no specific NRC requirement is cited, the Commission believes that the petitioner is referring to 10 CFR 50.75(f)(1), which requires each power reactor licensee to report to the NRC, on a calendar year basis, at least once every 2 years, on the status of its decommissioning funding for each reactor or part of a reactor that it owns.

The petitioner's basis and rationale for requesting these amendments is the belief that with the current state of the economy, a 2-year reporting requirement is not adequate to ensure the safety and adequacy of funds set aside for the decommissioning of a nuclear power plant. The petitioner also believes that without this additional assurance, host communities and taxpayers would be left with legacy sites,[1] for which communities and taxpayers would be responsible for funding the decommissioning activities.

b. Restrict Funding Mechanisms and Increase Financial Assurance

The petitioner requests that the financial assurance section of the NRC's decommissioning funding requirements be replaced to require that, before nuclear power plant operations commence, licensees deposit or create a financial mechanism (such as a trust fund) with the host State to be controlled and managed by that State to ensure that there will be sufficient funding for the ultimate decommissioning of the facility. Also, the NRC should require that licensees make additional deposits into the fund within 90 days of the identification of any shortfalls in funding. The petitioner believes that these measures would provide the public reasonable assurance that sufficient funds for cleanup will be available at the time of decommissioning. The petitioner does not provide a specific citation for the regulatory text to be revised; however, decommissioning trust fund options are included in 10 CFR 50.75(e)(1).

III. Changes to SAFSTOR and ENTOMB Decommissioning Options

The petitioner further requests that the ''rules'' governing alternative decommissioning strategies be modified. The first option for decommissioning is ENTOMB, which involves removing all fuel and radioactive fluids and wastes and possibly removing selected nuclear components. The remaining radioactive components are sealed into the containment structure. The second option is DECON, which involves the removal of radioactive components, total dismantlement of the facility, and decontamination of remaining structures to a level that permits release for unrestricted use and termination of the license. The last type is SAFSTOR, which is often considered ''delayed DECON,'' and involves initially removing all fuel and radioactive wastes and liquids, maintaining the facility in a condition that allows the decay of radioactivity to reduce radiation levels at the facility, and then decontaminating and dismantling the facility. The alternative decommissioning options, DECON, SAFSTOR, and ENTOMB, are not defined in NRC regulations but are described in a number of NRC documents. For example, NUREG–1713, ''Standard Review Plan for Decommissioning Cost Estimates for Nuclear Power Plants,'' (ADAMS Accession No. ML043510113) contains a description of the options, as does the NRC Fact Sheet, Decommissioning Nuclear Power Plants. Therefore, the NRC is treating this portion of the petition for rulemaking as a request to codify the options in 10 CFR 50.75, ''Reporting and Recordkeeping for Decommissioning Planning,'' as modified by the petitioner. The petitioner believes that the SAFSTOR decommissioning option allows licensees to turn the reactor sites into long-term high-level waste storage facilities. The petitioner cites the NRC Fact Sheet, Decommissioning Nuclear Power Plants (although the petitioner refers to it as ''the current rule''), which states that a decision by a licensee to adopt a combination of DECON and SAFSTOR may be based on factors such as the availability of waste disposal sites. The petitioner believes that this wording creates a loophole whereby a site choosing the SAFSTOR option would not be returned to unrestricted use within a period of 60 years from the time reactor operation ceases. The petitioner requests that the NRC amend its regulations to clarify that a licensee's choice of alternative decommissioning strategy must result in the return of the site to unrestricted use within 60 years and that the NRC eliminate the ENTOMB strategy as an option.

IV. Public Comments on the Petition

The NRC received one set of comments on PRM–50–94 from the Nuclear Energy Institute (NEI or the commenter), dated May 12, 2010 (ADAMS Accession No. ML101340042). The NEI's comments and the NRC responses are provided in this section.

Comment 1: Frequency of Reporting Decommissioning Funding Status

The NEI stated that requiring more frequent reporting on the status of decommissioning funds will not necessarily yield useful or actionable information when dealing with long-term investments, such as nuclear power plant decommissioning trust funds. The basis of the comment was that more frequent reporting during financially turbulent times will necessarily produce information reflecting short-term market fluctuations. The NEI stated that precipitous modifications to long-term investment strategies could result in tax consequences, negatively affect corporate credit ratings, and divert capital from the operation of existing plants. The NEI described how NRC regulations require more detailed cost estimates as a licensee approaches the cessation of operations and license termination. The NEI stated that NRC regulations allow the NRC to request information to confirm a licensee's compliance with financial assurance requirements. The NEI stated that it disagreed with the suggested revision because the petitioner did not provide an adequate basis for increasing the frequency of the decommissioning fund status reports required by 10 CFR 50.75(f)(1) and (2).

NRC Response

The NRC uses the information contained in licensee's periodic financial reports to conduct a compliance check and to assess the ability of the licensee to continue to provide financial assurance in the future. Depending on the result of the NRC's assessment, the information may indeed be actionable and may indicate

[1] A legacy site is a facility that is in decommissioning status with complex issues and an owner who cannot complete the decommissioning work for technical or financial reasons. (73 FR 3812, 3813; January 22, 2008).

that additional oversight is appropriate for a particular licensee. For example, during the financially turbulent times of 2009, the NRC increased the frequency of reporting on decommissioning funding, and the information obtained was used as the basis for taking action at numerous reactor facilities that reported shortfalls in financial assurance.

The commenter's statement regarding the potential adverse effects of making precipitous changes in the investment strategy is a separate issue from the frequency of submitting a decommissioning fund status report. Similarly, the commenter's description of the decommissioning cost estimates required as a power reactor approaches the cessation of operations and license termination are issues separate from the frequency of the fund status report.

The NRC staff finds analysis of the market impacts on available funding to be useful and actionable. The commenter's statement, that the NRC can require more frequent reporting under its existing rules, is correct. Section V, Reason for Denial, of this document provides additional discussion of how the NRC can, and in many cases does require, more frequent reporting under its existing rules.

Comment 2: Require Trust Fund Management by the Host State

The NEI stated that requiring the licensee's host State to manage the decommissioning trust funds and to periodically report on the status of such funds may not be constitutional. The NEI stated that management of funds by a State government does not immunize the funds from the effects of fluctuating market conditions, as demonstrated by the challenges associated with management of State pension funds. The NEI stated that the formation of subsidiaries and the buying and selling of property are legitimate means of doing business which do not clearly require an amendment to the NRC's regulations. The NEI stated that decommissioning funding, and continued compliance with the Commission's funding requirements, is already considered in the context of Commission reviews of license amendment requests related to changes in ownership and corporate structure.

NRC Response

The NRC does not need to reach the issue of constitutionality with respect to its authority to require a State government to manage a licensee's decommissioning trust funds. The NRC has no authority under the Atomic Energy Act of 1954, as amended, to require a State to act as a trustee.

Comment 3: Require Deposits Into Trust Fund Within 90 Days of a Shortfall

The NEI stated that requiring that all funding shortfalls be corrected within 90 days of discovery, if enacted, could have two adverse effects on a licensee. First, the NEI states that depositing funds into a trust account within 90 days of reporting a shortfall would force a utility to pay an unnecessary premium for decommissioning funds that might not be used for decades. Second, the premium would likely have an immediate impact on the company's financial health and operations. The NEI stated that the NRC's Chairman expressed confidence in the NRC's overall approach to decommissioning funding in view of the fact that most licensees maintained adequate funds during the economic downturn in 2008 and 2009. The NEI stated that over 70 percent of operating reactor units did not experience shortfalls in decommissioning funding in 2008. The NEI stated that the NRC should maintain the flexibility to work with a licensee in a reasonably expeditious manner, informed by the amount of the shortfall, current market conditions, and the date the funds will likely be needed.

NRC Response

The provisions of 10 CFR 50.75(e) allow several methods for a licensee to provide financial assurance in addition to making deposits into a trust fund. The NRC determined that each of the methods provides adequate financial assurance. The NRC agrees that the flexibility provided by its existing rules would be reduced if all funding shortfalls were required to be corrected by making deposits into the decommissioning trust fund within 90 days. The NRC also agrees that the agency's current requirements for the timeline to address funding shortfalls has continued to provide assurance of adequate funding.

Comment 4: Alternative Decommissioning Strategies

The commenter stated that, to the extent that the petition implicates enforcement action, the appropriate response should be through the request for enforcement process of 10 CFR 2.206, rather than the petition for rulemaking process of 10 CFR 2.802.

The commenter provided several reasons for its conclusion that the NRC should not amend its regulations or guidance to limit the SAFSTOR option or eliminate the ENTOMB option for decommissioning power reactors. The commenter stated that the information presented in the petition regarding SAFSTOR and ENTOMB does not appear in the NRC's regulations. Rather, it is found in an NRC fact sheet dated January 2008, and in several NRC guidance documents. The commenter concluded that the petition appears to request modification of the fact sheet and possibly the guidance documents, rather than the NRC's regulations. The commenter stated that the NRC's radiological criteria for license termination, Subpart E to 10 CFR part 20, were developed through a notice-and-comment rulemaking process. The rules of Subpart E permit license termination under restricted conditions. The commenter emphasized two provisions of 10 CFR 50.82(a)(3) that should be considered in developing a response to the petitioner's request: (1) The regulation permits the extension of the decommissioning period beyond 60 years only when necessary to protect public health and safety, and (2) the Commission will consider the unavailability of waste disposal capacity in its evaluation of the licensee's ability to carry out decommissioning. The commenter disagreed that the existing regulations jeopardize public health and safety. The commenter stated that the NRC does not have the authority to require the U.S. Department of Energy (DOE) or the U.S. Department of Defense (DOD) to store used nuclear fuel or other high-level radioactive wastes at sites under the jurisdiction of those agencies.

NRC Response

The NRC agrees with the commenter that requests for enforcement should not be addressed using the petition for rulemaking process.

In the context of a petition for rulemaking, the NRC concluded that the petitioner requests a change in the regulations to limit the use of SAFSTOR and eliminate the use of ENTOMB. The NRC agrees that its existing regulations and guidance allow for license termination under restricted use conditions; allow decommissioning time periods beyond 60 years when necessary to protect public health and safety; consider the availability of waste disposal capacity on a licensee's ability to carry out decommissioning; and do not jeopardize public health and safety. The bases for these determinations are described in a number of NRC rulemaking FRNs, for example, in its 1988 rulemaking (53 FR 24018; June 27, 1988). The NRC agrees that it does not have the authority to require the DOE or the DOD to store spent nuclear fuel or high-level waste at sites under the jurisdiction of those agencies, on

grounds that Congress has not delegated such authority to the NRC.

V. Reason for Denial

The NRC has determined that the petitioner has not provided an adequate basis upon which the NRC could act to amend its regulations as requested by the petitioner.

With respect to the petitioner's request for annual instead of biennial reporting of the decommissioning trust fund status, the Commission published a final rule in September 1998, ''Financial Assurance Requirements for Decommissioning Nuclear Power Reactors'' (63 FR 50465; September 22, 1998). In its 1998 rulemaking, the NRC established the 2-year frequency for the decommissioning fund status report after considering a range of frequencies from 1 to 5 years. The 2-year frequency was based on the following:

> Given NRC's information needs, and the multi-million-dollar size of the contributions that utilities make annually to their decommissioning funds, the potential pay-off per hour of staff labor that NRC invests in monitoring funds is likely to be significant (63 FR 50465, 50476).

Since the issuance of the 1998 rule, the 2-year reporting frequency has continued to be adequate for routine monitoring of the status of decommissioning financial assurance. In cases where a licensee reports a shortfall, the NRC can exercise increased oversight to monitor the licensee's progress in resolving the shortfall under the provisions of 10 CFR 50.75(e)(2). The oversight may require fund status information more frequently than annually, and the NRC adjusts its monitoring accordingly. For example, due to the market decline in 2008, the NRC issued numerous requests for additional information to monitor reactor facilities with shortfalls. The 1998 rule also addressed the request to increase the frequency of reporting from 1 year to every six months for reactors within 5 years of the expected end of operations. The 1-year frequency for reactors nearing the end of operations was endorsed by a majority of the commenter's on the 1998 rule. However, as with the 2-year reports, the NRC can increase the frequency of monitoring as needed to assure that the reactor facility has adequate financial assurance. The NRC's ability to adjust the frequency of monitoring enables the agency to obtain adequate information for cases where the licensee has a shortfall, but avoids imposing an unnecessary reporting burden on licensees that meet the funding assurance requirements. The NRC denies the petition to increase the reporting frequency for all reactors in response to the fact that some reactors have reported shortfalls because the existing regulatory framework already provides the NRC adequate flexibility to address oversight and reporting frequency for facilities with shortfalls.

The petitioner requests the NRC amend its rules to require the host State of a reactor facility to control, manage, and report the status of the licensee's decommissioning trust fund. However, the NRC does not have authority to require a State to become a trustee nor does the NRC view it as appropriate to impose trustee status on a non-licensee. In addition, the NRC's regulations at 10 CFR 50.75(e) do not preclude such an arrangement. The NRC denies the request to require the host State to become a trustee of licensee's decommissioning funds.

With respect to the request that the decommissioning funds should not be held by the licensee, the NRC agrees with the petitioner. However, current NRC regulations already specify that the licensee cannot hold decommissioning trust funds. The provisions in § 50.75(e)(1)(i) and (ii) for the prepayment and the external sinking fund methods require the funds to be held in an account segregated from licensee assets and outside the administrative control of the licensee and its subsidiaries or affiliates. Therefore, no amendment is necessary to achieve the goal of prohibiting the licensee from holding the funds itself.

The petitioner requests the NRC to amend its regulations to require a licensee to deposit funds into the licensee's decommissioning trust fund within 90 days of reporting a shortfall as the exclusive remedy for a shortfall. The petitioner states the amendment is needed to provide reasonable assurance that funds will be available when needed and to avoid legacy sites that must be cleaned up at taxpayer expense. In its Staff Requirements Memorandum on SECY–10–0084, ''Explanation of Changes to Revision 2 to Regulatory Guide 1.159, 'Assuring the Availability of Funds for Decommissioning Nuclear Reactors' '', dated October 25, 2010 (ADAMS Accession No. ML102980565), the Commission disapproved a proposed change that would have directed merchant licensees to adjust decommissioning funds annually and within 3 months of the annual recalculation of the regulatory minimum required by 10 CFR 50.75(b). The Commission stated that the guidance should retain the current directive that merchant licensees adjust their funding amounts at least once every two years, in conjunction with the biennial report, and interpreted that to mean that shortfalls reported in a biennial report must be corrected by the time the next biennial report is due two years later. The Commission also approved affording rate-regulated licensees 5 years to adjust the funding amounts.

Furthermore, the NRC has determined that several methods of providing financial assurance exist that can afford an adequate level of assurance that funds for decommissioning will be available when needed. The reason for providing several methods was to provide flexibility to permit licensees to select the method best suited to their needs. Specifically, the NRC has concluded that eliminating the flexibility of using all the currently existing methods of financial assurance would impose a burden on licensees without providing an increase in safety.

Based on the previously provided rationale, the NRC denies the request.

The petitioner requests that the NRC amend its regulations to require the SAFSTOR option to be limited such that decommissioning is completed within 60 years. The basis of the request is that the NRC promised the host community that the site would be decommissioned and returned to unrestricted use within 60 years and to avoid legacy sites with high level waste disposal and long-term storage facilities. However, the 60-year period was never intended to be an absolute limit, and the rule language has never stated it as an absolute limit. When the NRC issued its final rule, ''General Requirements for Decommissioning Nuclear Facilities'' (53 FR 24018; June 27, 1988), the NRC stated:

> The rule does not contain a specific limitation on the length of time for SAFSTOR beyond the time period indicated in the modified rule. The case-by-case considerations, such as shortage of radioactive waste disposal space offsite or presence of an adjacent reactor whose safety might be affected by dismantlement procedures, or other similar site specific considerations, mean that the appropriate delay for a specific facility must be based on factors unique to that facility and could result in extension of completion of decommissioning beyond 60 years. Based on this, the NRC considers the setting of an absolute time limit on SAFSTOR to be impractical and unnecessary. * * * [T]he rule contains requirements that a licensee must submit an alternative for decommissioning to the NRC for approval and that consideration will be given to an alternative which provides for completion of decommissioning beyond 60 years only when necessary to protect health and safety. (53 FR 24018, 24023).

In view of the NRC's conclusion that the setting of an absolute time limit on SAFSTOR would be impractical and

unnecessary, the NRC disagrees that a formal commitment was made that a reactor facility would be required to complete decommissioning within 60 years. The NRC denies the request to impose an absolute 60-year time limit for decommissioning.

The petitioner requests the NRC to amend its regulations to require that the SAFSTOR option may be used only if the license will be terminated based on meeting unrestricted use criteria. The bases of the request are the petitioner's beliefs that the NRC promised the host community that a site would be decommissioned and returned to unrestricted use within 60 years and to avoid legacy sites with high-level waste disposal and long-term storage facilities. When the 1988 Decommissioning Rule was issued, the definition of decommissioning was to remove (as a facility) safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of the license. (53 FR 24049; June 27, 1988). However, in July 1997 the NRC amended the definition of decommissioning to allow license termination under restricted conditions. (62 FR 39058; July 21, 1997). The NRC explained its reasoning with this statement:

> Restricted use has been retained in the final rule. Based on its analyses in the Final GEIS and its experiences with actual decommissioned sites, the Commission recognizes that, although unrestricted use is generally preferred, restricted use (when properly designed in accordance with the rule's provisions discussed in Section IV.B.3) can provide a cost-effective alternative to unrestricted use for some facilities and maintain the dose to the average member of the pertinent critical group at the same level. Thus, the Commission has replaced the prohibitively expensive provision for justifying restricted use with a reasonable cost provision. (62 FR 39058, 39072).

The amended definition of decommissioning in 10 CFR 50.2 was subject to a notice-and-comment rulemaking, and the Commission considered stakeholder comments before issuing the final rule. The petitioner did not raise any new issues that would cause the NRC to reconsider the conclusions reached in the 1997 rulemaking process. On that basis, the NRC denies the request to re-impose a requirement for a reactor facility to decontaminate its facility to meet unrestricted use criteria in all cases.

The petitioner requests the NRC to amend its regulations to prohibit a licensee from using a SAFSTOR facility for any activities related to other reactors onsite. Similar to the petitioner's other requests, the bases for this request are the petitioner's beliefs that the NRC promised the host community that a site would be decommissioned and returned to unrestricted use within 60 years to avoid legacy sites with high-level waste disposal and long-term storage facilities. The Commission notes that it is possible that the completion of decommissioning a facility in SAFSTOR could be delayed past the 60-year mark if the facility is used for activities related to an operating unit on the site. The need to use equipment shared by a shutdown unit and an operating unit could prevent completing the decommissioning of the shutdown unit until the operating unit was permanently shut down. However, the discussion of SAFSTOR in the Statement of Considerations demonstrated that the NRC's regulations allow the licensee to exceed the 60-year limit in cases where a shutdown unit is located on the same site as an operating unit, subject to NRC approval. In a case where the SAFSTOR facility shares equipment with an operating unit, the NRC would consider the risk of conducting decommissioning activities near an operating unit. That type of evaluation would necessarily depend on site-specific factors that are not well suited to codification in a rule.

The Commission shares the petitioner's concerns regarding legacy sites. To prevent the occurrence of legacy sites at reactor facilities, 10 CFR 50.75(f)(3) requires the licensee to submit a preliminary decommissioning cost estimate that includes an up-to-date assessment of the major factors that could affect the cost of decommissioning. The provisions of 10 CFR 50.54(bb) require the licensee to provide a plan for the management of spent fuel. In addition, the Commission recently issued a rule which requires licensees to minimize contamination; requires that licensees survey outside for radiological hazards, including the subsurface soil and groundwater; and revises the financial assurance regulations (76 FR 35512; June 17, 2011). These requirements work together before the end of operations to assure that the licensee has the financial ability to safely decommission the site and to manage the spent fuel. These requirements assure that a facility will not become a legacy site, even if a facility in SAFSTOR continues to share equipment with an operating unit onsite. The NRC denies the request to forbid the use of a facility in SAFSTOR for any activities related to another unit onsite.

The petitioner requests the NRC to forbid the licensee from placing additional waste streams on the SAFSTOR site that belong to other licensees, even if one company owns multiple licenses for multiple reactors on a singular piece of land. As noted, the 60-year timeline for decommissioning is not an absolute limit, and, considered alone, would not provide the basis for forbidding placement of waste streams from other onsite reactors in the SAFSTOR facility. Also, as noted, the legacy site issue depends on whether the licensee has the financial resources to complete decommissioning. The NRC addresses this issue through its financial assurance requirements. A licensee is required in 10 CFR 50.75 to provide assurance that at any time during the life of the facility, through termination of the license, adequate funds will be available to complete decommissioning. (61 FR 39278; July 29, 1996). As noted in the Statement of Considerations, when a licensee has a shortfall in financial assurance, the NRC increases its oversight activities until the matter is resolved. The NRC's regulations in 10 CFR Part 20, ''Standards for Protection Against Radiation,'' provide general requirements for ensuring that radioactive waste is stored safely. With respect to high level waste and spent fuel, the Commission recently updated its Waste Confidence Decision with the following statement: ''The Commission finds reasonable assurance that sufficient mined geologic repository capacity will be available to dispose of the commercial high-level radioactive waste and spent fuel generated in any reactor when necessary.'' (75 FR 81037, 81067; December 23, 2010). The requirements of 10 CFR 50.54(bb) require the licensee to provide a plan for managing spent fuel until it is transferred to the Secretary of Energy for final disposal. The Waste Confidence Decision combined with the ongoing requirement to provide adequate financial assurance for decommissioning, and to maintain a spent fuel management plan, indicate that a facility in SAFSTOR will not become a legacy site in the event some waste from another reactor on the site is placed in the SAFSTOR facility. The NRC denies this request.

The petitioner requests the NRC to amend its regulations to eliminate the use of ENTOMB as a decommissioning option. However, in its 1988 Decommissioning Rule, the NRC provided the following explanation for retaining the ENTOMB option for decommissioning:

It is the Commission's belief that the ENTOMB alternative for decommissioning should not be specifically precluded in the rule because there may be instances in which it would be an allowable alternative in protecting public health and safety and common defense and security. By not prohibiting ENTOMB, the rule is more flexible in enabling NRC to deal with these instances. These instances might include smaller reactor facilities, reactors which do not run to the end of their lifetimes, or other situations where long-lived isotopes do not build up to significant levels or where there are other site specific factors affecting the safe decommissioning of the facility, as for example, presence of other nuclear facilities at the site for extended periods. In addition there is potential for variations on the ENTOMB option where, for example, some decontamination has already been performed, thereby making the ENTOMB option more viable. * * * [C]oncerns were expressed by the commenter's that the ENTOMB option would cause environmental damage due to the presence of long-lived radionuclides which would be radioactive beyond the life of any concrete structure, that it is inconsistent with the definition of decommissioning requiring unrestricted release, and that some reactors are located in highly populous areas. In addition, the Supplementary Information to the proposed rule indicated, in general, that there may be difficulties with the use of ENTOMB, in particular in demonstrating that the radioactivity in the entombed structure had decayed to levels permitting unrestricted release of the property in a period on the order of 100 years. In response, the rule contains requirements that a licensee must submit an alternative for decommissioning to the NRC for approval and that consideration will be given to an alternative which provides for completion of decommissioning beyond 60 years only when necessary to protect health and safety. This provides the Commission with both sufficient leverage and flexibility to ensure that if the ENTOMB option is chosen by the licensee it will only be used in situations where it is reasonable and consistent with the definition of decommissioning which requires that decommissioning lead to unrestricted release. As indicated above, analysis of ENTOMB indicates that it can be carried out safely and with minimal environmental effect for the time periods presented in this Supplementary Information and in the guidance under preparation. However, based on the difficulties with ENTOMB described in the Supplementary Information to the proposed rule and by the commenter's, use of ENTOMB by a licensee would be carefully evaluated by NRC according to the requirements of the rule before its use is permitted. (53 FR 24018, 24023–24; June 27, 1988).

The decision to retain the ENTOMB option was subject to a notice-and-comment rulemaking. The petitioner has not raised any new or significant points that would cause the Commission to reconsider the conclusions reached in the 1988 rulemaking. On the bases noted, the NRC denies the request to eliminate the use of ENTOMB as an option for decommissioning a nuclear facility.

For these reasons, the NRC denies the petitioner's requests for the NRC to modify its requirements for reporting the status of licensee's decommissioning trust funds, to have host States manage these trust funds, to require a deposit into the trust fund within 90 days as the exclusive remedy for a shortfall, to amend the definition of the SAFSTOR decommissioning option in its regulations, and to eliminate the ENTOMB option.

Dated at Rockville, Maryland, this 1st day of December 2011.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 2011–31365 Filed 12–6–11; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 73

[Docket Nos. PRM–73–15; NRC–2011–0251]

Installation of Radiation Alarms for Rooms Housing Neutron Sources

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or the Commission) has received a petition for rulemaking (PRM) dated September 15, 2011, from George Hamawy (the petitioner). The petitioner requests that the NRC require installation of radiation alarms in rooms housing neutron sources.

DATES: Submit comments by February 21, 2012. Comments received after this date will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before this date.

ADDRESSES: Please include Docket ID NRC–2011–0251 in the subject line of your comments. For additional instructions on submitting comments and instructions on accessing documents related to this action, see ''Submitting Comments and Accessing Information'' in the **SUPPLEMENTARY INFORMATION** section of this document. You may submit comments by any one of the following methods:

- *Federal rulemaking Web site:* Go to *http://www.regulations.gov* and search for documents filed under Docket ID NRC–2011–0251. Address questions about NRC dockets to Carol Gallagher, *telephone:* (301) 492–3668; *email: Carol.Gallagher@nrc.gov.*
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, *Attn:* Rulemakings and Adjudications Staff.
- *Email comments to: Rulemaking.Comments@nrc.gov.* If you do not receive a reply email confirming that we have received your comments, contact us directly at (301) 415–1677.
- *Hand deliver comments to:* 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. Federal workdays (*telephone:* (301) 415–1677).
- *Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at (301) 415–1101.

FOR FURTHER INFORMATION CONTACT: Cindy Bladey, Chief, Rules, Announcements, and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, *telephone:* (301) 492–3667, *email: Cindy.Bladey@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Submitting Comments and Accessing Information

Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal rulemaking Web site, *http://www.regulations.gov.* Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed.

The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed.

You can access publicly available documents related to this document using the following methods:

- *NRC's Public Document Room (PDR):* The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* Publicly available documents created or received at the NRC are available online in the NRC Library at *http://www.nrc.gov/reading-rm/*

adams.html. From this page, the public can gain entry into ADAMS, which provides text and image files of the NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1–(800) 397–4209, (301) 415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for the incoming petition for rulemaking is ML112700682.

• *Federal Rulemaking Web Site:* Public comments and supporting materials related to this petition for rulemaking can be found at *http://www.regulations.gov* by searching on Docket ID NRC–2011–0251.

II. Petitioner

Mr. George Hamawy works at Columbia University in New York City, Radiation Safety for Research. Mr. Hamawy is concerned about the security of neutron sources.

III. Petition

The petitioner states that the construction of sources used at colleges and universities for irradiating foils makes the sources an easy target for theft. The petitioner states:

> The source is located at the end of a rod in the middle of a 55-gallon drum. The source is surrounded inside the drum by a plastic or wax shielding. The samples are lowered in holes next to the source for irradiation. The drum has a cover that can be easily removed and the source is taken out to be placed in a smaller drum for get away.

The petitioner explains that GTRI (the U.S. Department of Energy's Global Threat Reduction Initiative came) to the Columbia University facility and ''placed wires around the drum and was attached to the wall.'' The petitioner claims that ''if someone wants to take the source they do not have to disturb the wire just remove the cover [of the drum] and take the source.''

The petitioner states that there is no current requirement to install radiation alarms in rooms containing neutron sources. The petitioner requests that the NRC require installation of radiation alarms that are connected to the Public Safety Department that can be triggered when a source is removed. The petitioner believes installation of the radiation alarms will be effective in preventing source removal. The petitioner is especially concerned with hostage situations where the intruder gains entry to the room housing the sources.

IV. Conclusion

The NRC is soliciting comments on the petition for rulemaking requesting that the NRC require installation of radiation alarms for rooms housing neutron sources.

Dated at Rockville, Maryland, this 1st day of December 2011.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,

Secretary of the Commission.

[FR Doc. 2011–31367 Filed 12–6–11; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF ENERGY

10 CFR Parts 429 and 430

[Docket Number EERE–2011–BT–CE–0077]

RIN 1904–AC68

Energy Conservation Program: Enforcement of Regional Standards for Residential Furnaces and Central Air Conditioners and Heat Pumps

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of Data Availability (NODA).

SUMMARY: The U.S. Department of Energy (DOE or the Department) has developed three separate possible approaches to enforcement of regional standards for residential furnaces and residential central air conditioners and heat pumps set forth by direct final rule published in the **Federal Register** on June 27, 2011. The Department is considering these three approaches, or a combination of elements in these approaches, as a framework for developing an enforcement plan for regional standards. DOE seeks comment on the approaches to inform the rulemaking for enforcement of regional energy efficiency standards for residential furnaces and residential central air conditioners and heat pumps. DOE also seeks comment on a possible waiver process for regional standards applicability.

DATES: DOE will hold a public meeting on December 16, 2011, from 9 a.m. to 4 p.m., in Washington, DC. The meeting will also be broadcast as a webinar. See ''Public Participation,'' for webinar registration information, participant instructions, and information about the capabilities available to webinar participants.

DOE will accept comments, data, and information regarding this NODA before and after the public meeting, but no later than February 6, 2012. See ''Public Participation,'' for details.

ADDRESSES: The public meeting will be held at the U.S. Department of Energy, Forrestal Building, Room 8E–089, 1000 Independence Avenue SW., Washington, DC 20585. To attend, please notify Ms. Brenda Edwards at (202) 586–2945. Please note that foreign nationals visiting DOE Headquarters are subject to advance security screening procedures. Any foreign national wishing to participate in the meeting should advise DOE as soon as possible by contacting Ms. Brenda Edwards at (202) 586–2945 to initiate the necessary procedures.

Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE–2011–BT–CE–0077, by any of the following methods:

• *Email:* to *EnforcementFunCAC–2011–CE–0077@ee.doe.gov.* Include EERE–2011–BT–CE–0077 in the subject line of the message.

• *Mail:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, Mailstop EE–2J, Revisions to Energy Efficiency Enforcement Regulations, EERE–2011–BT–CE–0077, Independence Avenue SW., Washington, DC 20585–0121. *Phone:* (202) 586–2945. Please submit one signed paper original.

• *Hand Delivery/Courier:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, 6th Floor, 950 L'Enfant Plaza SW., Washington, DC 20024. *Phone:* (202) 586–2945. Please submit one signed paper original.

Instructions: All submissions received must include the agency name and docket number or RIN for this document.

Docket: For access to the docket to read background documents, or comments received, go to the Federal eRulemaking Portal at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information may be sent to Ms. Ashley Armstrong, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Program, EE–2J, 1000 Independence Avenue SW., Washington, DC 20585–0121. *Email: Ashley.Armstrong@ee.doe.gov*, and Ms. Laura Barhydt, U.S. Department of Energy, Office of the General Counsel, Forrestal Building, GC–32, 1000 Independence Avenue SW.,

Washington, DC 20585. *Telephone:* (202) 287–5772. *Email: Laura.Barhydt@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: The Energy Independence and Security Act (EISA) of 2007 modified the Energy Policy and Conservation Act (EPCA) to authorize DOE to consider regional standards for certain products if the regional standards can save significantly more energy than a national standard and are economically justified. Specifically, DOE was authorized to establish up to two additional regional standards for central air conditioners and heat pumps and one additional standard for furnaces in addition to national standards. (42 U.S.C. 6295(o)(6)(B)(ii))

EISA 2007 requires DOE to initiate an enforcement rulemaking not later than 90 days after the issuance of a final rule that establishes a regional standard. (42 U.S.C. 62905(o)(6)(G)(ii)(I)) EISA 2007also requires that a final rule for enforcement be issued not later than 15 months after the final rule that establishes a regional standard. (42 U.S.C. 62905(o)(6)(G)(ii)(III))

On June 27, 2011, DOE promulgated a direct final rule for these products that established regional standards. 76 FR 37549. In addition to the current base national standard, DOE established one additional regional standard for furnaces and two additional regional standards for central air conditioners and heat pumps. The Department published a notice of effective date and compliance dates for the direct final rule on October 31, 2011 (76 FR 67037), requiring compliance for non-weatherized furnaces on May 1, 2013, and for weatherized furnaces and central air conditioners and heat pumps on January 1, 2015.

The Department has developed three possible approaches to enforcement of regional energy conservation standards for residential furnaces and residential central air conditioners and heat pumps. Each approach includes a description of the obligations that would be imposed upon manufacturers, distributors, and contractors in the product supply chain. The Department is considering these approaches or some combination of these approaches as a framework for developing a proposed enforcement scheme for regional standards. Stakeholders are encouraged to review the approaches and submit comments on each approach, including the different aspects of each approach.

In addition, the Department discusses how the compliance dates apply to various parties such as manufacturers, distributors and contractors. The Department also seeks comment on a possible waiver process to permit installation of units to do not meet the applicable regional standard in limited circumstances.

Purpose: The purpose of this NODA is to inform stakeholders of three possible approaches for enforcement of regional energy efficiency standards for residential furnaces and residential central air conditioners and heat pumps and to solicit feedback from stakeholders on these approaches. Respondents are advised that this NODA is for information purposes only. DOE plans to use the information gathered through this NODA in developing a proposed rule for public comment.

Public Participation

A. Attendance at Public Meeting

The time, date and location of the public meeting are listed in the **DATES** and **ADDRESSES** sections at the beginning of this document. If you plan to attend the public meeting, please notify Ms. Brenda Edwards at (202) 586–2945 or *Brenda.Edwards@ee.doe.gov.* As explained in the **ADDRESSES** section, foreign nationals visiting DOE Headquarters are subject to advance security screening procedures.

In addition, you can attend the public meeting via webinar. Webinar registration information, participant instructions, and information about the capabilities available to webinar participants will be published on DOE's Web site at *http://www1.eere.energy.gov/buildings/appliance_standards/certification_enforcement.html.* Participants are responsible for ensuring their systems are compatible with the webinar software.

B. Procedure for Submitting Prepared General Statements for Distribution

Any person who has plans to present a prepared general statement may request that copies of his or her statement be made available at the public meeting. Such persons may submit requests, along with an advance electronic copy of their statement in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format, to the appropriate address shown in the **ADDRESSES** section at the beginning of this notice. The request and advance copy of statements must be received at least one week before the public meeting and may be emailed, hand-delivered, or sent by mail. DOE prefers to receive requests and advance copies via email. Please include a telephone number to enable DOE staff to make a follow-up contact, if needed.

C. Conduct of Public Meeting

DOE will designate a DOE official to preside at the public meeting and may also use a professional facilitator to aid discussion. The meeting will not be a judicial or evidentiary-type public hearing, but DOE will conduct it in accordance with section 336 of EPCA (42 U.S.C. 6306). A court reporter will be present to record the proceedings and prepare a transcript. DOE reserves the right to schedule the order of presentations and to establish the procedures governing the conduct of the public meeting. After the public meeting, interested parties may submit further comments on the proceedings as well as on any aspect of the rulemaking until the end of the comment period.

The public meeting will be conducted in an informal, conference style. DOE will present summaries of comments received before the public meeting, allow time for prepared general statements by participants, and encourage all interested parties to share their views on issues affecting this NODA. Each participant will be allowed to make a general statement (within time limits determined by DOE), before the discussion of specific topics. DOE will permit, as time permits, other participants to comment briefly on any general statements.

At the end of all prepared statements on a topic, DOE will permit participants to clarify their statements briefly and comment on statements made by others. Participants should be prepared to answer questions by DOE and by other participants concerning these issues. DOE representatives may also ask questions of participants concerning other matters relevant to this rulemaking. The official conducting the public meeting will accept additional comments or questions from those attending, as time permits. The presiding official will announce any further procedural rules or modification of the above procedures that may be needed for the proper conduct of the public meeting.

A transcript of the public meeting will be included in the docket, which can be viewed as described in the Docket section at the beginning of this notice. In addition, any person may buy a copy of the transcript from the transcribing reporter.

D. Submission of Comments

DOE will accept comments, data, and information regarding this notice before or after the public meeting, but no later than the date provided in the **DATES**

section at the beginning of this notice. Interested parties may submit comments using any of the methods described in the **ADDRESSES** section at the beginning of this notice.

Submitting comments via regulations.gov. The regulations.gov web page will require you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to regulations.gov information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (CBI)). Comments submitted through regulations.gov cannot be claimed as CBI. Comments received through the Web site will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through regulations.gov before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that regulations.gov provides after you have successfully uploaded your comment.

Submitting comments via email, hand delivery, or mail. Comments and documents submitted via email, hand delivery, or mail also will be posted to regulations.gov. If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information on a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. Email submissions are preferred. If you submit via mail or hand delivery, please provide all items on a CD, if feasible. It is not necessary to submit printed copies. No facsimiles (faxes) will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, written in English, and are free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. According to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email, postal mail, or hand delivery two well-marked copies: one copy of the document marked confidential including all the information believed to be confidential, and one copy of the document marked non-confidential with the information believed to be confidential deleted. Submit these documents via email or on a CD, if feasible. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

Factors of interest to DOE when evaluating requests to treat submitted information as confidential include: (1) A description of the items; (2) whether and why such items are customarily treated as confidential within the industry; (3) whether the information is generally known by or available from other sources; (4) whether the information has previously been made available to others without obligation concerning its confidentiality; (5) an explanation of the competitive injury to the submitting person which would result from public disclosure; (6) when such information might lose its confidential character due to the passage of time; and (7) why disclosure of the information would be contrary to the public interest.

It is DOE's policy that all comments may be included in the public without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

E. Issues on Which DOE Seeks Comment

Although DOE welcomes comments on any aspect of this NODA, DOE has identified a number of issues that it is particularly interested in receiving comments and views of interested parties. These are presented in the framework document.

Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this notice of data availability.

List of Subjects

10 CFR Part 429

Energy conservation, Household appliances, Reporting and recordkeeping requirements.

10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports.

Issued in Washington, DC, on November 29, 2011.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency, Office of Technology Development, Energy Efficiency and Renewable Energy.

[FR Doc. 2011–31419 Filed 12–6–11; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–1342; Directorate Identifier 2011–CE–038–AD]

RIN 2120–AA64

Airworthiness Directives; DG Flugzeugbau GmbH Sailplanes

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

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for DG

Flugzeugbau GmbH Models DG–500 Elan Orion sailplanes and DG–500M and DG–500MB powered sailplanes. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as incorrect re-installation of the rear cockpit securing rope for the headrest of the rear seat during maintenance, which could cause the rear seat to interfere with the control stick of the sailplane. We are issuing this proposed AD to require actions to correct the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by January 23, 2012.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact DG Flugzeugbau GmbH, Otto-Lilienthal-Weg 2, 76646 Bruchsal, Federal Republic of Germany; telephone: +49 (0) 7251 3020140; fax: +49 (0) 7251 3020149; *Internet: http://www.dg-flugzeugbau.de/tech-mitteilungen-e.html; email: dirks@dg-flugzeugbau.de.* You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Jim Rutherford, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; *telephone:* (816) 329–4165; *fax:* (816) 329–4090; *email: jim.rutherford@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2011–1342; Directorate Identifier 2011–CE–038–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued AD No.: 2011–0191, dated September 30, 2011 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> Several occurrences have been reported of incorrect re-installation of rear cockpit securing rope for the headrest of the rear seat during maintenance. In one of these occurrences, the aeroplane suffered an accident. The technical investigations following this accident have revealed that the rear cockpit headrest securing rope was too long, which caused the rear seat to interfere with the control stick of the aeroplane.
>
> This condition if not detected and corrected, could lead to loss of control of the aeroplane.
>
> To address this unsafe condition, DG Flugzeugbau have developed a modification to be accomplished in accordance with the Working Instruction No. 1 for Technical Note (TN) 348/20 in issue 3, dated 13 September 2011, for the English language version and in issue 2, dated 22 October 2008, for the German language version (English version revised at issue 3 to correct a translation discrepancy), which aims to prevent wrong re-installation of the headrest securing rope. TN 500/05 embodies this Working Instruction.
>
> For the reasons described above, this AD requires a one-time inspection of the length of the rear cockpit headrest securing rope and, in case of discrepancy, readjustment of the length. In addition, this AD requires the installation of a modified headrest securing rope with snap hook.

You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

DG Flugzeugbau GmbH has issued Technical Note No. 500/05, dated September 19, 2011, and Working Instruction No. 1 for TN348/20, Issue 3, dated September 13, 2011. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of the Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with this State of Design Authority, they have notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Differences Between This Proposed AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have proposed different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a NOTE within the proposed AD.

Costs of Compliance

We estimate that this proposed AD will affect 14 products of U.S. registry. We also estimate that it would take about 2.5 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Required parts would cost about $1,088 per product.

Based on these figures, we estimate the cost of the proposed AD on U.S.

operators to be $18,207 or $1,300.50 per product.

In addition, we estimate that any necessary follow-on actions would take about 0.5 work-hour, for a cost of $42.50 per product. We have no way of determining the number of products that may need these actions.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new AD:

DG Flugzeugbau GmbH: Docket No. FAA–2011–1342; Directorate Identifier 2011–CE–038–AD.

(a) Comments Due Date

We must receive comments by January 23, 2012.

(b) Affected ADs

None.

(c) Applicability

This AD applies to DG Flugzeugbau GmbH Models DG–500 Elan Orion sailplanes and DG–500M and DG–500MB powered sailplanes, all serial numbers, that are:

(i) Equipped with a headrest on the rear seat; and

(ii) certificated in any category.

(d) Subject

Air Transport Association of America (ATA) Code 25: Equipment/Furnishing.

(e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as incorrect re-installation of the rear cockpit securing rope for the headrest of the rear seat during maintenance. We are issuing this AD to correct the length of the rear cockpit headrest securing rope, which if too long, could cause the rear seat to interfere with the control stick of the sailplane and could result in loss of control of the sailplane.

(f) Actions and Compliance

Unless already done, do the following actions:

(1) Within the next 30 days after the effective date of this AD, inspect the rear cockpit headrest securing rope to determine the length. Do the inspection as specified in Instruction No. 2 of DG Flugzeugbau GmbH Technical Note No. 500/05, dated September 19, 2011.

(i) If the length of the rear cockpit headrest securing rope is more than 450 millimeters (mm) or less than 400 mm, before further flight, adjust the length of the rear cockpit headrest securing rope to a length between 400 mm and 450 mm as shown in Sketch 2 of DG Flugzeugbau GmbH Working Instruction No. 1 for TN348/20, Issue 3, dated September 13, 2011. After doing the adjustment, do the action required in paragraph (f)(2) of this AD.

(ii) If the length of the rear cockpit headrest securing rope is between 400 mm and 450 mm, do the action required in paragraph (f)(2) of this AD.

(2) Within 3 months after the effective date of this AD, replace the rear cockpit headrest securing rope with a rear cockpit headrest securing rope with a snap hook. Do the replacement following DG Flugzeugbau GmbH Working Instruction No. 1 for TN348/20, Issue 3, dated September 13, 2011, as specified in Instruction No. 3 of DG Flugzeugbau GmbH Technical Note No. 500/05, dated September 19, 2011.

(3) Replacement of the rear cockpit headrest securing rope with a rear cockpit headrest securing rope with a snap hook done before the effective date of this AD following DG Flugzeugbau GmbH Working Instruction No. 1 for TN348/20, Issue 2, is considered acceptable for compliance with paragraph (f)(2) of this AD.

(g) FAA AD Differences

Note: This AD differs from the MCAI and/or service information as follows: No differences.

(h) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to Attn: Jim Rutherford, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4165; fax: (816) 329–4090; email: *jim.rutherford@faa.gov*. Before using any approved AMOC on any sailplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, a federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

(i) Related Information

Refer to MCAI European Aviation Safety Agency (EASA) AD No.: 2011–0191, dated September 30, 2011; DG Flugzeugbau GmbH Technical Note No. 500/05, dated September 19, 2011; and DG Flugzeugbau GmbH Working Instruction No. 1 for TN348/20, Issue 3, dated September 13, 2011, for related information. For service information related to this AD, contact DG Flugzeugbau GmbH, Otto-Lilienthal-Weg 2, 76646 Bruchsal, Federal Republic of Germany; telephone: +49 (0) 7251 3020140; fax: +49 (0) 7251 3020149; Internet: *http://www.dg-flugzeugbau.de/tech-mitteilungen-e.html*; email: *dirks@dg-flugzeugbau.de*. You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on December 1, 2011.

John Colomy,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–31425 Filed 12–6–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 77

[Docket No.: FAA–2011–1279; Notice No. 11–07]

Notification for Airborne Wind Energy Systems (AWES)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of policy and request for information.

SUMMARY: The FAA seeks comments on revising its policy regarding the application of Title 14 of the Code of Federal Regulations (14 CFR) part 77, ''Safe, Efficient Use and Preservation of the Navigable Airspace,'' to airborne wind energy systems (AWES). In addition, this notice requests information from airborne wind energy system developers and the public related to these systems so that the FAA can comprehensively analyze the AWES and their integration into the National Airspace System (NAS).

DATES: Written comments must be received on or before February 6, 2012.

ADDRESSES: Send comments identified by docket number 2011–1279 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Privacy: The FAA will post all comments it receives, without change, to *http://www.regulations.gov,* including any personal information the commenter provides. Using the search function of the docket web site, anyone can find and read the electronic form of all comments received into any FAA dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, *etc.*). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478), as well as at *http://DocketsInfo.dot.gov.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: For questions concerning this action, contact Mr. René Joseph (RJ) Balanga, Mission Support Services, Airspace, Regulations and ATC Procedures Group, Air Traffic Organization, AJV–11, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–8783, email *rene.balanga@faa.gov.*

SUPPLEMENTARY INFORMATION:

Authority

Title 49 of the United States Code, section 40103 vests the Administrator with broad authority to regulate the safe and efficient use of the navigable airspace. The Administrator is authorized to issue rules and regulations to govern the flight, navigation, protection, and identification of aircraft for the protection of persons and property on the ground, and for the efficient use of the navigable airspace (49 U.S.C. 40103(b)). The Administrator also is authorized under § 44701(a)(5) to promote safe flight of civil aircraft in air commerce by prescribing regulations and minimum standards for other practices, methods, and procedures necessary for safety in air commerce and national security.

Background

During the past decade, there has been an increased focus on the use of clean renewable energy resources, including wind energy. The FAA has been approached by various entities, including manufacturers, scientists, engineers, and advocacy groups representing the wind energy community, who are researching the use of more sustained and consistent winds at higher altitudes where conventional ground-based wind turbines cannot reach. As part of their research, the energy community is examining various concepts for system designs to harness high altitude winds as a potential source of energy.

Airborne Wind Energy Systems (AWES) are described broadly as mechanical devices that are moored to the ground, via a tether or cabling component, for the purpose of capturing the fluid stream kinetic energy of winds. The kinetic energy captured by the device is then utilized in various fashions to generate electricity. In one option, the wind energy is immediately converted into consumable power, at the system component keeping the system aloft, and then transferred to the ground by a mechanical tether, cabling conductor, or other method. In another option, the combination of the wind, the aloft device, and the mooring cables are systematically utilized to drive an electrical generator located on the ground.

The basic overall components that comprise various AWESs are fairly similar in concept, however, the technologies and the specific devices that keep them aloft differ dramatically. Such devices have leveraged on similar engineering designs that apply to kites, balloons, kytoons, aircraft wings, aircraft, airfoils, as well as others.[1]

Although some of these AWES components could be covered by 14 CFR part 101, *Moored balloons, kites, amateur rockets and unmanned free balloons,* some conceptual designs include hybrid concepts or utilize new innovative techniques that are not as easily classifiable. For example, the FAA identified some AWESs employing ''balloon-like'' design structures with

[1] 14 CFR 1.1 defines a balloon as a ''lighter-than-air aircraft that is not engine driven, and that sustains flight through the use of either gas buoyancy or an airborne heater,'' and defines a kite as a ''framework, covered with paper, cloth, metal, or other material, intended to be flown at the end of a rope or cable, and having as its only support the force of the wind moving past its surfaces.''

motorized rotors for vertical and/or horizontal control, resembling a moored airship which does not fall within the category of 14 CFR part 101 devices.[2] Additionally, the FAA also identified some AWESs that employ a moored kite or balloon with one or more wind capturing devices (wings or blades) attached along the mooring cable that spin a separate cable and activate ground-based power generators. Consequently, the FAA has determined that AWES are unique and would not fall under 14 CFR part 101.

Furthermore, since AWES is a relatively new technology that will be used to support clean, renewable energy initiatives, the FAA finds that part 101 does not currently contain the necessary provisions to address these systems.

Whether designed with conventional 14 CFR part 101 type devices or non-conventional hybrid-type components, each AWES possesses differing attributes. These attributes include, but are not limited to, its physical design, how it operates, necessary airspace utilized, radar cross-section, and reflection coefficient. The FAA is concerned with these differing attributes and their unknown impacts to the NAS, navigable airspace, and to the flying public. Therefore, the FAA concludes that each AWES deployment needs to be studied on a case-by-case basis with respect to the surrounding aviation environment to ensure aviation safety.

Policy

Given the altitudes that these structures can operate and their operating characteristics, the FAA concludes that they should be studied and the potential impacts to the navigable airspace must be identified and addressed. Presently, the FAA has an existing regulatory framework that outlines standards for determining obstructions to air navigation or navigational aids or facilities (see 14 CFR part 77). 14 CFR part 77 is utilized to evaluate the impact of wind turbines and other forms of renewable energy on the navigable airspace. Therefore, we conclude that any new forms of wind gathering devices would be included in the Obstruction Evaluation Process, which is administered under 14 CFR part 77.

Accordingly, the FAA announces that the provision of part 77 will apply to temporary AWES proposals that will be used for data collection purposes. The FAA finds that the provisions of 14 CFR part 77 can be applied to these ''structures'' without the need to amend the regulations. Permanent and operational AWES may be addressed in the future upon further evaluations and risk assessments are performed. The purpose of this change in policy is to allow for the continued development of this emerging technology and to provide the FAA with data regarding these devices so that the safety and integrity of the NAS is maintained. Persons proposing to conduct temporary airborne testing of AWES for data collection purposes must provide notice to the FAA pursuant to 14 CFR 77.13(a)(1), which requires notice of any construction or alternation of more than 200 feet above ground level.

In order to facilitate the timely manner in which AWES proposals are reviewed, AWES developers and operators are requested to limit temporary operations to the following:

(1) Airborne operations of AWES should be temporary in nature for testing and data collection purposes only;

(2) Single AWES devices only (e.g.—no ''farms'' or multiple simultaneous testing);

(3) AWES should be limited to a single fixed location (e.g.—no mobile ground facilities);

(4) Testing is confined to heights at or below 499 feet above ground level (AGL);

(5) Airborne flight testing of AWES will only occur during daylight hours; and

(6) AWES will be made conspicuous to the flying public. (The sponsor of the AWES will provide the FAA with their marking and lighting scheme. FAA Advisory Circular 70/7460–1K (AC 70/7460–1K), *Obstruction Marking and Lighting,* currently does not address AWES, but may be used as a guide, as some portions may be applicable.)

Request for Information

The FAA is working jointly with industry, the Department of Energy, as well as other airspace stakeholders, and believes that additional information from AWES developers would be beneficial. The information will assist the FAA as it considers long-term policies and guidance to integrate the AWES safely into the NAS.

The FAA has several concerns regarding AWES operations in the NAS, including:

(1) Impact(s) to various surveillance systems (radars);

(2) Conspicuity to aircraft (marking and lighting);

(3) Overall safety—safety to other airspace users, safety to persons and property on the ground, safety to the efficient and effective use of NAS facilities, safety to airports, safety to air commerce, and safety to the efficient operations and managing of the NAS;

(4) AWES fly-away protection (mooring cable is severed);

(5) AWES physical dimensions per unit and per farm;

(6) AWES operating dimensions per unit and per farm (amt. of airspace it may require);

(7) AWES mobility (potential for AWES to relocate from physical ground location to a different ground location); and

(8) Wake turbulence or vortices of wind capturing component(s).

The FAA recognizes the various design concepts utilized by AWES developers for components of their overall AWES. These may include the components that keep the system aloft, the power generating equipment, the energy transferring equipment, the maneuvering controls, and the physical and operational dimensions, amongst others. Given these variations in technologies, the FAA seeks information from the industry to help us evaluate the potential risks of permanent AWES and AWES farms operating in the NAS.

The FAA is requesting AWES sponsors provide information on the following. Additional information may be requested upon further contact and coordination. This information must be submitted by February 6, 2012.

- General information on a developer's specific AWES design concept and plans for operation.
  - What type(s) of mechanical devices are you employing to keep the system aloft?
  - What are the physical dimensions of the device(s) with relation to the above?
  - What kind of materials will comprise this device?
  - What are the operational dimensions (requirement for airspace) for the system?
  - Is there a requirement to operate more than one device in the air?
  - What are your long-term plans for this system?
- Marking and lighting.
  - Can you comply with marking and lighting requirements?
  - Can you identify any impacts to your system when complying with current guidance for marking and lighting standards?
  - What are your plans or how is your system designed to make the system conspicuous to the flying public?
- Safety to other airspace users and persons and property on the ground.
  - What safety mechanisms or devices have you designed into the system to ensure all aspects of aviation safety?

[2] 14 CFR 1.1 defines an airship as, ''an engine-driven lighter-than-air aircraft that can be steered.''

○ What safety mechanisms or devices have you designed into the system to minimize or mitigate hazards to persons or property on the ground?

• Minimized impacts to NAS facilities.

○ What are your plans or how is your system designed to reduce a large radar cross-section and become less conspicuous to surveillance systems?

○ What are your plans or how is your system designed to reduce impacts to any communication or navigation systems supporting the NAS?

In addition, the FAA is requesting input from airspace users regarding the impact AWES would have on the NAS. Specifically, we request airspace users provide comments to the following. Additional information may be requested upon further contact and coordination. This information must be submitted by February 6, 2012.

• What safety implications do you foresee of AWES operations with respect to your use of the airspace or your interest to the NAS?

• Would you have any concerns about AWES permanently operating at altitudes above 500 feet AGL, but, under 1,999 feet AGL? If so, what and why?

• If AWES were permitted to permanently operate in altitudes at or above 2,000 feet AGL, how do you foresee this as negatively impacting your missions, use of the airspace, or other interests in the NAS?

• What other concerns and/or issues might you have with respect to AWES co-existing in the NAS?

Comments Invited

The FAA invites interested persons to submit written comments, data, or views. The agency also invites comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

The FAA will file in the docket all comments it receives. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The agency may change this proposal in light of the comments it receives.

Proprietary or Confidential Business Information: Commenters should not file proprietary or confidential business information in the docket. Such information must be sent or delivered directly to the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this document, and marked as proprietary or confidential. If submitting information on a disk or CD–ROM, mark the outside of the disk or CD–ROM, and identify electronically within the disk or CD–ROM the specific information that is proprietary or confidential.

Under 14 CFR 11.35(b), the FAA is aware of proprietary information filed with a comment, the agency does not place it in the docket. It is held in a separate file to which the public does not have access, and the FAA places a note in the docket that it has received it. If the FAA receives a request to examine or copy this information, it treats it as any other request under the Freedom of Information Act (5 U.S.C. 552). The FAA processes such a request under Department of Transportation procedures found in 49 CFR part 7.

Issued in Washington, DC, on November 30, 2011.

Dennis E. Roberts,

Director of Airspace Services.

[FR Doc. 2011–31430 Filed 12–6–11; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 152

[EPA–HQ–OPP–2010–0305; FRL–9328–5]

RIN 2070–AJ79

Notification of Draft Proposed Rule Submission to the Secretaries of Agriculture and Health and Human Services

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification of submission to the Secretaries of Agriculture and Health and Human Services.

SUMMARY: This document notifies the public that EPA has forwarded to the Secretary of the United States Department of Agriculture and the Secretary of the United States Department of Health and Human Services a draft proposed rule under sections 21(b) and 25(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), entitled ''*Pesticides; Revisions to Minimum Risk Exemptions*'' and identified in the Regulatory Agenda under RIN 2070–AJ79. FIFRA requires EPA to publish a notice in the **Federal Register** whenever such a submission occurs. The draft proposed rule is not available to the public until after it has been signed by EPA.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0305. All documents in the docket are listed in the docket index available in *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Martha Shimkin, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington DC 20460–0001; *telephone number:* (703) 305–5160; *email address: shimkin.martha@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Does this action apply to me?

This action is directed to the public in general. It simply announces the submission of a draft proposed rule to the Secretary of Agriculture and the Secretary of Health and Human Services and does not otherwise affect any specific entities. This action may, however, be of particular interest to manufacturers, distributors, retailers, and users of minimum risk pesticide products as described in 40 CFR 152.25(f). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be interested in this action. If you have any questions regarding this action, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

II. What action is EPA taking?

Section 25(a)(2)(A) of FIFRA requires EPA to provide the Secretary of Agriculture with a copy of any draft proposed rule at least 60 days before signing it in proposed form for publication in the **Federal Register**. Similarly, FIFRA section 21(b) requires EPA to provide the Secretary of Health and Human Services with a copy of any draft proposed rule pertaining to a public health pesticide at least 60 days before publishing it in the **Federal Register**. The draft proposed rule is not available to the public until after it has been signed by EPA. If either Secretary comments in writing regarding the draft proposed rule within 30 days after receiving it, EPA shall include in the proposed rule, when published in the **Federal Register**, the comments of the Secretaries and the EPA Administrator's response to those comments. If either Secretary does not comment in writing within 30 days after receiving the draft proposed rule, EPA may proceed with signing the proposed rule notwithstanding the 60 day time requirement imposed on EPA.

III. Do any statutory and Executive Order reviews apply to this notification?

No. This document is not a proposed rule. It is merely a notification of submission to the Secretary of Agriculture and the Secretary of Health and Human Services. As such, none of the regulatory assessment requirements apply to this document.

List of Subjects in 40 CFR Part 152

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

Dated: November 28, 2011.

Steven Bradbury,

Director, Office of Pesticide Programs.

[FR Doc. 2011–31540 Filed 12–6–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–2000–0003; FRL–9501–1]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Notice of Intent for Deletion of the Palmer Barge Line Superfund Site

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) Region 6 is issuing a Notice of Intent to Delete the Palmer Barge Line (PBL) Superfund Site located in Port Arthur, Texas, from the National Priorities List (NPL) and requests public comments on this proposed action. The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The EPA and the State of Texas, through the Texas Commission on Environmental Quality, have determined that all appropriate response actions at these identified parcels under CERCLA, other than operation, maintenance, and Five-Year Reviews, have been completed. However, this deletion does not preclude future actions under Superfund.

DATES: Comments must be received by January 6, 2012.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–SFUND–2000–0003, by one of the following methods:

- *http://www.regulations.gov:* Follow Internet on-line instructions for submitting comments.
- *Email:* Rafael Casanova, *casanova.rafael@epa.gov*.
- *Fax:* (214) 665–6660.
- *Mail:* Rafael A. Casanova; U.S. Environmental Protection Agency, Region 6; Superfund Division (6SF–RA); 1445 Ross Avenue, Suite 1200; Dallas, Texas 75202–2733.
- *Hand delivery:* U.S. Environmental Protection Agency, Region 6; 1445 Ross Avenue, Suite 700; Dallas, Texas 75202–2733; Contact: Rafael A. Casanova (214) 665–7437. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–SFUND–2000–0003. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or email. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *http://www.regulations.gov*, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at:

1. U.S. Environmental Protection Agency, Region 6; 1445 Ross Avenue, Suite 700; Dallas, Texas 75202–2733; Hours of operation: Monday thru Friday, 9 a.m. to 12 p.m. and 1 p.m. to 4 p.m. Contact: Rafael A. Casanova (214) 665–7437.
2. Port Arthur Public Library; 4615 9th Avenue; Port Arthur, Texas 77642–5799; Hours of operation: Monday thru Thursday, 9 a.m. to 9 p.m.; Friday, 9 a.m. to 6 p.m.; Saturday, 9 a.m. to 5 p.m.; and Sunday, 2 p.m. to 5 p.m.

FOR FURTHER INFORMATION CONTACT: Rafael A. Casanova, Remedial Project Manager; U.S. Environmental Protection Agency, Region 6; Superfund Division (6SF–RA); 1445 Ross Avenue, Suite 1200; Dallas, Texas 75202–2733; *telephone number:* (214) 665–7437; *email: casanova.rafael@epa.gov.*

SUPPLEMENTARY INFORMATION: In the ''Rules and Regulations'' Section of today's **Federal Register**, we are publishing a direct final Notice of Deletion for the PBL Superfund Site without prior Notice of Intent for Deletion because EPA views this as a noncontroversial revision and anticipates no adverse comments. We have explained our reason for this

deletion in the preamble to the direct final Notice of Deletion, and those reasons are incorporated herein. If we receive no adverse comment(s) on this deletion action, we will not take further action on this Notice of Intent for Deletion. If we receive adverse comment(s), we will withdraw the direct final Notice of Deletion and it will not take effect. We will, as appropriate, address all public comments in a subsequent final Notice of Deletion based on this Notice of Intent for Deletion. We will not institute a second comment period on this Notice of Intent for Deletion. Any parties interested in commenting must do so at this time.

For additional information, see the direct final Notice of Deletion which is located in the Rules section of this **Federal Register**.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923; 3 CFR, 1987 Comp., p. 193.

Dated: November 14, 2011.

Al Armendariz,

Regional Administrator, Region 6.

[FR Doc. 2011–31266 Filed 12–6–11; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 11–192, RM–11646; DA 11–1924]

Television Broadcasting Services; Lincoln, NE

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission has before it a petition for rulemaking filed by Lincoln Broadcasting, LLC (''LBL''), the licensee of KFXL–TV, channel 51, Lincoln, Nebraska, requesting the substitution of channel 15 for channel 51 at Lincoln. LBL's proposal complies with the Commission announcement that it would lift the current freeze on the acceptance of channel substitution rulemaking proceeding for petitions proposing to relocate from channel 51. LBL also states that the proposed facility will increase the net total population served by the station by almost 700,000 persons. LBL believes the grant of this petition would serve the public interest.

DATES: Comments must be filed on or before January 6, 2012, and reply comments on or before January 23, 2012.

ADDRESSES: Federal Communications Commission, Office of the Secretary, 445 12th Street SW., Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve counsel for petitioner as follows: Howard M. Liberman, *Esq.,* Drinker Biddle & Reath, 1500 K Street NW., Suite 1100, Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: Joyce L. Bernstein, *joyce.bernstein@fcc.gov,* Media Bureau, (202) 418–1647.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MB Docket No. 11–192, adopted November 21, 2011, and released November 22, 2011. The full text of this document is available for public inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY–A257, 445 12th Street SW., Washington, DC 20554. This document will also be available via ECFS *(http://www.fcc.gov/cgb/ecfs/).* (Documents will be available electronically in ASCII, Word 97, and/or Adobe Acrobat.) This document may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street SW., Room CY–B402, Washington, DC 20554, telephone 1–(800) 478–3160 or via email *http://www.BCPIWEB.com.* To request this document in accessible formats (computer diskettes, large print, audio recording, and Braille), send an email to *fcc504@fcc.gov* or call the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY). This document does not contain proposed information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding. Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts (other than *ex parte* presentations exempt under 47 CFR 1.1204(a)) are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1208 for rules governing restricted proceedings.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Television, Television broadcasting.

Federal Communications Commission

Barbara A. Kreisman,

Chief, Video Division, Media Bureau.

Proposed Rules

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR Part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, 336, and 339.

§ 73.622(i) [Amended]

2. Section 73.622(i), the Post-Transition Table of DTV Allotments under Nebraska is amended by removing channel 51 and adding channel 15 at Lincoln.

[FR Doc. 2011–31403 Filed 12–6–11; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R8–ES–2011–0097; 4500030114]

RIN 1018–AX41

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for Lost River Sucker and Shortnose Sucker

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; reproposal.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to designate critical habitat for the Lost River sucker (*Deltistes luxatus*) and shortnose sucker (*Chasmistes brevirostris*) under the Endangered Species Act of 1973, as amended (Act). In total, we are proposing as critical

habitat approximately 146 miles (234 kilometers) of streams and 117,848 acres (47,691 hectares) of lakes and reservoirs for Lost River sucker and approximately 128 miles (207 kilometers) of streams and 123,590 acres (50,015 hectares) of lakes and reservoirs for shortnose sucker. The proposed critical habitat is located in Klamath and Lake Counties, Oregon, and Modoc County, California. On December 1, 1994, we published proposed critical habitat for Lost River sucker and shortnose sucker. This new proposed rule uses updated information concerning Lost River sucker's and shortnose sucker's ecology, as well as the technological advancements made available since preparing the 1994 proposed rule, to inform our proposed critical habitat designation for Lost River sucker and shortnose sucker.

DATES: We will accept comments received or postmarked on or before February 6, 2012. We must receive requests for public hearings, in writing, at the address shown in the **FOR FURTHER INFORMATION CONTACT** section by January 23, 2012.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Enter Keyword or ID box, enter Docket No. FWS–R8–ES–2011–0097, which is the docket number for this rulemaking.

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, *Attn:* FWS–R8–ES–2011–0097; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042–PDM; Arlington, VA 22203.

We will not accept email or faxes. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Public Comments section below for more information).

FOR FURTHER INFORMATION CONTACT: Laurie R. Sada, Field Supervisor, U.S. Fish and Wildlife Service, Klamath Falls Fish and Wildlife Office, 1936 California Avenue, Klamath Falls, OR 97601; telephone 541–885–8481; facsimile 541–885–7837. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Public Comments

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from government agencies, the scientific community, industry, or any other interested party concerning this proposed rule. We particularly seek comments concerning:

(1) The reasons why we should or should not designate habitat as ''critical habitat'' under section 4 of the Act (16 U.S.C. 1531 *et seq.*), including whether there are threats to the species from human activity, the degree of which can be expected to increase due to the designation, and whether that increase in threat outweighs the benefit of designation such that the designation of critical habitat may not be prudent.

(2) Specific information on:

(a) The amount and distribution of Lost River sucker and shortnose sucker habitat;

(b) What areas, that were occupied at the time of listing (or are currently occupied) contain physical and biological features essential to the conservation of the species, should be included in the designation and why;

(c) Special management considerations or protection that may be needed for the physical and biological features essential to the conservation of the species in critical habitat areas we are proposing, including managing for the potential effects of climate change; and

(d) What areas not occupied at the time of listing that meet our criteria for being essential for the conservation of the species should be included in the designation and why.

(3) Land use designations and current or planned activities in the subject areas and their possible impacts on proposed critical habitat.

(4) Information on the projected and reasonably likely impacts of climate change on the Lost River sucker and shortnose sucker, the features essential to its conservation, and the areas proposed as critical habitat.

(5) Whether any specific areas we are proposing for critical habitat designation should be considered for exclusion under section 4(b)(2) of the Act, and whether the benefits of potentially excluding any specific area outweigh the benefits of including that area under section 4(b)(2) of the Act;

(6) Any probable economic, national security, environmental, cultural, or other relevant impacts of designating as critical habitat any area that may be included in the final designation. In particular, we seek information on any impacts on small entities, and the benefits of including or excluding areas that exhibit these impacts; and

(7) Whether we could improve or modify our approach to designating critical habitat in any way to provide for greater public participation and understanding, or to better accommodate public concerns and comments.

You may submit your comments and materials concerning this proposed rule by one of the methods listed in the **ADDRESSES** section. We will not accept comments sent by email or fax or to an address not listed in the **ADDRESSES** section. We will post your entire comment—including your personal identifying information—on *http://www.regulations.gov.* You may request at the top of your document that we withhold personal information such as your street address, phone number, or email address from public review; however, we cannot guarantee that we will be able to do so.

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov,* or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Klamath Falls Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Background

It is our intent to discuss only those topics directly relevant to the designation of critical habitat for these species in this proposed rule. For further information on the Lost River sucker's and shortnose sucker's biology and habitat, population abundance and trend, distribution, demographic features, habitat use and conditions, threats, and conservation measures, please see the final listing rule (53 FR 27130; July 18, 1988), the 2007 5–year reviews completed for the Lost River sucker and shortnose sucker (Service 2007a and 2007b), and the Draft Revised Lost River Sucker and Shortnose Sucker Recovery Plan (Service 2011). These documents are available on the Klamath Falls Fish and Wildlife Office web site at *http://www.fws.gov/klamathfallsfwo/ or* on the Environmental Conservation Online System *http://ecos.fws.gov/ecos/indexPublic.do*).

Lost River sucker and shortnose sucker are members of the fish family Catostomidae and are endemic to the upper Klamath River basin (National Research Council of the National Academies (NRC) 2004, pp. 184, 189). Both species predominantly inhabit lake environments but also utilize riverine, marsh, and shoreline habitats for portions of their life history. Lost River sucker and shortnose sucker spawn in the spring in rivers and creeks in areas with a moderate velocity of water flow

containing gravel or cobble substrate at depths less than 1.3 meters (m) (4.3 feet (ft)) (Moyle 2002, pp. 200, 204). In addition, a small group of Lost River sucker spawns at several shoreline springs along the eastern portion of Upper Klamath Lake (Janney *et al.* 2008, p. 1813).

Lost River sucker are distributed within Upper Klamath Lake and its tributaries (Klamath County, Oregon), Clear Lake Reservoir and its tributaries (Modoc County, California), Tule Lake (Siskiyou and Modoc Counties, California), Lost River (Klamath County, Oregon, and Modoc County, California), Link River (Klamath County, Oregon), and the Klamath River mainstem, including Keno, J.C. Boyle, Copco, and Iron Gate Reservoirs (Klamath County, Oregon, and Siskiyou County, California; Moyle 2002, p. 199; NRC 2004, pp. 190–192). The distribution of shortnose sucker overlaps with that of Lost River sucker, but shortnose sucker also occurs in Gerber Reservoir (Klamath County, Oregon) and upper Willow Creek (Modoc County, California, and Lake County, Oregon), a tributary to Clear Lake Reservoir (Buettner and Scoppettone 1991, p. 18; Moyle 2002, p. 203; NRC 2004, pp. 190–192).

Lost River sucker and shortnose sucker were once widespread in the upper Klamath River basin and were important to subsistence, commercial, and recreational fishers (Moyle 2002, pp. 200–201, 204; Service 2011, pp. 1, 28–29). Lost River sucker and shortnose sucker have been extirpated from portions of their historic range (Moyle 2002, pp. 200, 204), and previous efforts to monitor angler catch rates have indicated extreme population declines relative to former levels (Scoppettone and Vinyard 1991, p. 367; NRC 2004, p. 203). Putative factors for declines include introduction of exotic species and habitat loss and alteration, primarily due to construction of dams, water diversions, and draining of wetlands (Scoppettone and Vinyard 1991, pp. 368–369, 371; Moyle 2002, pp. 200–201, 204).

Previous Federal Actions

The Lost River sucker and shortnose sucker were listed as endangered on July 18, 1988 (53 FR 27130). A recovery plan for Lost River sucker and shortnose sucker was finalized on March 17, 1993 (Service 1993). Five-year reviews for the Lost River sucker and shortnose sucker were completed on July 19, 2007 (73 FR 11945; March 5, 2008). A considerable amount of scientific information has been collected since the 1993 recovery plan and an updated, revised draft recovery plan for the Lost River sucker and shortnose sucker was released in 2011 (Service 2011).

On September 9, 1991, the Service received a 60–day notice of intent to sue from the Oregon Natural Resources Council (ONRC) for failure to prepare a recovery plan and to designate critical habitat for the Lost River sucker and shortnose sucker. On November 12, 1991, ONRC filed suit in Federal Court (*Wendell Wood et al.* v. *Marvin Plenert, et al.* (Case No. 91–06496–TC (D. Or.))). The Service entered into a settlement agreement and agreed to complete a final recovery plan by March 1, 1993, and a proposal to designate critical habitat on or before March 10, 1994, and publish a final critical habitat rule by November 29, 1994.

On December 1, 1994, we published proposed critical habitat for Lost River sucker and shortnose sucker (59 FR 61744); that proposal was never finalized. The ONRC (now known as Oregon Wild) recently contacted the Department of Justice and requested that we issue a final critical habitat rule within a reasonable amount of time. On May 10, 2010, a settlement agreement was reached that stipulated the Service submit a final rule designating critical habitat for the Lost River sucker and the shortnose sucker to the **Federal Register** no later than November 30, 2012 (*Wood et al.* v. *Thorson et al.,* No. 91–cv–6496–TC (D. Or.)). Given this settlement agreement, advancement in our understanding of Lost River sucker's and shortnose sucker's ecology, and the technological advancements made available since preparing the former proposed rule, we now issue a new proposed critical habitat rule.

Critical Habitat

Background

Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features

(a) Essential to the conservation of the species and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the requirement that Federal agencies insure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation does not allow the government or public to access private lands. Such designation does not require implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Where a landowner seeks or requests Federal agency funding or authorization for an action that may affect a listed species or critical habitat, the consultation requirements of section 7(a)(2) would apply, but even in the event of a destruction or adverse modification finding, the obligation of the Federal action agency and the landowner is not to restore or recover the species, but to implement reasonable and prudent alternatives to avoid destruction or adverse modification of critical habitat.

For inclusion in a critical habitat designation, the habitat within the geographical area occupied by the species at the time it was listed must contain physical and biological features which are essential to the conservation of the species and which may require special management considerations or protection. Critical habitat designations identify, to the extent known using the best scientific and commercial data available, those physical and biological features that are essential to the conservation of the species (such as space, food, cover, and protected habitat), focusing on the principal biological or physical constituent elements (primary constituent elements) within an area that are essential to the conservation of the species (such as roost sites, nesting grounds, seasonal

wetlands, water quality, tide, soil type). Primary constituent elements are the elements of physical and biological features that, when laid out in the appropriate quantity and spatial arrangement to provide for a species' life-history processes, are essential to the conservation of the species.

Under the Act, we can designate critical habitat in areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. We designate as critical habitat areas outside the geographical area presently occupied by a species only when a designation limited to its present range would be inadequate to ensure the conservation of the species. When the best available scientific data do not demonstrate that the conservation needs of the species require such additional areas, we will not designate critical habitat in areas outside the geographical area occupied by the species. An area currently occupied by the species but that was not occupied at the time of listing may, however, be essential to the conservation of the species and may be included in the critical habitat designation.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific and commercial data available. Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658)), and our associated Information Quality Guidelines, provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

When we are determining which areas should be designated as critical habitat, our primary source of information is generally the information developed during the listing process for the species. Additional information sources may include the recovery plan for the species, articles in peer-reviewed journals, conservation plans developed by States and counties, scientific status surveys and studies, biological assessments, or other unpublished materials and expert opinion or personal knowledge.

Habitat is dynamic, and species may move from one area to another over time. Climate change will be a particular challenge for biodiversity because the interaction of additional stressors associated with climate change and current stressors may push species beyond their ability to survive (Lovejoy 2005, pp. 325–326). The synergistic implications of climate change and habitat fragmentation are the most threatening facet of climate change for biodiversity (Hannah *et al.* 2005, p.4). Current climate change predictions for terrestrial areas in the Northern Hemisphere indicate warmer air temperatures, more intense precipitation events, and increased summer continental drying (Field *et al.* 1999, pp. 1–3; Hayhoe *et al.* 2004, p. 12422; Cayan *et al.* 2005, p. 6; Intergovernmental Panel on Climate Change (IPCC) 2007, p. 1181). Climate change may lead to increased frequency and duration of severe storms and droughts (McLaughlin *et al.* 2002, p. 6074; Cook *et al.* 2004, p. 1015; Golladay *et al.* 2004, p. 504).

The specific effects of climate change on the upper Klamath River basin have not been thoroughly investigated; however, potential effects include increased temperatures, drier summers, and higher snowpack elevation (Koopman *et al.* 2009, p. 3). As a result of increased temperatures, it is anticipated the peak spring runoff of tributary streams will shift earlier in the year from spring to late winter (Poff *et al.* 2002, p. 11). Thus, we anticipate Lost River sucker and shortnose sucker may experience altered timing of spawning migrations, *i.e.,* spawning migrations may occur earlier in the year. Furthermore, altered stream flow into lakes may lead to lower lake levels (Poff *et al.* 2002, p. 15). Lower lake levels may prevent fish from accessing refugia or shoreline spawning areas, such as spring-influenced habitat, that may be important during periods of poor water quality (Banish *et al.* 2009, p. 165). As lakes warm in response to increased temperatures, algal production increases (Poff *et al.* 2002, p. 13), which may exacerbate hypereutrophic (nutrient rich) systems, such as Upper Klamath Lake. Nuisance algal blooms are already considered a threat to Lost River sucker and shortnose sucker (Perkins *et al.* 2000, pp. 24–25, 30), and therefore may be a heightened threat in the face of climate change. Diseases such as gill rot caused by the Columnaris bacterium also are likely to become more of a concern with higher water temperatures (NRC 2004, p. 201).

We recognize that critical habitat designated at a particular point in time may not include all of the habitat areas that we may later determine are necessary for the recovery of the species. For these reasons, a critical habitat designation does not signal that habitat outside the designated area is unimportant or may not be required for recovery of the species. Areas that are important to the conservation of the species, both inside and outside the critical habitat designation, will continue to be subject to: (1) Conservation actions implemented under section 7(a)(1) of the Act, (2) regulatory protections afforded by the requirement in section 7(a)(2) of the Act for Federal agencies to insure their actions are not likely to jeopardize the continued existence of any endangered or threatened species, and (3) the prohibitions of section 9 of the Act if actions occurring in these areas may affect the species. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. These protections and conservation tools will continue to contribute to recovery of this species. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans (HCPs), or other species conservation planning efforts if new information available at the time of these planning efforts calls for a different outcome.

Physical or Biological Features

In accordance with sections 3(5)(A)(i) and 4(b)(1)(A) of the Act and regulations at 50 CFR 424.12, in determining which areas within the geographical area occupied by the species at the time of listing to designate as critical habitat, we consider the physical and biological features essential to the conservation of the species which may require special management considerations or protection. These include, but are not limited to:

(1) Space for individual and population growth and for normal behavior;

(2) Food, water, air, light, minerals, or other nutritional or physiological requirements;

(3) Cover or shelter;

(4) Sites for breeding, reproduction, or rearing (or development) of offspring; and

(5) Habitats that are protected from disturbance or are representative of the

historical, geographical, and ecological distributions of a species.

We derive the specific physical or biological features required for Lost River sucker and shortnose sucker from studies of this species' habitat, ecology, and life history as described below. Additional information can be found in the final listing rule published in the **Federal Register** on July 18, 1988 (53 FR 27130), and the Draft Revised Recovery Plan for the Lost River Sucker and Shortnose Sucker (Service 2011). We have determined that Lost River sucker and shortnose sucker require the following physical or biological features:

Space for Individual and Population Growth and for Normal Behavior

Lakes, streams, marshes, and spring habitats with migratory corridors between these habitats provide space for individual and population growth and for normal behavior of Lost River sucker.

Lost River sucker spend most of their lives within lakes although they primarily spawn in streams (Moyle 2002, p. 199). Spawning occurs in late winter and early spring in major tributaries to lakes where they occur. In addition, a small proportion of Lost River sucker utilize spring areas within Upper Klamath Lake for spawning (Janney *et al.* 2008, p. 1813). After hatching, larval Lost River sucker drift downstream within spawning tributaries and reach lakes by mid-summer. Larval habitat is generally along the shoreline, in water 10 centimeters (cm) to 50 cm (6 inches (in) to 20 in) deep where emergent vegetation provides cover from predators, protection from currents and turbulence, and abundant food (Cooperman and Markle 2004, p. 375). As larval suckers grow into the juvenile stage, they increasingly use deeper habitat with and without emergent vegetation. Adult Lost River sucker primarily use deep (greater than 2.0 m (6.6 ft)), open-water habitat as well as spring-influenced habitats that act as refugia during poor water quality events (Banish *et al.* 2009, pp. 159–161, 165).

Reservoirs also figure prominently in meeting the requirements for space for individual and population growth and for normal behavior of Lost River sucker. Much of the upper Klamath River basin landscape has been hydrologically altered since Anglo-European settlement, including construction of reservoirs. Some reservoirs have adversely affected Lost River sucker, while others may provide benefits. For example, the dam on Malone Reservoir blocks access to historical Lost River sucker habitat for individuals migrating in the mainstem Lost River. In contrast, construction of hydroelectric dams on the mainstem Klamath River and construction of Clear Lake Reservoir likely have increased the amount of available habitat.

Because shortnose sucker share the same habitats as Lost River sucker, the lakes, reservoirs, streams, marshes, and spring habitats with migratory corridors between these habitats also provide space for individual and population growth and for normal behavior of shortnose sucker. Therefore, based on the information above, we identify lakes, reservoirs, streams, marshes, and spring habitats with migratory corridors between these habitats to be a physical or biological feature essential for the conservation of both Lost River sucker and shortnose sucker.

Food, Water, Air, Light, Minerals, or Other Nutritional or Physiological Requirements

Adult Lost River sucker have subterminal mouths and gill raker structures that are adapted for feeding primarily on benthic macroinvertebrates in lake environments (NRC 2004, p. 190). Prey selection, however, appears to be a function of developmental shifts in habitat use. Lost River sucker larvae feed near the surface of the water column, primarily on chironomids (commonly called ''midges''; a family of small flies whose larval and pupal stages are mainly aquatic) (Markle and Clauson 2006, pp. 494–495). Juvenile Lost River sucker rely less on surface-oriented feeding and shift to prey items from benthic areas. For instance, Markle and Clauson (2006, pp. 495–496) documented that juvenile Lost River suckers consumed chironomid larvae as well as micro-crustaceans (amphipods, copepods, cladocerans, and ostracods). As adults, Lost River sucker consume many of these same items (Moyle 2002, pp. 199–200).

Shortnose sucker have terminal mouths and gill raker structures adapted for feeding on zooplankton (Moyle 2002, p. 203; NRC 2004, p. 190). Similar to Lost River sucker, shortnose sucker also exhibit an ontogenetic shift in prey selection (Markle and Clauson 2006, pp. 494–495). Adult shortnose sucker also consume many of the same prey items as juveniles, including chironomid larvae, amphipods, copepods, cladocerans, and ostracods (Moyle 2002, p. 203; Markle and Clauson 2006, pp. 494–495).

Habitats must provide the necessary conditions, including water with sufficient phytoplankton and fine aquatic substrate, to harbor prey species in sufficient quantity and diversity to meet the nutritional and physiological requirements necessary to maintain Lost River sucker and shortnose sucker populations. Therefore, based on the information above, we identify an abundant food base, including a broad array of chironomids, micro-crustaceans, and other small aquatic macroinvertebrates, to be a biological feature necessary for both Lost River sucker and shortnose sucker.

Cover or Shelter

The cover and shelter components, including emergent vegetation and depth, are the same for shortnose sucker as for Lost River sucker. Lost River sucker and shortnose sucker larvae density is generally higher within and adjacent to emergent vegetation than in areas devoid of vegetation (Cooperman and Markle 2004, p. 374; Crandall *et al.* 2008, p. 413; Erdman and Hendrixson 2009, p. 18; Cooperman *et al.* 2010, p. 34). Emergent vegetation provides cover from predators and habitat for prey such as zooplankton, macroinvertebrates, and periphyton (Klamath Tribes 1996, p. 12; Cooperman and Markle 2004, p. 375). Such areas also may provide refuge from wind-blown current and turbulence, as well as areas of warmer water temperature, which may facilitate larval growth (Cooperman and Markle 2004, p. 375; Crandall 2004, p. 7; Cooperman *et al.* 2010, pp. 35–36).

Different life stages use different water depths as cover or shelter. Juvenile Lost River sucker and shortnose sucker primarily use relatively shallow (less than approximately 1.2 m (3.9 ft)) vegetated areas, but may also begin to move into deeper, unvegetated, off-shore habitats (Buettner and Scoppettone 1990, pp. 33, 51; Markle and Clauson 2006, p. 499). Data from Upper Klamath Lake indicate juveniles of less than 1 year often are found at depths less than 1.0 m (3 ft) in May and June, but shift in late July to water 1.5 to 2.0 m (5 to 6.5 ft) deep (Burdick and Brown 2010, p. 50; no similar data exist from other occupied water bodies). Similarly, 1-year-old juveniles occupy shallow habitats during April and May, but may move into deeper areas along the western shore of Upper Klamath Lake (*e.g.,* Eagle Ridge trench) until dissolved oxygen levels become reduced in mid- to late-July (Bottcher and Burdick 2010, p. 17; Burdick and VanderKooi 2010, p. 13). Juveniles then appear to move into shallower habitat along the eastern shore or main part of Upper Klamath Lake (Bottcher and Burdick 2010, p. 17).

It is assumed that sub-adults, *i.e.,* individuals that display all of the

characteristics of adults with the exception of reproductive maturity and reproductive structures (*e.g.,* tubercles), utilize habitats similar to adults (NRC 2004, p. 199). Adult Lost River sucker and shortnose sucker inhabit water depths of 0.9 to 4.8 m (3.0 to 15.7 ft) (Reiser *et al.* 2001, p. 5–26; Banish *et al.* 2009, p. 161). In addition, cover (e.g., large woody debris) is sparse in many of the lentic habitats occupied by adult Lost River sucker and shortnose sucker, so water depth or turbidity may provide concealment from avian predators (Banish *et al.* 2009, p. 164).

Therefore, based on the information above, we identify lakes and reservoirs with adequate amounts of emergent vegetation of appropriate depth and water quality to provide for cover and shelter as described above to be a physical or biological feature for Lost River sucker and shortnose sucker.

Sites for Breeding, Reproduction, or Rearing (or Development) of Offspring

Throughout their range, Lost River sucker ascend large tributary streams to spawn, generally from February through April, often corresponding with spring snowmelt (Moyle 2002, p. 200; NRC 2004, p. 194). They have been documented migrating upstream as many as 120 kilometers (km) in the Sprague River (75 miles (mi)) (Ellsworth *et al.* 2007, p. 20). Beginning at the same time, a segment of the Lost River sucker population uses shoreline areas affected by input of spring discharge for spawning in Upper Klamath Lake (Janney *et al.* 2008, p. 1813). In rivers, spawning occurs in riffles and pools over gravel and cobble substrate at depths less than 1.3 m (4.3 ft) and velocities up to 85 cm per second (2.8 ft per second; Buettner and Scoppettonne 1990, p. 20; Moyle 2002, p. 200; NRC 2004, p. 194). At shoreline spring habitat, spawning occurs over similar substrate and at similar depths. Females broadcast their eggs, which are fertilized most commonly by two accompanying males (Buettner and Scoppettone 1990, p. 17). The fertilized eggs settle within the top few inches of the substrate until hatching, around 1 week later. Generally, larvae spend little time in rivers after swim-up, but quickly drift downstream to lakes (Cooperman and Markle 2003, pp. 1147–1149). Downstream movement occurs mostly at night near the water surface (Ellsworth *et al.* 2010, pp. 51–52). Larvae transform into juveniles by mid-July at about 25 mm (0.98 in) total length. Juvenile Lost River sucker primarily occupy relatively shallow (less than approximately 50 cm (1.6 ft)), vegetated areas, but also may begin to move into deeper, unvegetated, off-shore habitats as they grow (Buettner and Scoppettone 1990, pp. 32–33; NRC 2004, p. 198).

Throughout their range, shortnose sucker ascend large tributary streams to spawn, generally from February through May, often corresponding with spring snowmelt (Moyle 2002, p. 204; NRC 2004, p. 194). Shortnose sucker have been documented migrating upstream as far as 13 km (8 mi) in the Sprague River (Ellsworth *et al.* 2007, p. 20). Spawning at shoreline springs in Upper Klamath Lake by shortnose sucker is presently rare (NRC 2004, p. 194). In lotic habitat, spawning occurs in similar habitat as Lost River sucker spawning, although spawning may occur in areas with greater stream flow (up to 125 cm per second (4.1 ft per second); Moyle 2002, p. 204). At shoreline spring habitat, spawning occurs over similar substrate and at similar depths to Lost River sucker spawning. Females broadcast their eggs, which are fertilized most commonly by two accompanying males (Buettner and Scoppettone 1990, p. 44). Larval out-migration, and larval and juvenile rearing patterns, are similar to Lost River sucker (Buettner and Scoppettone 1990, p. 51; Cooperman and Markle 2004, pp. 374–375; NRC 2004, p. 198; Ellsworth *et al.* 2010, pp. 51–52).

Therefore, based on the information above, we identify accessible lake and river spawning locations with suitable water flow, gravel and cobble substrate, and water depth (as well as flowing water) for larval out-migration and juvenile rearing habitat as described above to be physical features for both Lost River sucker and shortnose sucker.

Primary Constituent Elements for Lost River Sucker and Shortnose Sucker

Under the Act and its implementing regulations, we are required to identify the physical and biological features essential to the conservation of Lost River sucker and shortnose sucker in areas occupied at the time of listing, focusing on the features' primary constituent elements. We consider primary constituent elements to be the specific elements of physical and biological features that are essential to the conservation of the species.

Based on our current knowledge of the physical or biological features and habitat characteristics required to sustain the species' life-history processes, we determine that the primary constituent elements specific to self-sustaining Lost River sucker and shortnose sucker populations are:

(1) *Water.* Areas with sufficient water quantity and depth within lakes, reservoirs, streams, marshes, springs, groundwater sources, and refugia habitats with minimal physical, biological, or chemical impediments to connectivity. Water should exhibit depths ranging from less than 1.0 m (3.28 ft) up to 4.5 m (14.8 ft) to accommodate each life stage. The water quality characteristics should include water temperatures of less than 28.0 °Celsius (82.4 °F); pH less than 9.75; dissolved oxygen levels greater than 4.0 mg per L; algal toxins (less than 1.0 microgram (μg) per L); and un-ionized ammonia (less than 0.5 mg per L). Elements also include natural flow regimes that provide flows during the appropriate time of year or, if flows are controlled, minimal flow departure from a natural hydrograph.

(2) *Spawning and rearing habitat.* Streams and shoreline springs with gravel and cobble substrate at depths typically less than 1.3 m (4.3 ft) with adequate stream velocity to allow spawning to occur. Areas identified in PCE1 containing emergent vegetation adjacent to open water that provides habitat for rearing . This facilitates growth and survival of suckers, as well as protection from predation and protection from currents and turbulence.

(3) *Food.* Areas that contain an abundant forage base, including a broad array of chironomidae, crustacea, and other aquatic macroinvertebrates.

With this proposed designation of critical habitat, we intend to identify the physical and biological features essential to the conservation of the species, through the identification of the appropriate quantity and spatial arrangement of the primary constituent elements sufficient to support the life-history processes of the species.

Special Management Considerations or Protection

When designating critical habitat, we assess whether the specific areas within the geographical area occupied by the species at the time of listing contain features which are essential to the conservation of the species and which may require special management considerations or protection. Special management considerations or protection may be necessary to eliminate or reduce the magnitude of threats that affect these species. Threats identified in the final listing rule for these species include: (1) Poor water quality; (2) potential entrainment at water diversion structures; (3) lack of access to essential spawning habitat; (4) lack of connectivity to historical habitat (*i.e.,* migratory impediments); (5) degradation of spawning, rearing, and

adult habitat; and (6) predation by or competition with nonnative fish.

Poor water quality is particularly associated with high abundance of the blue-green alga *Aphanizomenon flos-aque.* Core samples of bottom sediments indicate that A. *flos-aque* was not present in Upper Klamath Lake prior to the 1900s (Bradbury et al. 2004, p. 162; Eilers *et al.* 2004, p. 14). Its appearance is believed to be associated with increases in productivity of the lake through human influence (NRC 2004, pp. 108–110). This alga now dominates the algal community from June to November, and, because of the high phosphorus concentrations and its ability to fix nitrogen, is able to reach seasonally high biomass levels that eventually produce highly degraded water quality (Boyd *et al.* 2002, p. 34). Once the algal bloom subsides, decomposition of the massive amounts of biomass can lower dissolved oxygen and raise pH to levels harmful or fatal to fish (Perkins et al. 2000, pp. 24–25; Wood *et al.* 2006, p. 1). Additionally, other cyanobacteria (*Microcystis* sp.) may produce toxins harmful to sucker liver tissue (VanderKooi *et al.* 2010, p. 2). Special management considerations or protections are therefore needed to protect water quality from the deleterious effects of algal blooms and may include reducing excess phosphorus concentrations by fencing cattle out of riparian areas, reconfiguring agricultural waterways, increasing riparian stands of vegetation, and restoring wetland habitat that is crucial for filtering sediment and nutrients.

Hydrographs of both Clear Lake Reservoir and Upper Klamath Lake exhibit patterns of a snow-melt driven system with highest inflows and levels during spring and early summer, although groundwater also is a significant contributor to Upper Klamath Lake (Gannett *et al.* 2007, p. 1). However, Clear Lake Reservoir, Gerber Reservoir, and Upper Klamath Lake are managed to store and divert water for irrigation every year. Clear Lake Reservoir is highly sensitive to drought and downstream water delivery because of its small watershed, low precipitation, minimal groundwater input, and high evaporation rates (NRC 2004, p. 129). In the dry years of 1991 and 1992, the U.S. Bureau of Reclamation (BOR) drew down the level of Clear Lake Reservoir to extremely low levels for irrigation supply (Moyle 2002, p. 201). In 1992, Lost River sucker within Clear Lake Reservoir were examined and exhibited signs of stress, including high rates of parasitism and poor body condition (NRC 2004, p. 132). These signs of stress began to decline as the water level in Clear Lake Reservoir rose in 1993, at the end of the drought (NRC 2004, p. 132). In 2009, when lake levels were again low due to drought, diversions from Clear Lake Reservoir were halted in mid-summer, and there were no diversions in 2010. Additionally, low lake levels adversely affect Clear Lake Reservoir sucker populations by limiting access to Willow Creek, the sole spawning tributary (Barry *et al.* 2009, p. 3). Likewise, the amount of available larval habitat and suitable shoreline spring spawning habitat in Upper Klamath Lake is significantly affected by even minor changes in lake elevation (Service 2008, p. 79). Therefore, special management considerations or protections are needed to address fluctuations in water levels due to regulated flow and lake elevation management. Special management may include the following actions: managing bodies of water such that there is minimal flow departure from a natural hydrograph; maintaining, improving, or reestablishing instream flows to improve the quantity of water available for use; and maintaining or improving groundwater use.

The effects of fluctuations in water levels due to regulated flow management may affect the ability of Lost River sucker and shortnose sucker to access refugia during periods of poor water quality. For example, Pelican Bay appears to act as a key refugium during periods of poor water quality, and efforts to maintain the quality and quantity of the habitat there may be beneficial for suckers (Banish *et al.* 2009, p. 167). Therefore, special management considerations or protections are needed to address access to refugia and may include the following: maintaining appropriate lake depths to allow access to refugia; restoring degraded habitats to improve quantity of flow at refugia as well as refugia quality; and maintaining or establishing riparian buffers around refugia to improve refugia water quality.

The Klamath Project (Project) stores and later diverts water from Upper Klamath Lake for a variety of Project purposes. These operations result in lake levels and flows at the outlet of the lake that differ from historic conditions, some of which increase movement of juvenile fish downstream of Upper Klamath Lake. As such, special management considerations or protections for water quantity may be needed to address water intake at water diversion structures to improve water diversion efficiency to increase the quantity of water available as habitat.

Throughout the Upper Klamath Lake and Lost River Basin, timber harvesting and associated activities (*e.g.,* road building) by Federal, State, tribal, and private landowners have resulted in soil erosion on harvested lands and transport of sediment into streams and rivers adjacent to or downstream from those lands (Service 2002, p. 65; NRC 2004, pp. 65–66). Past logging and road building practices often did not provide for adequate soil stabilization and erosion control. A high density of forest roads remain in the upper Klamath River basin, and many of these are located near streams where they likely contribute sediment (USFS 1995, p. 7), which results in an increase of fine soil particles that can cover spawning substrata. The major agricultural activity in the upper Klamath River basin, livestock grazing, also has likely led to an increase in sediment and nutrient loading rates by accelerating erosion (Moyle 2002, p. 201; Service 2002, pp. 56, 65; McCormick and Campbell 2007, pp. 6–7). Livestock, particularly cattle, have heavily grazed flood plains, wetlands, forest, rangelands, and riparian areas, resulting in the degradation of these areas. Grazing alters the streamside riparian vegetation and compacts soil surfaces, increasing groundwater runoff, lowering streambank stability, and reducing cover. The increase in sediment accumulation and nutrient loading is consistent with the changes in land use in the upper Klamath River basin occurring over the last century (Bradbury *et al.* 2004, pp. 163–164; Eilers *et al.* 2004, pp. 14–16). Therefore, special management considerations or protections may be required to improve water quality and include: reducing sediment and nutrient loading by protecting riparian areas from agricultural and forestry impacts, reducing road density to prevent excess sediment loading, and improving cattle management practices.

Lost River sucker and shortnose sucker have limited hydrologic connection to spawning or rearing habitat. For example, low lake levels adversely affect Clear Lake Reservoir sucker populations by limiting access to the Willow Creek drainage, the sole spawning tributary (Barry *et al.* 2009, p. 3). Likewise, the amount of suitable shoreline spring spawning habitat in Upper Klamath Lake is significantly affected by even minor changes in lake elevation, but it is unknown exactly how such levels directly affect annual productivity. Several shoreline spring-spawning populations, including Harriman Springs and Barkley Springs,

have been lost or significantly altered due to railroad construction (Andreasen 1975, pp. 39–40; NRC 2004, p. 228). Historically, wetlands comprised hundreds of thousands of hectares throughout the range of the species (Gearhart *et al.* 1995, pp. 119–120; Moyle 2002, p. 200; NRC 2004, pp. 72–73), some of which likely functioned as crucial habitat for larvae and juveniles. Other wetlands may have played vital roles in the quality and quantity of water. Loss of ecosystem functions such as these, due to alteration or separation of the habitat, is as detrimental as physical loss of the habitat. Approximately 70 percent of the original 20,400 ha (50,400 ac) of wetlands surrounding Upper Klamath Lake was diked, drained, or significantly altered beginning around 1889 (Akins 1970, pp. 73–76; Gearhart *et al.* 1995, p. 2). Additionally, of the approximately 13,816 ha (34,140 ac) of wetlands connected to Upper Klamath Lake, relatively little functions as rearing habitat for larvae and juveniles, partly due to lack of connectivity with current spawning areas (NRC 2004, pp. 72–73). Therefore, special management considerations or protections may be needed for water quantity to improve access to spawning locations and quality and quantity of wetlands used as rearing habitat. This may be accomplished by: improving lake level management to allow access to spawning locations during late winter and early spring, restoring access to wetland rearing habitat, and creating wetland rearing habitat adjacent to lakes and reservoirs.

The exotic fish species most likely to affect Lost River sucker and shortnose sucker is the fathead minnow. This species may prey on young Lost River sucker and shortnose sucker and compete with them for food or space (Markle and Dunsmoor 2007, pp. 571–573). For example, fathead minnow were first documented in the upper Klamath River basin in the 1970s and are now the numerically dominant exotic fish in Upper Klamath Lake (Simon and Markle 1997, p. 142; Bottcher and Burdick 2010, p. 40; Burdick and VanderKooi 2010, p. 33). Additional exotic, predatory fishes found in sucker habitats, although typically in relatively low numbers, include yellow perch (*Perca flavescens*), bullhead (*Ameiurus* species), largemouth bass (*Micropterus salmoides*), crappie (*Pomoxis* species), green sunfish (*Lepomis cyanellus*), pumpkinseed (*Lepomis gibbosus*), and Sacramento perch (*Archoplites interruptus*) (NRC 2004, pp. 188–189). Special management considerations or protections may be needed to protect the forage base from predation by exotic fish species and could be accomplished by the following: reducing conditions that allow exotic fishes to be successful and restoring conditions that allow Lost River sucker and shortnose sucker to thrive, conducting evaluations to determine methods to remove exotic fish species, and determining methods to reduce or eliminate competition for the forage base upon which Lost River sucker and shortnose sucker depend to survive.

Criteria Used To Identify Critical Habitat

As required by section 4(b)(1)(A) of the Act, we use the best scientific and commercial data available to designate critical habitat. We review available information pertaining to the habitat requirements of the species. In accordance with the Act and its implementing regulation at 50 CFR 424.12(e), we consider whether designating additional areas—outside those currently occupied as well as those occupied at the time of listing—are necessary to ensure the conservation of the species. We are proposing to designate only areas within the geographical area occupied by the species at the time of listing, and that are also presently occupied, because these areas are sufficient for the conservation of Lost River sucker and shortnose sucker and have all of the physical or biological features essential to the conservation of Lost River sucker and shortnose sucker. The Draft Lost River Sucker and Shortnose Sucker Recovery Plan (Service 2011) recognizes two recovery units, each containing occupied management units. The steps we followed in identifying critical habitat were:

1. Our initial step in identifying critical habitat was to determine, in accordance with section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12, the physical or biological habitat features essential to the conservation of the species, as explained in the previous section.

2. We reviewed the best available scientific data pertaining to the habitat requirements of this species, including information obtained from the Lost River and Shortnose Sucker Recovery Team and the Recovery Implementation Committee, which included biologists from partner agencies and entities including Federal, State, tribal, and private biologists; experts from other scientific disciplines, such as hydrology and forestry; resource users; and other stakeholders with an interest in Lost River sucker and shortnose sucker and the habitats they depend on for survival or recovery. We also reviewed available data concerning Lost River sucker and shortnose sucker habitat use and preferences, habitat conditions, threats, population demographics, and known locations, distribution, and abundances of Lost River sucker and shortnose sucker.

We identified the geographical areas occupied by Lost River sucker and shortnose sucker at the time of listing that contain the PBFs essential for the conservation of the species and which contained one or more of the primary constituent elements identified above. This was done by gathering information from the entities listed above and mapping Lost River sucker and shortnose sucker distribution.

We used data gathered during the Lost River sucker and shortnose sucker recovery planning process and the Draft Lost River Sucker and Shortnose Sucker Recovery Plan (Service 2011), and supplemented those data with recent data developed by State agencies, tribes, the U.S. Forest Service, Bureau of Land Management, and other entities. These data were used to update Lost River sucker and shortnose sucker status and distribution data for purposes of the proposed critical habitat designation.

For areas where we had data gaps, we solicited expert opinions from knowledgeable fisheries biologists in the local area. Material reviewed included data in reports submitted during section 7 consultations, reports from biologists holding section 10(a)(1)(A) recovery permits, research published in peer-reviewed scientific journals, academic theses, State and Federal government agency reports, and GIS data.

In streams, critical habitat includes the stream channel within the designated stream reach and a lateral extent as defined by the bankfull elevation on one bank to the bankfull elevation on the opposite bank. The lateral extent of critical habitat in lakes and reservoirs is defined by the perimeter of the water body as mapped according to the U.S. Geological Survey 2009 National Hydrography Dataset. Land ownership calculations were based on 2011 Oregon and California Bureau of Land Management State office data layers. An updated data layer of Upper Klamath Lake and newly restored wetlands was provided by the U.S. Geological Survey (USGS), Western Fisheries Research Center, and Klamath Falls Field Station.

3. In selecting areas to propose as critical habitat, we considered factors such as size, connectivity to other aquatic habitats, and rangewide

recovery considerations. We took into account the fact that Lost River sucker and shortnose sucker habitats include streams used largely for spawning and outmigration; lakes and reservoirs used for rearing, foraging, and migration; and springs used for spawning and refugia.

4. In determining areas to propose as critical habitat, we relied upon principles of conservation biology, including: (a) Resistance and resiliency, to ensure sufficient habitat is protected throughout the range of the species to support population viability (e.g., demographic parameters); (b) Redundancy, to ensure multiple viable populations are conserved throughout the species' range; and (c) Representation, to ensure the representative genetic and life history of suckers (*e.g.,* spring spawning and river spawning) were conserved.

5. Using the conservation biology principles and primary constituent elements, we examined the distribution of Lost River sucker and shortnose sucker to determine critical habitat based on the following criteria: Largest occupied areas or populations, most highly connected populations and habitat, areas that can contribute to Lost River sucker and shortnose sucker conservation, and areas with highest conservation potential (*e.g.,* essential PBFs). We then used these criteria to identify those areas that contain habitats essential to the conservation of Lost River sucker and shortnose sucker. Using the conservation biology principles and primary constituent elements, we examined the distribution of Lost River sucker and shortnose sucker to assess whether or not to propose areas as critical habitat. We emphasized areas as essential to the conservation of the Lost River and shortnose sucker which contained populations of highest conservation value with characteristics such as: (a) The largest occupied areas or populations, (b) the most highly connected populations and habitat, (c) areas that can contribute to Lost River sucker and shortnose sucker conservation and recovery.

6. We examined geographic locations currently occupied by Lost River sucker and shortnose sucker and determined that certain areas did not contain the PBFs essential for the conservation of these species, and we have not proposed these areas as critical habitat. Such determinations include those areas where Lost River sucker or shortnose sucker: Are not viable, are not connected to spawning habitat, occur in low densities or abundances in very isolated populations, are greatly impacted by nonnative species, have very low potential for conservation or restoration, or have low connectivity among populations and severe habitat degradation.

When determining proposed critical habitat boundaries, we made every effort to avoid including developed areas such as lands covered by buildings, pavement, and other structures because such lands lack physical and biological features for Lost River sucker and shortnose sucker. The scale of the maps we prepared under the parameters for publication within the Code of Federal Regulations may not reflect the exclusion of such developed lands. Any such lands inadvertently left inside critical habitat boundaries shown on the maps of this proposed rule have been excluded by text in the proposed rule and are not proposed for designation as critical habitat. Therefore, if the critical habitat is finalized as proposed, a Federal action involving these lands would not trigger section 7 consultation with respect to critical habitat and the requirement of no adverse modification unless the specific action would affect the physical and biological features in the adjacent critical habitat.

We are proposing for designation of critical habitat lands that we have determined were occupied at the time of listing and contain sufficient elements of physical and biological features to support life-history processes essential to the conservation of the Lost River sucker and shortnose sucker.

Proposed Critical Habitat Designation

We are proposing two units as critical habitat for Lost River sucker and two units for shortnose sucker with each unit being composed of streams, lakes, and reservoirs. The critical habitat areas we describe below constitute our current best assessment of areas that meet the definition of critical habitat for Lost River sucker and shortnose sucker.

The two units we propose as critical habitat for the Lost River sucker, which were both occupied at the time of listing, are:

(1) Upper Klamath Lake Unit, including Upper Klamath Lake and tributaries as well as the Link River and Keno Reservoir.

(2) Lost River Basin Unit, including Clear Lake Reservoir and tributaries.

The two units we propose as critical habitat for the shortnose sucker, which were occupied at the time of listing, are:

(1) Upper Klamath Lake Unit, including Upper Klamath Lake and tributaries as well as the Link River and Keno Reservoir.

(2) Lost River Basin Unit, including Clear Lake Reservoir and tributaries, and Gerber Reservoir and tributaries.

The approximate area and stream length within each proposed critical habitat unit is shown in Tables 1 through 4.

TABLE 1—AREA OF LAKES AND RESERVOIRS PROPOSED AS CRITICAL HABITAT FOR LOST RIVER SUCKER

[Area estimates reflect all land within critical habitat unit boundaries]

Critical habitat unit	Land ownership by type	Acres (hectares)
1. Upper Klamath Lake	Federal	15,198 (6,151)
	State	533 (216)
	Private/Other	74,684 (30,224)
2. Lost River Basin	Federal	27,238 (11,023)
	State	0
	Private/Other	194 (79)
Total	Federal	42,437 (17,174)
	State	533 (216)
	Private/Other	75,249 (30,452)
Total		118,219 (47,842)

Note: Area sizes may not sum due to rounding.

TABLE 2—STREAM LENGTH PROPOSED AS CRITICAL HABITAT FOR LOST RIVER SUCKER

[Area estimates reflect all land within critical habitat unit boundaries]

Critical habitat unit	Land ownership by type	Miles (kilometers)
1. Upper Klamath Lake	Federal	13 (21).
	State	0.
	Private/Other	106 (171).
2. Lost River Basin	Federal	23 (37).
	State	Less than 1.
	Private/Other	3 (5).
Total	Federal	36 (58).
	State	Less than 1.
	Private/Other	109 (176).
Total		146 (234).

Note: Lengths may not sum due to rounding.

TABLE 3—AREA OF LAKES AND RESERVOIRS PROPOSED AS CRITICAL HABITAT FOR SHORTNOSE SUCKER

[Area estimates reflect all land within critical habitat unit boundaries]

Critical habitat unit	Land ownership by type	Acres (hectares)
1. Upper Klamath Lake	Federal	15,198 (6,151)
	State	533 (216)
	Private/Other	74,684 (30,224)
2. Lost River Basin	Federal	32,051 (12,971)
	State	0
	Private/Other	1,124 (455)
Total	Federal	47,250 (19,121)
	State	533 (216)
	Private/Other	76,179 (30,829)
Total		123,961 (50,166)

Note: Area sizes may not sum due to rounding.

TABLE 4—STREAM LENGTH PROPOSED AS CRITICAL HABITAT FOR SHORTNOSE SUCKER

[Area estimates reflect all land within critical habitat unit boundaries]

Critical habitat unit	Land ownership by type	Miles (kilometers)
1. Upper Klamath Lake	Federal	6 (9).
	State	0.
	Private/Other	34 (54).
2. Lost River Basin	Federal	72 (116).
	State	Less than 1.
	Private/Other	16 (26).
Total	Federal	78 (125).
	State	Less than 1.
	Private/Other	50 (80).
Total		128 (207).

Note: Length may not sum due to rounding.

We present brief descriptions of the two critical habitat units for Lost River sucker and two critical habitat units for shortnose sucker and the reasons why they meet the definition of critical habitat, below. The areas we are proposing as critical habitat below satisfy each of the criteria stated above under ''Criteria Used To Identify Critical Habitat'' considerations. These areas will:

- Provide sufficient habitat throughout the range of the species to ensure multiple populations are conserved throughout the species' range;
- Support viability of each population;
- Ensure Lost River sucker and shortnose sucker are distributed across various habitat types required by different life stages; and
- Conserve the full genetic variability and variable life histories (*e.g.,* stream-spawning and lake-spawning) of Lost River sucker and shortnose sucker. Each unit for Lost River and shortnose sucker was occupied at the time of listing.

Unit 1: Upper Klamath Lake

Lost River Sucker

The Upper Klamath Lake unit is located in south-central Oregon within Klamath County and consists of 90,415 ac (36,590 ha) and 119 mi (192 km) of proposed critical habitat. This unit includes Upper Klamath Lake and Agency Lake, together with some wetland habitat; portions of the Williamson and Sprague Rivers; Link River; Lake Ewauna; and the Klamath River from the outlet of Lake Ewauna downstream to Keno Dam. This unit is proposed as critical habitat for Lost River sucker because it contains those physical or biological features essential to the conservation of the species which may require special management or protection. This unit, at least seasonally, contains primary constituent elements 1, 2, and 3. The unit represents the largest population of Lost River sucker and provides redundancy in the number of Lost River sucker populations that are needed for conservation. Additionally, this unit contains areas for both river and spring spawning life histories, which is not known to occur elsewhere throughout the range of the species. The physical and biological features which may require special management or protection include maintaining: Water quality by preventing the deleterious effects of nuisance algal blooms, increased sedimentation, excess nutrients, and other factors affecting water quality; water quantity to prevent reductions in water levels that may limit access to spawning locations or refugia and reduce the depth of water used as cover, and cause a lack of access to essential rearing habitat (*i.e.,* marsh and wetland areas); gravel and cobble substrata to prevent the degradation of spawning, rearing, and adult habitat caused by past land management practices; and the forage base to prevent predation by or competition with nonnative fish that may reduce available forage for Lost River sucker.

Shortnose Sucker

The unit is the same as for Lost River sucker, except that it contains 40 mi (63 km) of streams in proposed critical habitat (because shortnose sucker are not known to occur as far upstream within the Sprague River), along with the 90,415 ac (36,590 ha) of lakes and reservoirs. This unit is proposed as critical habitat for shortnose sucker because it contains those physical and biological features essential to the conservation of the species and which may require special management or protection. This unit, at least seasonally, contains primary constituent elements 1, 2, and 3. This unit is essential to shortnose sucker conservation because it supports the largest population of shortnose sucker and provides redundancy in the number of shortnose sucker populations that are needed for conservation. Additionally, this unit ensures shortnose sucker are distributed across various habitat types required by different life stages. The physical and biological features which may require special management or protection include maintaining: Water quality by preventing the deleterious effects of nuisance algal blooms, increased sedimentation, excess nutrients, and other factors affecting water quality; water quantity to prevent reductions in water levels that may limit access to spawning locations or refugia and reduce the depth of water used as cover, and cause a lack of access to essential rearing habitat (*i.e.,* marsh and wetland areas); gravel and cobble substrata to prevent the degradation of spawning, rearing, and adult habitat caused by past land management practices; and the forage base to prevent predation by or competition with nonnative fish that may reduce available forage for shortnose sucker.

Unit 2: Lost River Basin

Lost River Sucker

The Lost River Basin unit is located in south-central Oregon in Klamath and Lake Counties as well as northeastern California in Modoc County and consists of 27,432 ac (11,102 ha) and 26 mi (42 km) of proposed critical habitat. This unit includes Clear Lake Reservoir and its principal tributary. This unit is proposed as critical habitat for Lost River sucker because it contains those physical and biological features essential to the conservation of the species and which may require special management or protection. This unit, at least seasonally, contains primary constituent elements 1, 2, and 3. This unit supports a large population of Lost River sucker and provides redundancy in the number of Lost River sucker populations that are needed for conservation. Additionally, this unit ensures Lost River sucker are distributed across various habitat types required by different life stages. The physical and biological features which may require special management or protection include maintaining: Water quality by preventing the deleterious effects of nuisance algal blooms, increased sedimentation, excess nutrients, and other factors affecting water quality; water quantity to prevent reductions in water levels that may limit access to spawning locations or refugia and reduce the depth of water used as cover, and cause a lack of access to essential rearing habitat (i.e., marsh and wetland areas); gravel and cobble substrata to prevent the degradation of spawning, rearing, and adult habitat caused by past land management practices; and the forage base to prevent predation by or competition with nonnative fish that may reduce available forage for Lost River sucker.

Shortnose Sucker

The unit is the same as for Lost River sucker, but also includes Gerber Reservoir and its principal tributaries. This unit contains 33,175 ac (13,426 ha) and 88 mi (142 km) of proposed critical habitat. This unit is proposed as critical habitat for shortnose sucker because it contains those physical and biological features essential to the conservation of the species and which may require special management or protection. This unit, at least seasonally, contains primary constituent elements 1, 2, and 3. This unit represents a large population of shortnose sucker and provides redundancy in the number of shortnose sucker populations that are needed for conservation. Additionally, this unit is essential because it ensures shortnose sucker are distributed across various habitat types required by different life stages. The physical and biological features which may require special management or protection include maintaining: Water quality by preventing the deleterious effects of nuisance algal blooms, increased sedimentation, excess nutrients, and other factors affecting water quality; water quantity to prevent reductions in water levels that may limit access to spawning locations or refugia and reduce the depth of water used as cover, and cause a lack of access to essential rearing habitat (i.e., marsh and wetland areas); gravel and cobble substrata to prevent the degradation of spawning, rearing, and adult habitat caused by past land management practices; and the forage base to prevent predation by or competition with nonnative fish that may reduce available forage for shortnose sucker.

Effects of Critical Habitat Designation

Section 7 Consultation

Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that action they fund, authorize, or carry out is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of designated critical habitat of such species. In

addition, section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any agency action which is likely to jeopardize the continued existence of any species proposed to be listed under the Act or result in the destruction or adverse modification of proposed critical habitat.

Decisions by the 5th and 9th Circuit Courts of Appeals have invalidated our regulatory definition of ''destruction or adverse modification'' (50 CFR 402.02) (see *Gifford Pinchot Task Force* v. *U.S. Fish and Wildlife Service,* 378 F. 3d 1059 (9th Cir. 2004) and *Sierra Club* v. *U.S. Fish and Wildlife Service et al.,* 245 F.3d 434, 442 (5th Cir. 2001)), and we do not rely on this regulatory definition when analyzing whether an action is likely to destroy or adversely modify critical habitat. Under the statutory provisions of the Act, we determine destruction or adverse modification on the basis of whether, with implementation of the proposed Federal action, the affected critical habitat would continue to serve its intended conservation role for the species.

If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. Examples of actions that are subject to the section 7 consultation process are actions on State, tribal, local, or private lands that require a Federal permit (such as a permit from the U.S. Army Corps of Engineers under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or a permit from the Service under section 10 of the Act) or that involve some other Federal action (such as funding from the Federal Highway Administration, Federal Aviation Administration, or the Federal Emergency Management Agency). Federal actions not affecting listed species or critical habitat, and actions on State, tribal, local, or private lands that are not federally funded or authorized, do not require section 7 consultation.

As a result of this consultation, we document compliance with the requirements of section 7(a)(2) through our issuance of:

(1) A concurrence letter for Federal actions that may affect, but are not likely to adversely affect, listed species or critical habitat; or

(2) A biological opinion for Federal actions that may affect, and are likely to adversely affect, listed species or critical habitat.

When we issue a biological opinion concluding that a project is likely to jeopardize the continued existence of a listed species or destroy or adversely modify critical habitat, we provide reasonable and prudent alternatives to the project, if any are identifiable, that would avoid the likelihood of jeopardy, or destruction or adverse modification of critical habitat, or both. We define ''reasonable and prudent alternatives'' (at 50 CFR 402.02) as alternative actions identified during consultation that:

(1) Can be implemented in a manner consistent with the intended purpose of the action,

(2) Can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction,

(3) Are economically and technologically feasible, and

(4) Would, in the Director's opinion, avoid the likelihood of jeopardizing the continued existence of the listed species and/or avoid the likelihood of destroying or adversely modifying critical habitat.

Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 require Federal agencies to reinitiate consultation on previously reviewed actions in instances where we have listed a new species or subsequently designated critical habitat that may be affected and the Federal agency has retained discretionary involvement or control over the action (or the agency's discretionary involvement or control is authorized by law). Consequently, Federal agencies may sometimes need to request reinitiation of consultation with us on actions for which formal consultation has been completed, if those actions with discretionary involvement or control may affect subsequently listed species or designated critical habitat.

Application of the ''Adverse Modification'' Standard

The key factor related to the adverse modification determination is whether, with implementation of the proposed Federal action, the affected critical habitat would continue to serve its intended conservation role for the species. Activities that may destroy or adversely modify critical habitat are those that alter the physical and biological features to an extent that appreciably reduces the conservation value of critical habitat for Lost River sucker and shortnose sucker. As discussed above, the role of critical habitat is to support life-history needs of the species and provide for the conservation of the species.

Section 4(b)(8) of the Act requires us to briefly evaluate and describe, in any proposed or final regulation that designates critical habitat, activities involving a Federal action that may destroy or adversely modify such habitat, or that may be affected by such designation.

Activities that may affect critical habitat, when carried out, funded, or authorized by a Federal agency, should result in consultation for the Lost River sucker and shortnose sucker. These activities include, but are not limited to:

(1) Actions that would significantly alter the level of lakes or reservoirs. Such activities could include, but are not limited to, water diversions or water withdrawals. These activities could reduce the amount of habitat necessary for rearing of larvae and juvenile Lost River sucker and shortnose sucker, preclude access to spawning habitat, reduce or prevent access to refugia, and reduce the amount of water needed to provide the physical and biological features necessary for adult Lost River sucker and shortnose sucker.

(2) Actions that would significantly increase sediment deposition within stream channels. Such activities could include, but are not limited to, excessive sedimentation from livestock grazing, road construction, channel alteration, timber harvest and management, off-road vehicle use, and other watershed and floodplain disturbances. These activities could reduce and degrade spawning habitat of Lost River sucker and shortnose sucker by increasing the sediment deposition to deleterious levels.

(3) Actions that would significantly alter lake, reservoir, and/or channel morphology or geometry. Such activities could include, but are not limited to, channelization, impoundment, road and bridge construction, mining, dredging, and destruction of riparian vegetation. These activities may lead to changes in water flows and levels that would degrade or eliminate Lost River sucker and shortnose sucker habitats. These actions can also lead to increased sedimentation and degradation in water quality to levels that are beyond the tolerances of Lost River sucker and shortnose sucker.

Exemptions

Application of Section 4(a)(3) of the Act

The Sikes Act Improvement Act of 1997 (Sikes Act) (16 U.S.C. 670a) required each military installation that includes land and water suitable for the conservation and management of natural resources to complete an integrated natural resources

management plan (INRMP) by November 17, 2001. An INRMP integrates implementation of the military mission of the installation with stewardship of the natural resources found on the base. Each INRMP includes:

(1) An assessment of the ecological needs on the installation, including the need to provide for the conservation of listed species;

(2) A statement of goals and priorities;

(3) A detailed description of management actions to be implemented to provide for these ecological needs; and

(4) A monitoring and adaptive management plan.

Among other things, each INRMP must, to the extent appropriate and applicable, provide for fish and wildlife management; fish and wildlife habitat enhancement or modification; wetland protection, enhancement, and restoration where necessary to support fish and wildlife; and enforcement of applicable natural resource laws.

The National Defense Authorization Act for Fiscal Year 2004 (Pub. L. 108–136) amended the Act to limit areas eligible for designation as critical habitat. Specifically, section 4(a)(3)(B)(i) of the Act (16 U.S.C. 1533(a)(3)(B)(i)) now provides: ''The Secretary shall not designate as critical habitat any lands or other geographical areas owned or controlled by the Department of Defense, or designated for its use, that are subject to an integrated natural resources management plan prepared under section 101 of the Sikes Act (16 U.S.C. 670a), if the Secretary determines in writing that such plan provides a benefit to the species for which critical habitat is proposed for designation.''

There are no Department of Defense lands within the proposed critical habitat designation; as a result no lands are being exempted under section 4(a)(3) of the Act.

Exclusions

Application of Section 4(b)(2) of the Act

Section 4(b)(2) of the Act states that the Secretary shall designate and make revisions to critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat. The Secretary may exclude an area from critical habitat if he determines that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless he determines, based on the best scientific data available, that the failure to designate such area as critical habitat will result in the extinction of the species. In making that determination, the statute on its face, as well as the legislative history, are clear that the Secretary has broad discretion regarding which factor(s) to use and how much weight to give to any factor.

Under section 4(b)(2) of the Act, we may exclude an area from designated critical habitat based on economic impacts, impacts on national security, or any other relevant impacts. In considering whether to exclude a particular area from the designation, we must identify the benefits of including the area in the designation, identify the benefits of excluding the area from the designation, and determine whether the benefits of exclusion outweigh the benefits of inclusion. If the analysis indicates that the benefits of exclusion outweigh the benefits of inclusion, the Secretary may exercise his discretion to exclude the area only if such exclusion would not result in the extinction of the species.

Exclusions Based on Economic Impacts

Under section 4(b)(2) of the Act, we consider the economic impacts of specifying any particular area as critical habitat. In order to consider economic impacts, we are preparing an analysis of the economic impacts of the proposed critical habitat designation and related factors.

An economic analysis was conducted for the December 1, 1994, proposed rule (59 FR 61744) to estimate the economic effects of the proposed critical habitat designation. The previous economic analysis acknowledges the proposed designation would constrain the ability of Federal agencies to engage in activities, or to support the activities of others, that would adversely modify or destroy critical habitat. Major Federal agencies in the upper Klamath River basin indicated their activities would be altered to protect Lost River sucker and shortnose sucker. However, different conclusions were reached by these agencies as to whether these changes were a result of Lost River sucker and shortnose sucker being listed as endangered, from proposed critical habitat designation, or both. The economic analysis further indicated critical habitat designation would negatively affect local employment due to a change in the output of goods and services, primarily from the resource extraction businesses. Conversely, designation also would enhance natural resource amenities, causing economic growth as a result of immigration of people seeking a heightened local and regional quality of life. The economic analysis concluded by determining the effect of designation would be neutral. Additional details can be found in that 1994 proposed rule (59 FR 61750–61753; December 1, 1994).

We are conducting a new economic analysis for this proposed rule, and we will announce the availability of that draft economic analysis as soon as it is completed, at which time we will seek public review and comment. At that time, copies of the draft economic analysis will be available for downloading from the Internet at *http://www.regulations.gov,* or by contacting the Klamath Falls Fish and Wildlife Office directly (see **FOR FURTHER INFORMATION CONTACT** section). During the development of a final designation, we will consider economic impacts, public comments, and other new information, and areas may be excluded from the final critical habitat designation under section 4(b)(2) of the Act and our implementing regulations at 50 CFR 424.19.

Exclusions Based on National Security Impacts

Under section 4(b)(2) of the Act, we consider whether there are lands owned or managed by the Department of Defense where a national security impact might exist. In preparing this proposal, we have determined that the lands within the proposed designation of critical habitat for Lost River sucker and shortnose sucker are not owned or managed by the Department of Defense, and, therefore, we anticipate no impact on national security. Consequently, the Secretary does not propose to exercise his discretion to exclude any areas from the final designation based on impacts on national security.

Exclusions Based on Other Relevant Impacts

Under section 4(b)(2) of the Act, we consider any other relevant impacts, in addition to economic impacts and impacts on national security. We consider a number of factors, including whether the landowners have developed any HCPs or other management plans for the area, or whether there are conservation partnerships that would be encouraged by designation of, or exclusion from, critical habitat. In addition, we look at any tribal issues, and consider the government-to-government relationship of the United States with tribal entities. We also consider any social impacts that might occur because of the designation.

In preparing this proposal, we have determined that there are currently no HCPs or other management plans for Lost River sucker and shortnose sucker,

and the proposed designation does not include any tribal lands or trust resources. We anticipate no impact on tribal lands, partnerships, or HCPs from this proposed critical habitat designation. Accordingly, the Secretary does not propose to exercise his discretion to exclude any areas from the final designation based on other relevant impacts.

Peer Review

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), we are seeking the expert opinions of at least three appropriate and independent specialists regarding this proposed rule. The purpose of peer review is to ensure that our critical habitat designation is based on scientifically sound data, assumptions, and analyses. We have invited these peer reviewers to comment during this public comment period on our specific assumptions and conclusions in this proposed designation of critical habitat.

We will consider all comments and information we receive during the comment period on this proposed rule during our preparation of a final determination. Accordingly, the final decision may differ from this proposal.

Public Hearings

Section 4(b)(5) of the Act provides for one or more public hearings on this proposal, if requested. Requests must be received within 45 days after the date of publication of this proposed rule in the **Federal Register**. Such requests must be sent to the address shown in the **FOR FURTHER INFORMATION CONTACT** section. We will schedule public hearings on this proposal, if any are requested, and announce the dates, times, and places of those hearings, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing.

Required Determinations

Regulatory Planning and Review—Executive Order 12866

The Office of Management and Budget (OMB) has determined that this rule is not significant and has not reviewed this proposed rule under Executive Order 12866 (Regulatory Planning and Review). OMB bases its determination upon the following four criteria:

(1) Whether the rule will have an annual effect of $100 million or more on the economy or adversely affect an economic sector, productivity, jobs, the environment, or other units of the government.

(2) Whether the rule will create inconsistencies with other Federal agencies' actions.

(3) Whether the rule will materially affect entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients.

(4) Whether the rule raises novel legal or policy issues.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*) as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 (5 U.S.C. 801 *et seq.*), whenever an agency must publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended RFA to require Federal agencies to provide a certification statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities.

At this time, we lack the available economic information necessary to provide an adequate factual basis for the required RFA finding. Therefore, we defer the RFA finding until completion of the draft economic analysis prepared under section 4(b)(2) of the Act and Executive Order 12866. This draft economic analysis will provide the required factual basis for the RFA finding. Upon completion of the draft economic analysis, we will announce availability of the draft economic analysis of the proposed designation in the **Federal Register** and reopen the public comment period for the proposed designation. We will include with this announcement, as appropriate, an initial regulatory flexibility analysis or a certification that the rule will not have a significant economic impact on a substantial number of small entities accompanied by the factual basis for that determination.

The previous economic analysis (see our 1994 proposed rule at 59 FR 61750–61753, December 1, 1994) indicated dislocation of workers in the local resource extraction industries would be offset, in the long run, by the creation of additional jobs in other sectors locally or in other areas. At that time, the analysis determined the national adjustment to the proposed designation would be essentially imperceptible as the U.S. economy redeployed labor and other resources that might become unemployed because of the designation. Further, the analysis stated that as buyers, sellers, workers, firms, households, and communities adjusted to the proposed designation, its economic impacts would be spread over a broad economic and spatial landscape.

We have concluded that deferring the RFA finding until completion of the new draft economic analysis is necessary to meet the purposes and requirements of the RFA. Deferring the RFA finding in this manner will ensure that we make a sufficiently informed determination based on adequate, current economic information and provide the necessary opportunity for public comment.

Energy Supply, Distribution, or Use—Executive Order 13211

Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) requires agencies to prepare Statements of Energy Effects when undertaking certain actions. We do not expect that the proposed critical habitat designation for the Lost River sucker and shortnose sucker would significantly affect energy supplies, distribution, or use.

Although there is a large natural gas pipeline within the Lost River Basin Unit, the Federal Energy Regulatory Commission recently completed a formal biological opinion and conference report with the Service regarding the effect of those operations on Lost River sucker and shortnose sucker and proposed critical habitat. The biological opinion (Service 2010) established strict Terms and Conditions for the conservation of Lost River sucker and shortnose sucker in those habitats that would be impacted by pipeline operations; several of these habitats are included in this proposal. The designation of critical habitat in the areas adjacent to the pipeline will not change current Lost River sucker and shortnose sucker conservation practices surrounding pipeline operations. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required. However, we will further evaluate this issue as we conduct our economic analysis, and review and revise this assessment as warranted.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we make the following findings:

(1) This rule would not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or tribal governments, or the private sector, and includes both ''Federal intergovernmental mandates'' and ''Federal private sector mandates.'' These terms are defined in 2 U.S.C. 658(5)–(7). ''Federal intergovernmental mandate'' includes a regulation that ''would impose an enforceable duty upon State, local, or tribal governments'' with two exceptions. It excludes ''a condition of Federal assistance.'' It also excludes ''a duty arising from participation in a voluntary Federal program,'' unless the regulation ''relates to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and tribal governments under entitlement authority,'' if the provision would ''increase the stringency of conditions of assistance'' or ''place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding,'' and the State, local, or tribal governments ''lack authority'' to adjust accordingly. At the time of enactment, these entitlement programs were: Medicaid; Aid to Families with Dependent Children work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement. ''Federal private sector mandate'' includes a regulation that ''would impose an enforceable duty upon the private sector, except (i) A condition of Federal assistance or (ii) a duty arising from participation in a voluntary Federal program.''

The designation of critical habitat does not impose a legally binding duty on non-Federal Government entities or private parties. Under the Act, the only regulatory effect is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under section 7. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply, nor would critical habitat shift the costs of the large entitlement programs listed above onto State governments.

(2) We do not believe that this rule would significantly or uniquely affect small governments because, based in part on an analysis conducted for the previous proposed designation of critical habitat and extrapolated to this designation, we do not expect this rule to significantly or uniquely affect small governments. Therefore, a Small Government Agency Plan is not required. However, we will further evaluate this issue as we conduct our economic analysis, and review and revise this assessment if appropriate.

Takings—Executive Order 12630

In accordance with Executive Order 12630 (Government Actions and Interference with Constitutionally Protected Private Property Rights), we have analyzed the potential takings implications of designating critical habitat for Lost River sucker and shortnose sucker in a takings implications assessment. Critical habitat designation does not affect landowner actions that do not require Federal funding or permits, nor does it preclude development of habitat conservation programs or issuance of incidental take permits to permit actions that do require Federal funding or permits to go forward. The takings implications assessment concludes that this proposed designation of critical habitat for Lost River sucker and shortnose sucker does not pose significant takings implications for lands within or affected by the designation.

Federalism—Executive Order 13132

In accordance with Executive Order 13132 (Federalism), this proposed rule does not have significant Federalism effects. A federalism summary impact statement is not required. In keeping with Department of the Interior and Department of Commerce policy, we requested information from, and coordinated development of, this proposed critical habitat designation with appropriate State resource agencies in Oregon and California. The designation of critical habitat in areas currently occupied by the Lost River sucker and shortnose sucker imposes no additional restrictions to those currently in place and, therefore, has little incremental impact on State and local governments and their activities. The designation may have some benefit to these governments because the areas that contain the physical and biological features essential to the conservation of the species are more clearly defined, and the elements of the features of the habitat necessary to the conservation of the species are specifically identified. This information does not alter where and what federally sponsored activities may occur. However, it may assist local governments in long-range planning (rather than having them wait for case-by-case section 7 consultations to occur).

Where State and local governments require approval or authorization from a Federal agency for actions that may affect critical habitat, consultation under section 7(a)(2) would be required. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency.

Civil Justice Reform—Executive Order 12988

In accordance with Executive Order 12988 (Civil Justice Reform), the Office of the Solicitor has determined that the rule does not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of the Order. We have proposed designating critical habitat in accordance with the provisions of the Act. This proposed rule uses standard property descriptions and identifies the elements of physical and biological features essential to the conservation of the Lost River sucker and shortnose sucker within the designated areas to assist the public in understanding the habitat needs of the species.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain any new collections of information that require approval by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This rule will not impose recordkeeping 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.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

It is our position that, outside the jurisdiction of the U.S. Court of Appeals for the Tenth Circuit, we do not need to prepare environmental analyses pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) in connection with designating critical habitat under the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This position was upheld by the U.S. Court of Appeals for the Ninth Circuit (*Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. 1995), cert. denied 516 U.S. 1042 (1996)).

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, *etc.*

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes.

We determined that there are no tribal lands that were occupied by the Lost River sucker and shortnose sucker at the time of listing that contain the features essential for conservation of the species, and no tribal lands unoccupied by the Lost River sucker and shortnose sucker that are essential for the conservation of the species. Therefore, we are not proposing to designate critical habitat for the Lost River sucker and shortnose sucker on tribal lands.

References Cited

A complete list of references cited is available on the Internet at *http://www.regulations.gov* and upon request from the Klamath Falls Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this package are the staff members of the Klamath Falls Fish and Wildlife Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

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

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

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. In § 17.11(h), revise the entry for ''Sucker, Lost River'' and ''Sucker, shortnose'' under ''FISHES'' in the List of Endangered and Threatened Wildlife to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
*	*	*	*	*	*		*
FISHES							
*	*	*	*	*	*		*
Sucker, Lost River	*Deltistes luxatus*	U.S.A. (CA, OR)	Entire	E	313	17.95(e)	NA
*	*	*	*	*	*		*
Sucker, shortnose	*Chasmistes brevirostris.*	U.S.A. (CA, OR)	Entire	E	313	17.95(e)	NA
*	*	*	*	*	*		*

3. In § 17.95, amend paragraph (e) by adding entries for ''Lost River Sucker (*Deltistes luxatus*)'' and ''Shortnose Sucker (*Chasmistes brevirostris*),'' in the same alphabetical order that the species appear in the table at § 17.11(h), to read as follows:

§ 17.95 Critical habitat—fish and wildlife.

* * * * *

(e) *Fishes.*

* * * * *

Lost River Sucker (*Deltistes luxatus*)

(1) Critical habitat units are depicted for Klamath and Lake Counties, Oregon,

and Modoc County, California, on the maps below.

(2) Within these areas, the primary constituent elements of the physical and biological features essential to the conservation of Lost River sucker consist of three components:

(i) *Water.* Areas with sufficient water quantity and depth within lakes, reservoirs, streams, marshes, springs, groundwater sources, and refugia habitats with minimal physical, biological, or chemical impediments to connectivity. Water should exhibit depths ranging from less than 1.0 m (3.28 ft) up to 4.5 m (14.8 ft) to accommodate each life stage. The water quality characteristics should include water temperatures of less than 28.0 °Celsius (82.4 °F); pH less than 9.75; dissolved oxygen levels greater than 4.0 mg per L; algal toxins (less than 1.0 microgram (μg) per L); and un-ionized ammonia (less than 0.5 mg per L). Elements also include natural flow regimes that provide flows during the appropriate time of year or, if flows are controlled, minimal flow departure from a natural hydrograph.

(ii) *Spawning and rearing habitat.* Streams and shoreline springs with gravel and cobble substrate at depths typically less than 1.3 m (4.3 ft) with adequate stream velocity to allow spawning to occur. Areas identified in PCE1 containing emergent vegetation adjacent to open water that provides habitat for rearing . This facilitates growth and survival of suckers, as well as protection from predation and protection from currents and turbulence.

(iii) *Food.* Areas that contain an abundant forage base, including a broad array of chironomidae, crustacea, and other aquatic macroinvertebrates.

(3) Critical habitat does not include manmade structures (such as buildings, aqueducts, runways, roads, and other paved areas) and the land on which they are located existing within the legal boundaries on the effective date of this rule.

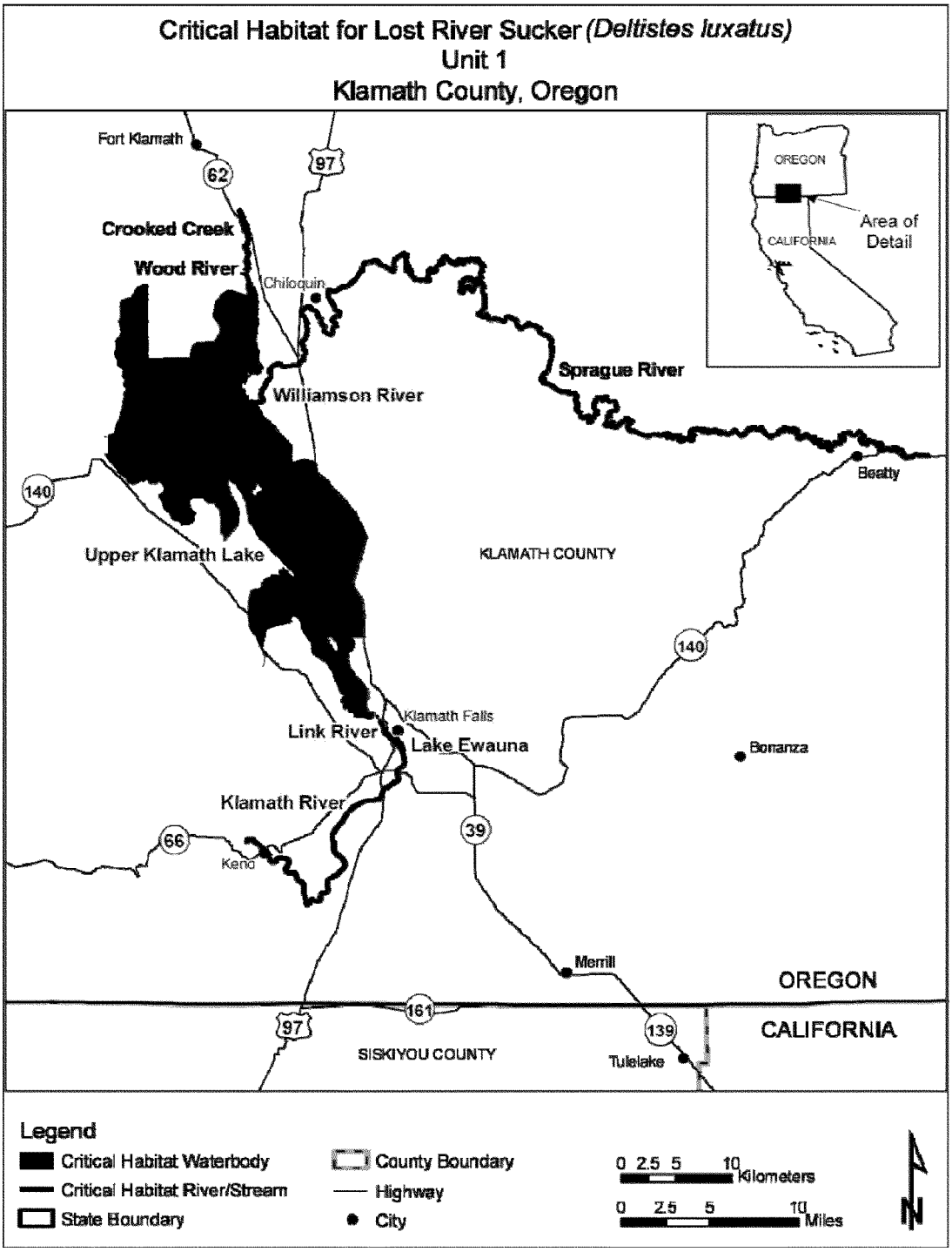
(4) *Critical habitat map units.* Data layers defining map units were created on a base of the U.S. Geological Survey 2009 National Hydrography Dataset, and critical habitat was then mapped using North American Datum (NAD) 83, Universal Transverse Mercator Zone 10N coordinates.

(5) Unit 1: Upper Klamath Lake Unit, Klamath County, Oregon.

(i) [Reserved for textual description of Unit 1.]

(ii) *Note:* Map of Unit 1, Upper Klamath Lake, follows:

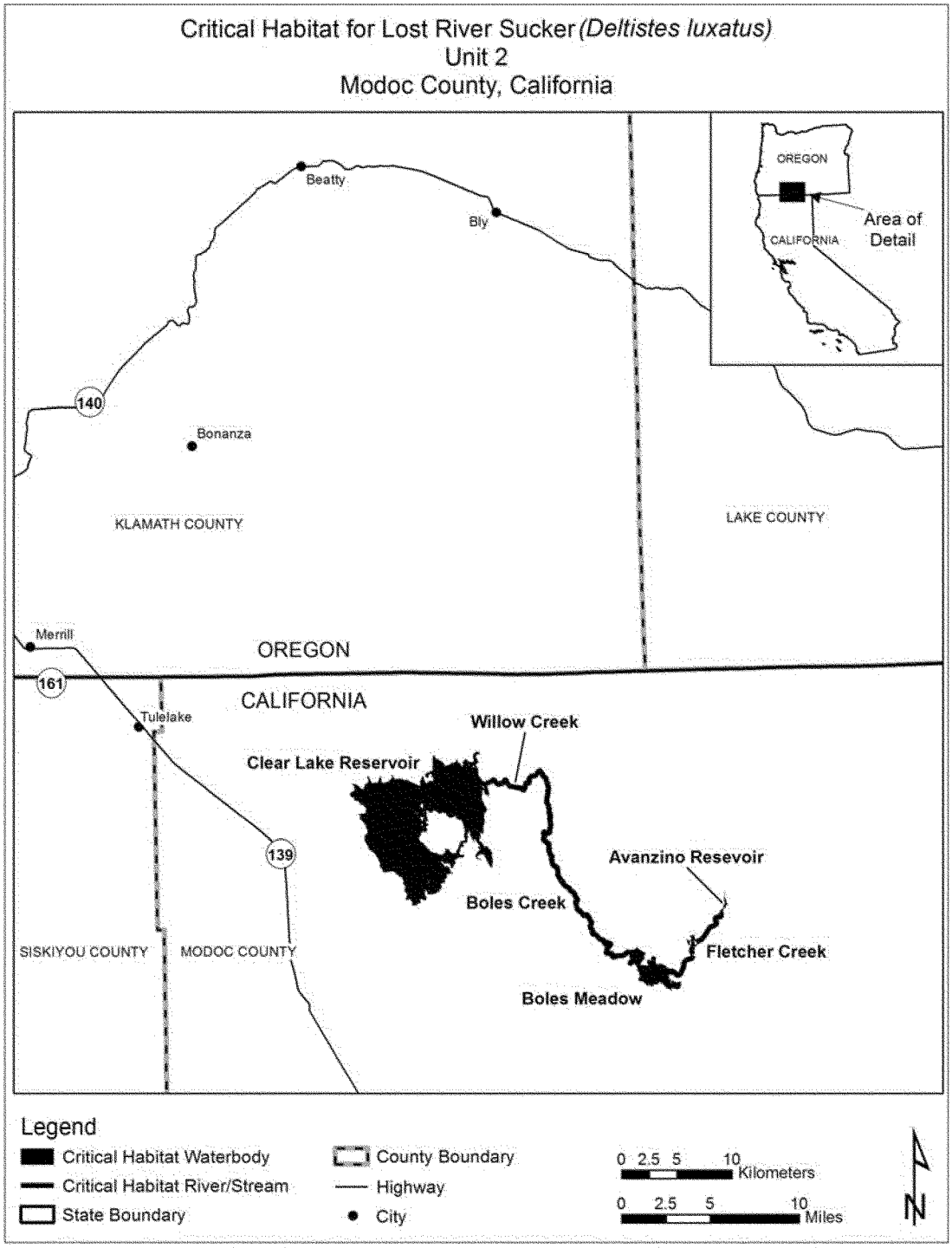
BILLING CODE 4310–55–P



(6) Unit 2: Lost River Basin Unit, Modoc County, California.

(i) [Reserved for textual description of Unit 2.]

(ii) *Note:* Map of Unit 2, Lost River Basin, follows:



* * * * *

Shortnose Sucker (*Chasmistes brevirostris*)

(1) Critical habitat units are depicted for Klamath and Lake Counties, Oregon, and Modoc County, California, on the maps below.

(2) Within these areas, the primary constituent elements of the physical and biological features essential to the conservation of the shortnose sucker consist of three components:

(i) *Water.* Areas with sufficient water quantity and depth within lakes, reservoirs, streams, marshes, springs, groundwater sources, and refugia habitats with minimal physical, biological, or chemical impediments to connectivity. Water should exhibit depths ranging from less than 1.0 m (3.28 ft) up to 4.5 m (14.8 ft) to accommodate each life stage. The water quality characteristics should include water temperatures of less than 28.0 °Celsius (82.4 °F); pH less than 9.75; dissolved oxygen levels greater than 4.0 mg per L; algal toxins (less than 1.0 microgram (μg) per L); and un-ionized ammonia (less than 0.5 mg per L). Elements also include natural flow regimes that provide flows during the appropriate time of year or, if flows are controlled, minimal flow departure from a natural hydrograph.

(ii) *Spawning and rearing habitat.* Streams and shoreline springs with gravel and cobble substrate at depths typically less than 1.3 m (4.3 ft) with adequate stream velocity to allow spawning to occur. Areas identified in PCE1 containing emergent vegetation adjacent to open water that provides habitat for rearing . This facilitates growth and survival of suckers, as well as protection from predation and protection from currents and turbulence.

(iii) *Food.* Areas that contain an abundant forage base, including a broad array of chironomidae, crustacea, and other aquatic macroinvertebrates.

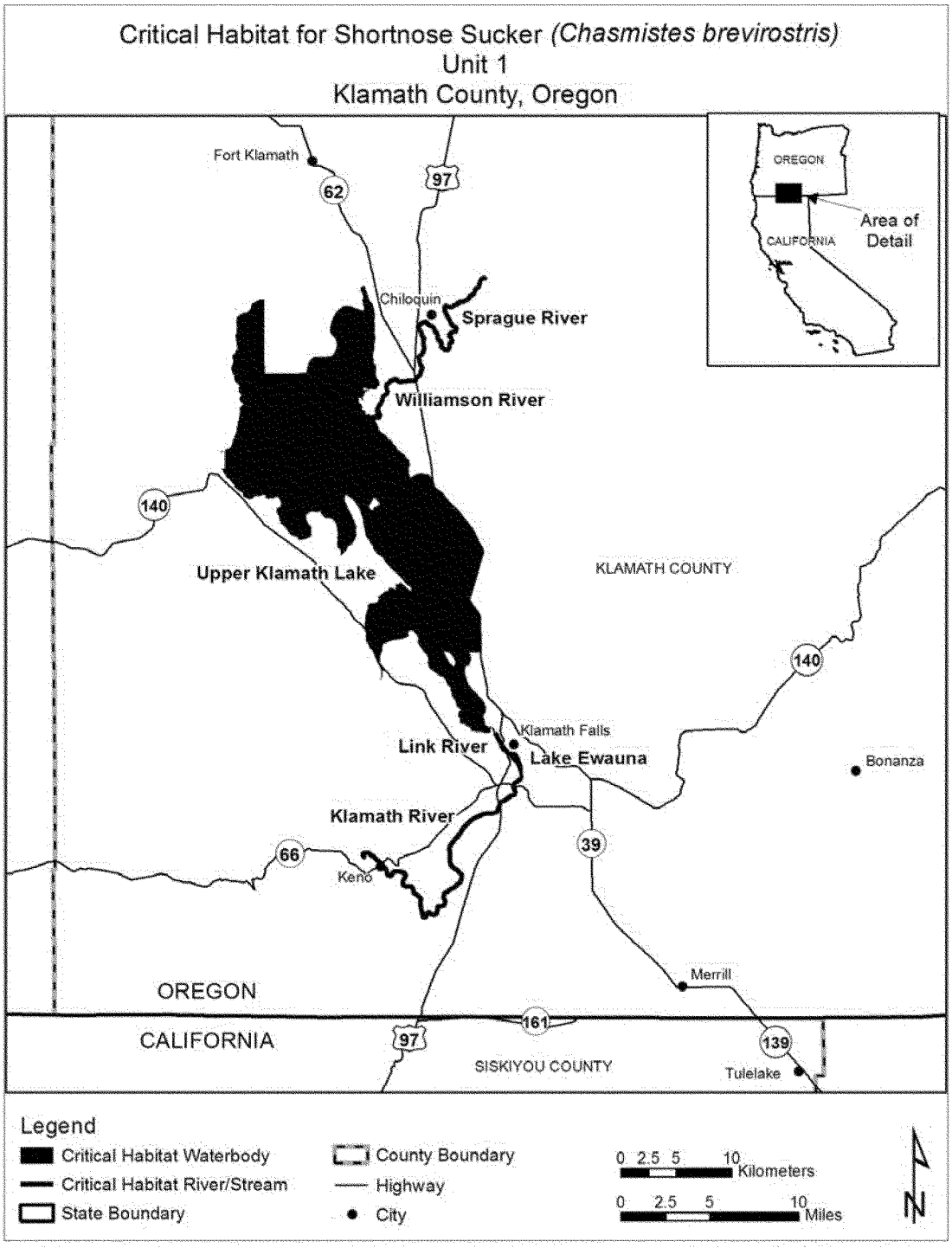
(3) Critical habitat does not include manmade structures (such as buildings, aqueducts, runways, roads, and other paved areas) and the land on which they are located existing within the legal boundaries on the effective date of this rule.

(4) *Critical habitat map units.* Data layers defining map units were created on a base of the U.S. Geological Survey 2009 National Hydrography Dataset, and critical habitat was then mapped using North American Datum (NAD) 83, Universal Transverse Mercator Zone 10N coordinates.

(5) Unit 1: Upper Klamath Lake Unit, Klamath County, Oregon.

(i) [Reserved for textual description of Unit 1.]

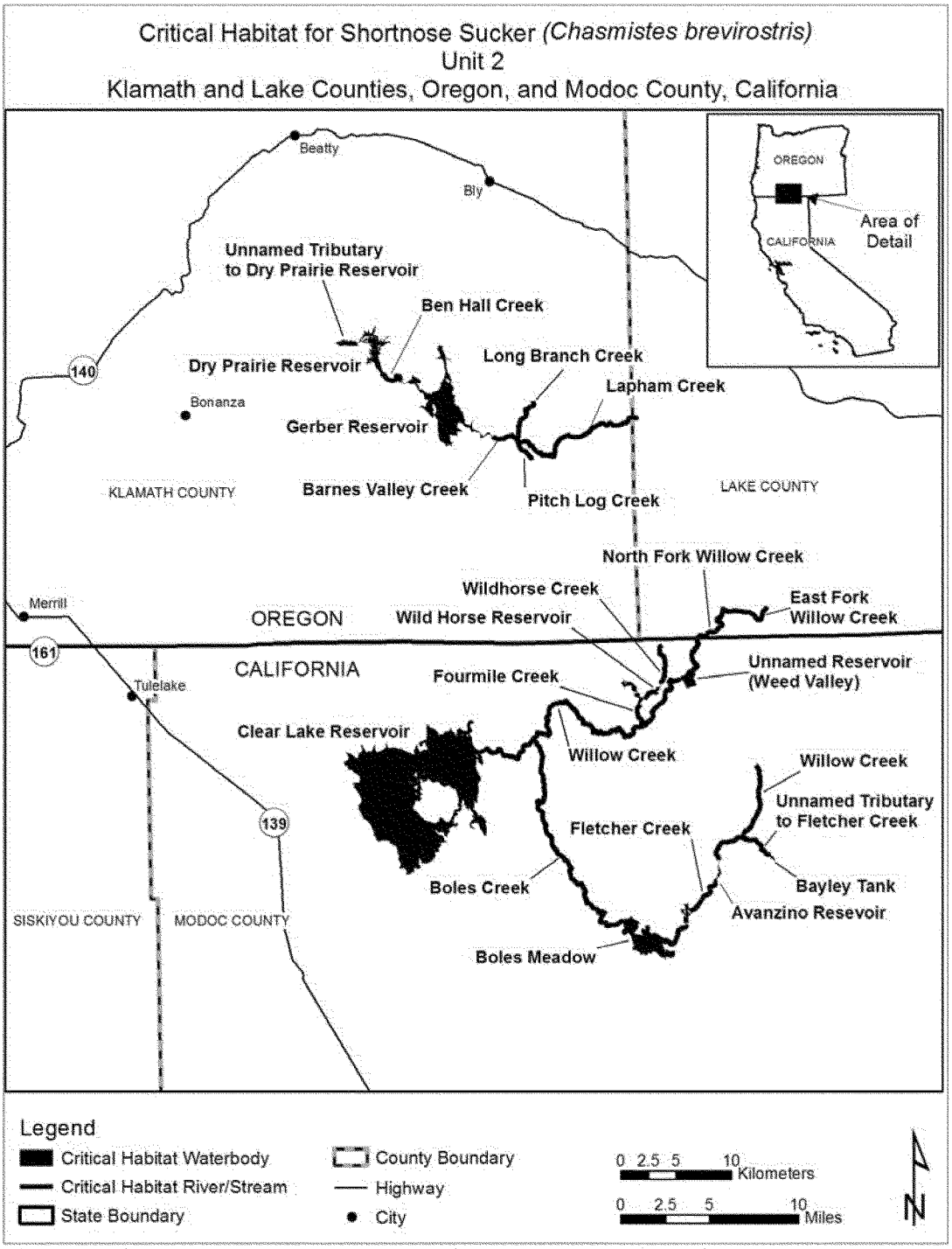
(ii) *Note:* Map of Unit 1, Upper Klamath Lake, follows:



(6) Unit 2: Lost River Basin Unit, Klamath and Lake Counties, Oregon, and Modoc County, California.

(i) [Reserved for textual description of Unit 2.]

(ii) *Note:* Map of Unit 2, Lost River Basin, follows:



* * * * *

Dated: November 22, 2011.

Eileen Sobeck,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2011–31380 Filed 12–6–11; 8:45 am]

BILLING CODE 4310–55–C

Notices

Federal Register

Vol. 76, No. 235

Wednesday, December 7, 2011

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.

AGENCY FOR INTERNATIONAL DEVELOPMENT

Notice of Public Information Collection Requirements Submitted to OMB for Review

SUMMARY: U.S. Agency for International Development (USAID) has submitted the following information collections to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding this information collection are best assured of having their full effect if received within 30 days of this notification. Comments should be sent via email to *OIRA_Submission@omb.eop.gov.* The USAID submission to OMB is attached hereto.

SUPPLEMENTARY INFORMATION:

OMB Number: OMB 0412–0577.

Form Number: AID 500–13.

Title: Partner Information Form.

Type of Submission: Extension of Information Collection.

Purpose: USAID intends to collect information from approximately 10,000 individuals and/or officers of non-governmental organizations (NGOs) who apply for USAID contracts, grants, cooperative agreements, other funding from USAID, or who apply for registration with USAID as Private and Voluntary Organizations (PVO). Collection of personally identifiable information from these individuals is specifically used to conduct screening to ensure that neither USAID funds nor USAID-funded activities inadvertently provide support to entities or individuals associated with terrorism.

Annual Reporting Burden

Respondents: 44,000.

Total Annual Responses: 44,000.

Total Annual Hours Requested: 11,000.

Dated: November 30, 2011.

Lynn P. Winston,

Chief, Information and Records Division, Office of Management Services, Bureau for Management.

[FR Doc. 2011–31244 Filed 12–6–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Deschutes Provincial Advisory Committee (DPAC)

AGENCY: Forest Service, USDA.

ACTION: Notice of Meeting.

SUMMARY: The Deschutes Provincial Advisory Committee will meet on December 12, 2011 to introduce new nominees and current PAC members; review key principals and goals; and identify key areas of interest for 2012 meetings and field trips. The meeting will also provide updates on the forest restoration and sustainable recreation subcommittees.

Members will meet at the Deschutes National Forest Supervisors office, Aspen conference room (63095 Deschutes Market Road, Bend, Oregon) from 9 AM until 2 PM. All Deschutes Provincial Advisory Committee meetings are open to the public.

FOR FURTHER INFORMATION CONTACT: Michael Keown, Province Liaison, Sisters Ranger District, Pine Street and Highway 20, Sisters, Oregon 97759, Phone (541) 549–7735.

John Allen,

Deschutes National Forest Supervisor.

[FR Doc. 2011–31112 Filed 12–6–11; 8:45 am]

BILLING CODE 3410–11–M

COMMISSION ON CIVIL RIGHTS

Sunshine Act Notice

AGENCY: United States Commission on Civil Rights.

ACTION: Notice of meeting.

DATE AND TIME: Monday, December 19, 2011; 1 p.m. EST.

PLACE: 624 Ninth Street NW., Room 540, Washington, DC 20425.

Meeting Agenda

This meeting is open to the public.

I. Approval of Agenda

II. Approval of the November 18, 2011 Meeting Minutes

III. Program Planning Update and Discussion of Projects:
- Update on 2012 Statutory Enforcement Report Planning

IV. Management and Operations:
- Staff Director's Report
- Chief of Regional Programs Report

V. State Advisory Committee Issues:
- Re-Chartering the Hawaii SAC
- New Chair for Alaska
- New Chair for North Dakota

VI. Adjourn

CONTACT PERSON FOR FURTHER INFORMATION: Lenore Ostrowsky, Acting Chief, Public Affairs Unit (202) 376–8591.

Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact Pamela Dunston at (202) 376–8105 or at *signlanguage@usccr.gov* at least seven business days before the scheduled date of the meeting.

Dated: December 5, 2011.

Kimberly A. Tolhurst,

Senior Attorney-Advisor.

[FR Doc. 2011–31502 Filed 12–5–11; 11:15 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: U.S. Pacific Albacore Logbook.

OMB Control Number: 0648–0223.

Form Number(s): 88–197.

Type of Request: Regular submission (extension of a current information collection).

Number of Respondents: 1,000.

Average Hours per Response: 1 hour.

Burden Hours: 4,000.

Needs and Uses: This request is for an extension of a current information collection.

The National Oceanic and Atmospheric Administrations, Southwest Fisheries Science Center operates a Pacific Albacore Data Collection Program. Fishermen participating on the Pacific albacore

tuna fishery are required to complete and submit logbooks documenting their catch and effort on fishing trips. This is a requirement under the Highly Migratory Species Fishery Management Plan and the High-Seas Fisheries Compliance Act permit for logbook submissions. The information obtained is used by the agency to assess the status of albacore stocks and to monitor the fishery. Fishermen are also provided an electronic logbook computer program that they can voluntarily use in place of the paper copy of the logbook.

Affected Public: Business or other for-profit organizations.

Frequency: On occasion.

Respondent's Obligation: Mandatory.

OMB Desk Officer: *OIRA_Submission@omb.eop.gov.*

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov*.

Dated: December 2, 2011.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2011–31340 Filed 12–6–11; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–601]

Tapered Roller Bearings and Parts Thereof, Finished or Unfinished, From the People's Republic of China: Notice of Second Extension of Time Limit for the Final Results of the Antidumping Duty Administrative Review

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

DATES: *Effective Date:* December 7, 2011.

FOR FURTHER INFORMATION CONTACT: Demitri Kalogeropoulos or Frances Veith, AD/CVD Operations, Office 8, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; *telephone:* (202) 482–2623 or (202) 482–4295, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 28, 2010, the Department of Commerce (''Department'') published the initiation of the administrative review of the antidumping duty order on tapered roller bearings and parts thereof, finished or unfinished, (''TRBs'') from the People's Republic of China (''PRC''). *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocation in Part,* 75 FR 44224 (July 28, 2010). On July 13, 2011, the Department published the preliminary results of the review. *See Tapered Roller Bearings and Parts Thereof, Finished or Unfinished, From the People's Republic of China: Preliminary Results of the 2009–2010 Administrative Review of the Antidumping Duty Order and Intent To Rescind Administrative Review, in Part,* 76 FR 41207 (July 13, 2011). On November 8, 2011, the Department partially extended the deadline for the final results by 30 days. *See Tapered Roller Bearings and Parts Thereof, Finished or Unfinished, From the People's Republic of China: Extension of Time Limit for the Final Results of the Antidumping Duty Administrative Review,* 76 FR 69241 (November 8, 2011). The final results are currently due no later than December 12, 2011. The 2009–2010 administrative review covers the period June 1, 2009, through May 31, 2010.

Extension of Time Limit for Final Results of Review

Pursuant to section 751(a)(3)(A) of the Tariff Act of 1930, as amended (''Act''), the Department shall make a final determination in an administrative review of an antidumping duty order within 120 days after the date on which the preliminary results are published. The Act further provides, however, that the Department may extend that 120-day period to 180 days if it determines it is not practicable to complete the review within the foregoing time. On November 8, 2011, the Department extended the deadline of the final results by 30 days. Thus, the Department may extend the deadline of the final results by an additional 30 days.

The Department finds that it is not practicable to complete the final results of the 2009–2010 administrative review of TRBs from the PRC within the current deadline due to issues requiring additional analysis, including consumption allocation factors and a successor-in-interest determination. Therefore, given the complex issues in this case, in accordance with section 751(a)(3)(A) of the Act, the Department is fully extending the time period for completion of the final results of this review to January 9, 2012.

This notice is published in accordance with sections 751(a)(3)(A) and 777(i) of the Act.

Dated: December 1, 2011.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2011–31434 Filed 12–6–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–428–840]

Lightweight Thermal Paper From Germany: Notice of Preliminary Results of Antidumping Duty Administrative Review

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

SUMMARY: The Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on lightweight thermal paper from Germany. For the period November 1, 2009, through October 31, 2010, we have preliminarily determined that Papierfabrik August Koehler AG made sales of subject merchandise at less than normal value (NV).

If these preliminary results are adopted in the final results of this administrative review, we will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries of subject merchandise during the period of review (POR). *See* ''Preliminary Results of Review'' section of this notice. Interested parties are invited to comment on these preliminary results.

DATES: *Effective Date:* December 7, 2011.

FOR FURTHER INFORMATION CONTACT: Stephanie Moore or George McMahon, AD/CVD Operations, Office 3, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–3692 or (202) 482–1167, respectively.

SUPPLEMENTARY INFORMATION:

Background

On November 1, 2010, the Department issued a notice of opportunity to request an administrative review of this order for the period of review (POR) of November 1, 2009, through October 31,

2010. *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 75 FR 67079 (November 1, 2010).

On November 30, 2009, we received a timely request from Appleton Papers, Inc. (petitioner) for the Department to conduct an administrative review of Mitsubishi HiTec Paper Flensburg GmbH, Mitsubishi HiTec Paper Bielefeld GmbH and Mitsubishi International Corporation (collectively, Mitsubishi), and Papierfabrik August Koehler AG (Koehler). We also received a request from Koehler for the Department to conduct an administrative review of Koehler.

On December 28, 2010, the Department published the notice of initiation of this antidumping duty administrative review covering the period November 1, 2009, through October 31, 2010, naming Mitsubishi and Koehler as respondents. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part,* 75 FR 81565 (December 28, 2010) (*Initiation Notice*).

On January 3, 2011, the Department issued initial questionnaires covering sections A, B, C, and E to Mitsubishi and Koehler with a due date of February 9, 2011. On January 25, 2011, petitioner requested that the Department determine whether antidumping duties have been absorbed by Koehler and Mitsubishi. After granting extensions to Mitsubishi and Koehler, Koehler submitted its section A response to the initial questionnaire on February 23, 2011, and sections B and C on March 2, 2011. On March 11, 2011, Mitsubishi submitted its sections A through C response to the initial questionnaire.

On March 23, 2011, petitioner submitted deficiency comments concerning Koehler's initial questionnaire responses. On March 28, 2011, petitioner, the sole party that requested a review of Mitsubishi, timely withdrew its request for a review of Mitsubishi. Accordingly, the Department rescinded the admininstrative review with respect to Mitsubishi. *See Lightweight Thermal Paper from Germany: Notice of Partial Rescission of Antidumping Duty Administrative Review,* 76 FR 20951 (April 14, 2011) (*Partial Rescission*).

On July 16, 2010, the Department published a notice extending the time period for issuing the preliminary results of the administrative review from August 2, 2011, to November 30, 2011. *See Lightweight Thermal Paper from Germany: Extension of Time Limits for the Preliminary Results of Antidumping Duty Administrative Review,* 76 FR 40689 (July 11, 2011).

The Department issued supplemental questionnaires to Koehler on May 9, 2011, July 22, 2011, October 17, 2011, and on October 28, 2011. Koehler submitted responses on June 6, 2011, August 18, 2011, October 25, 2011, and on November 14, 2011, respectively.

On July 7, 2011, petitioner submitted pre-preliminary comments stating that the Department should disregard Koehler's home market monthly rebates on sales of certain products. On August 30, 2010, petitioner submitted a rebuttal of factual information contained in Koehler's August 17, 2011, supplemental questionnaire response. On August 31, 2011, petitioner submitted comments on Koehler's August 18, 2011, supplemental questionnaire response. On November 15, 2011, petitioner submitted supplemental pre-preliminary comments stating that the Department should disregard Koehler's monthly rebates. On November 18, 2011, Koehler submitted pre-preliminary comments stating that the Department should accept Koehler's reported home market rebates, including its monthly rebates.

Period of Review

The POR is November 1, 2009, through October 31, 2010.

Scope of the Order

The scope of this order includes certain lightweight thermal paper, which is thermal paper with a basis weight of 70 grams per square meter (g/m^2) (with a tolerance of $\pm$ 4.0 g/m^2) or less; irrespective of dimensions; [1] with or without a base coat [2] on one or both sides; with thermal active coating(s) [3] on one or both sides that is a mixture of the dye and the developer that react and form an image when heat is applied; with or without a top coat; [4] and without an adhesive backing. Certain lightweight thermal paper is typically (but not exclusively) used in point-of-sale applications such as ATM receipts, credit card receipts, gas pump receipts, and retail store receipts. The merchandise subject to this order may be classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 3703.10.60, 4811.59.20, 4811.90.8040, 4811.90.9090, 4820.10.20, and 4823.40.00.[5] Although HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this order is dispositive.

Product Comparisons

In accordance with section 771(16) of the Tariff Act of 1930, as amended (the Act), all products produced by Koehler covered by the description in the ''Scope of the Order'' section above and sold in Germany during the POR are considered to be foreign like products for purposes of determining appropriate product comparisons to U.S. sales. We have relied on 12 criteria to match U.S. sales of subject merchandise to comparison market sales of the foreign like product: (1) Form, (2) thermal active coating, (3) top coating, (4) basis weight, (5) maximum optical density units, (6) static sensitivity, (7) dynamic sensitivity, (8) color coating, (9) printing, (10) width, (11) length, and (12) core material. Where there were no sales of identical merchandise in the home market made in the ordinary course of trade 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.

Comparisons to Normal Value

To determine whether sales of LWTP from Germany were made in the United States at less than NV, we compared the export price (EP) or constructed export price (CEP) to the NV, as described in the *Export Price and Constructed 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 NV and compared these to individual U.S. transaction prices.

Rebates

Koehler reports a number of customer-specific rebates, which could apply to all products or be product-specific depending on the customer.

[1] LWTP is typically produced in jumbo rolls that are slit to the specifications of the converting equipment and then converted into finished slit rolls. Both jumbo and converted rolls (as well as LWTP in any other form, presentation, or dimension) are covered by the scope of these orders.

[2] A base coat, when applied, is typically made of clay and/or latex and like materials and is intended to cover the rough surface of the paper substrate and to provide insulating value.

[3] A thermal active coating is typically made of sensitizer, dye, and co-reactant.

[4] A top coat, when applied, is typically made of polyvinyl acetone, polyvinyl alcohol, and/or like materials and is intended to provide environmental protection, an improved surface for press printing, and/or wear protection for the thermal print head.

[5] HTSUS subheading 4811.90.8000 was a classification used for LWTP until January 1, 2007. Effective that date, subheading 4811.90.8000 was replaced with 4811.90.8020 (for gift wrap, a non-subject product) and 4811.90.8040 (for ''other'' including LWTP). HTSUS subheading 4811.90.9000 was a classification for LWTP until July 1, 2005. Effective that date, subheading 4811.90.9000 was replaced with 4811.90.9010 (for tissue paper, a non-subject product) and 4811.90.9090 (for ''other,'' including LWTP).

Rebates are granted and paid out on a periodic basis (monthly, quarterly, or annually). Koehler states that there were no written rebate agreements covering sales of the subject merchandise during the POR. As in the prior review, Koehler claims that there were initially written agreements with customers in 2002/2003, but the rebate practices became routine enough that the parties did not bother with formalized written rebate agreements since that time. Koehler states that the rebate percentage is simply specified on the relevant customer-specific price lists or in emails with the customer.

On March 23, 2011, petitioner alleged that the margin in the instant review, as in the first review, is affected by Koehler's granting of monthly rebates (*i.e.,* monatsbonus) in the home market. Petitioner also alleged that these monthly rebates are post-sale price adjustments used by Koehler as a mechanism by which to artificially eliminate its dumping margin.[6] Further, petitioner incorporated by reference, in the instant review, its case brief submitted in the prior administrative review. *Id.*

In the *Final Results*[7] of the prior review, the Department disallowed the monthly rebates because the data on the record showed that there were significant adjustments to the rebate percentages which were retroactively applied by Koehler without sufficient documentation to support a finding that the customer was aware of such changes prior to the sales. Furthermore, we found that in certain instances, neither an ''approximate'' nor a ''precise'' rebate percentage was known to Koehler's customer prior to the time that it made the home market sales in question. Thus, because the record did not indicate that Koehler's customers were aware of the monatsbonus (monthly) rebate terms and conditions prior to the sales, and because of the significant volatility associated with the percentage changes of the monatsbonus program, the Department concluded that the monatsbonus program was not a legitimate rebate that should be treated as a price adjustment. *See LWTP Decision Memo,* at Comment 3.

However, the Department allowed Koehler's quarterly and annual rebates. The Department stated that, the written rebate documentation for 2002/03 provided by Koehler was not relevant to the monatsbonus; instead, it pertained to rebates that were based on a longer periods of time (*e.g.,* quarterly and annual periods). The Department found that, although Koehler referenced relatively minor changes that occurred with respect to the quartalsbonus (quarterly rebate) over a quarterly period, the degree of such a change was relatively insignificant compared to those reported by Koehler for the monatbonus over a monthly period. Further, in contrast to the monatsbonus, the quartalsbonus percentage applied had been stable and there was no evidence that it was retroactively applied on a routine basis. Therefore, the Department determined that there was a clear distinction between the monatbonus and the quartalsbonus program. Moreover, the Department determined that a customer could reasonably rely on the fact that it would receive a specific quartalsbonus percentage rebate at the time that it made its respective purchases. *See Id.*

In the instant review, Koehler has created a flag field (REB1AFLAG) in its home market sales database for each KT 48 F20 (product code that appears on the invoice to the customer) transaction. Koehler asserts that based on email communications and credit notes, it can show whether the customer who received monthly rebates was aware of the rebate terms at the time of sale. Specifically, Koehler coded an ''N'' for sales where it claims it has no documentation to prove that the customer was aware of the rebate terms prior to sale and, thus, the customer may not have known of the precise rebate percentage prior to the sales. Koehler coded a ''Y'' for transactions where it claims there is documentation regarding knowledge of the rebate terms by the customer prior to sale, and thus, the customer must have known of the rebate percentage prior to the sale. *See* supplemental questionnaire response dated June 6, 2011, at 18. *See* also fourth supplemental questionnaire response dated November 11, 2011, at 5.

The Department preliminarily finds that it is inappropriate to examine this rebate program on a transaction-specific basis, given the fact pattern. Instead, as in the prior review, we evaluate the monatsbonus rebate program as a whole to determine whether customers under this program knew of the terms of the rebate and rebate percentage prior to the sale. *See LWTP Decision Memo* at Comment 3; *see also Certain Hot-Rolled Carbon Steel Flat Products from India: Notice of Final Results of Antidumping Duty Administrative Review,* 73 FR 31961 (June 5, 2008), and accompanying Issues and Decision Memorandum at Comment 27 (analyzing rebates as a program). In this review, record evidence shows that the monatsbonus rebate program is unique because it is only offered to certain customers, it is applied retroactively to sales, and Koehler randomly changes the monthly rebate percentages.

Next, we preliminarily find that the documents that Koehler claims are the basis for its flagging methodology do not indicate that the customers were knowledgeable of the final rebate amount prior to the sale date. Koehler states that with respect to the change in rebate percentage for the monthly rebate for KT 48 F20 beginning in April 2010, it has been unable to locate any documentation or communication confirming the change of the rebate percentage with the customer, and therefore does not know whether the customer received written notification prior to commencement of the applicable rebate period. However, according to Koehler, it is able to identify the latest possible date on which the customer could have known of the changed rebate percentage, and thus, Koehler used this date in its flagging methodology. *Id.,* at 18. Due to the proprietary nature of this issue, please refer to the preliminary results calculation memo. *See* Calculation Memorandum for the Preliminary Results—Koehler for further discussion, dated November 30, 2011 (Preliminary Results Calculation Memo—Koehler).

We preliminarily find that Koehler's flagging methodology does not provide proof that, prior to the sale, the customer knew the rebate percentage or the amount of the rebate. As a hypothetical example, if Koehler approved a monthly rebate of 18 percent on August 31, 2010, and retroactively applied it to all KT 48F20 sales in August, a customer might assume or guess that the 18 percent rebate will also be applicable to purchases made after August 31, 2010. However, the customer cannot know with certainty that the 18 percent rebate will be applicable to its purchases in September 2010, because Koehler may change the rebate to 12 percent on September 30, 2010, and retroactively apply a 12 percent rebate to September sales. Thus, we preliminarily find that Koehler created its flag methodology with information that was subject to change, and not always contemporaneous with the sales. Further, the customer has no knowledge of the amount of the ''monatsbonus'' monthly rebate or the terms and conditions at the time of purchase. Therefore, because of the inconsistent and retroactive application of the

[6] *See* March 23, 2011, submission from petitioner at 5, and Attachment 1.

[7] *See Lightweight Thermal Paper From Germany: Notice of Final Results of the First Antidumping Duty Administrative Review,* 76 FR 22078 (April 20, 2011) (*Final Results*), and accompanying Issues and Decision Memorandum (*LWTP Decision Memo*) at Comment 3.

monthly rebates, the Department preliminarily continues to find in the instant review, as in the prior review, that the monatsbonus program is not a legitimate rebate program that should be treated as a price adjustment.

Also, consistent with the Department's findings in the *Final Results,* we continue to find that the quarterly and annual rebates are allowable adjustments because there is a clear, long-standing consistent practice compared to those reported by Koehler for the monatbonus over a monthly period. Further, in contrast to the monatsbonus, the quartalsbonus percentage applied has been relatively stable and there is no evidence that it is retroactively applied on a routine basis. Therefore, we continue to find that a customer can reasonably rely on the fact that it will receive the specific quartalsbonus percentage rebate at the time that it makes its respective purchases.

Export Price and Constructed Export Price

For the price to the United States, we used, as appropriate, EP or CEP, in accordance with sections 772(a) and (b) of the Act. Pursuant to section 772(a) of the Act, we used the EP methodology when the merchandise was first sold by the producer or exporter outside the United States directly to the unaffiliated purchaser in the United States prior to importation and when CEP was not otherwise warranted based on the facts on the record. We calculated CEP for those sales where a person in the United States, affiliated with the foreign exporter or acting for the account of the exporter, made the first sale to the unaffiliated purchaser in the United States of the subject merchandise. *See* section 772(b) of the Act. We based EP and CEP on the packed prices charged to the first unaffiliated customer in the United States and the applicable terms of sale. When appropriate, we adjusted prices to reflect billing adjustments, rebates, and early payment discounts, and commissions.

In accordance with section 772(c)(2) of the Act, we made deductions, where appropriate, for movement expenses including U.S. warehouse expense, inland freight, inland insurance, brokerage & handling, international freight, marine insurance, freight rebate revenue, and U.S. customs duties.

For CEP, in accordance with section 772(d)(1) of the Act, when appropriate, we deducted from the starting price those selling expenses that were incurred in selling the subject merchandise in the United States, including direct selling expenses (cost of credit, warranty, and other direct selling expenses). These expenses also include certain indirect selling expenses incurred by affiliated U.S. distributors. *See* Preliminary Results Calculations Memo—Koehler.

CEP Profit Calculation

The Department's initial questionnaire dated January 3, 2011, directed Koehler to report the actual variable unit cost of manufacturing (VCOM) including materials, labor and overhead, and the total unit cost of manufacturing (TCOM), including materials, labor and variable and fixed overhead, if Koehler was not submitting the full cost of production in response to section D of the Department's questionnaire. The Department's initial questionnaire also states, for fields 55 (VCOMU) and 56 (TCOMU), ''{i}f for each product you sold during the POR in the United States, you sold the identical product in the foreign market, it is not necessary to supply this information. However, if you elect not to supply this information and the Department later determines that a U.S. sale should be compared to a sale of a similar product in the foreign market, the Department may have to resort to the facts available. Refer to difference in merchandise adjustments in the Glossary of Terms at Appendix I.'' *See* Section C of the Department's questionnaire at pages C–38 and C–39.

The petitioner did not submit a sales below the cost of production (COP) allegation with respect to Koehler and the Department did not issue Koehler a section D questionnaire to require the reporting of Koehler's COP. With respect to its sales, Koehler stated that because it ''sold identical merchandise in the foreign product for each product sold during the POR in the United States, Koehler is not providing VCOM or TCOM information.'' *See* section C questionnaire response dated March 2, 2011, at C–50 and C–51. Although Koehler was not required to provide COP data if all of its U.S. sales matched to sales of identical merchandise in the home market, COP data is necessary for the Department to calculate a CEP profit for CEP sales. Therefore, because the necessary COP information is not on the record of the current review, in accordance with sections 772(f)(1) and (2)(C)(iii) of the Act, we calculated the CEP profit percentage using information from Koehler AG's 2010 audited financial statements. We deducted from CEP an amount for profit in accordance with section 772(d)(3) and (f) of the Act. *See* Preliminary Results Calculation Memo—Koehler.

Normal Value

A. Selection of Comparison Market

To determine whether there was a sufficient volume of sales in the home market to serve as a viable basis for calculating NV, we compared Koehler's volume of home market sales of the foreign like product to the volume of its U.S. sales of the subject merchandise. Pursuant to section 773(a)(1)(B)(i) of the Act, because Koehler had an aggregate volume of home market sales of the foreign like product that was greater than five percent of its aggregate volume of U.S. sales of the subject merchandise, we determined that the home market was viable.

B. Arm's-Length Test

Because Koehler reported that its sales of the foreign like product were made to unaffiliated customers, the arm's-length test is not applicable.

C. Calculation of Normal Value Based on Comparison Market Prices

We based home market prices on packed prices to unaffiliated purchasers in Germany. The Department excluded certain sales transactions reported as samples by Koehler. We adjusted the starting price for billing adjustments, early payment discounts, rebates, warehouse expenses, and inland freight where appropriate, pursuant to section 773(a)(6) of the Act. In addition, for comparisons made to EP sales, we made adjustments for differences in circumstances of sale (COS) pursuant to section 773(a)(6)(C)(iii) of the Act. We made COS adjustments by deducting direct selling expenses incurred for home market sales (credit expense, warranty directly linked to sales transactions, royalties, and other direct selling expenses) and adding U.S. direct selling expenses (credit, commissions, warranty directly linked to sales transactions, and other direct selling expenses), where appropriate. *See* 19 CFR 351.410.

When comparing U.S. sales with comparison market sales of similar, but not identical, merchandise, we also made adjustments for physical differences in the merchandise in accordance with section 773(a)(6)(C)(ii) of the Act and 19 CFR 351.411. We based this adjustment on the difference in the VCOM for the foreign like product and subject merchandise, using weighted-average costs. *See* 19 CFR 351.411(b).

D. Level of Trade

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 level of trade (LOT) as the EP or CEP sales. In identifying LOTs for EP and comparison market sales (*i.e.,* NV based on home market), we consider the starting prices before any adjustments. For CEP sales, we consider only the selling activities reflected in the price after the deduction of expenses and profit under section 772(d) of the Act. *See Micron Technology, Inc.* v. *United States,* 243 F.3d 1301, 1314 (Fed. Cir. 2001).

Consistent with 19 CFR 351.412, to determine whether comparison market sales were 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 an LOT adjustment under section 773(a)(7)(A) of the Act. For CEP sales, if the NV level is more remote from the factory than the CEP level and there is no basis for determining whether the difference in the levels between NV and CEP affects price comparability, we will grant a CEP offset, as provided in section 773(a)(7)(B) of the Act.[8]

Koehler reported its sales in the home market and the U.S. market at the same single LOT. In the home market, Koehler reported that its sales were made through two channels of distribution: (1) Direct sales and (2) consignment sales. In the U.S. market, Koehler reported that its sales were made through three channels of distribution: (1) Market direct-shipment sales through its U.S. affiliated distributor, Koehler America, Inc. (*i.e.,* CEP sales), (2) warehouse sales made through Koehler America, Inc. (*i.e.,* CEP sales), (3) and direct sales from Koehler AG to the customer (*i.e.,* EP sales).

Based on our analysis, we find that Koehler's sales to the U.S. and home market were made at the same LOT, and as a result, no LOT adjustment is warranted. Furthermore, our analysis shows that Koehler's home market sales were not made at a more advanced LOT than Koehler's U.S. sales. Accordingly, we have not made a CEP offset to NV. *See* 773(a)(7)(B) of the Act.

For a detailed description of our LOT methodology and a summary of company-specific LOT findings for these preliminary results, see our analysis contained in the Preliminary Results Calculation Memo—Koehler.

Duty Absorption

On January 25, 2011, petitioner requested that the Department determine whether antidumping duties have been absorbed by Koehler and Mitsubishi. Koehler has reported that it served as the importer of record for all of its U.S. sales during the POR. *See* second supplemental questionnaire response dated August 17, 2011, at 3. Because the subject merchandise was not sold through an importer who is affiliated with the foreign producer/exporter, we are not examining duty absorption. *See* section 751(a)(4) of the Act and *Agro Dutch Industries, Ltd.* v. *United States,* 508 F.3d 1024 (Fed. Cir. 2007).

On April 14, 2011, the Department rescinded the review of Mitsubishi. *See Partial Rescission.* Due to the partial rescission of the review of Mitsubishi, we are not examining duty absorption with respect to Mitsubishi.

Currency Conversion

We made currency conversions into U.S. dollars in accordance with section 773A(a) of the Act, based on the official exchange rates published by the Federal Reserve Bank.

Preliminary Results of Review

As a result of our review, we preliminarily determine that the following weighted-average percentage margin exists for the period November 1, 2009, through October 31, 2010.

Manufacturer/exporter	Weighted-average margin (percent)
Papierfabrik August Koehler AG	3.16

Public Comment

The Department will disclose calculations performed within five days of the date of publication of this notice to the parties to this proceeding in accordance with 19 CFR 351.224(b). Interested parties may submit case briefs no later than 30 days after the date of publication of these preliminary results of review. *See* 19 CFR 351.309(c)(1)(ii). Rebuttal briefs are limited to issues raised in the case briefs and may be filed no later than five days after the time limit for filing the case briefs. *See* 19 CFR 351.309(d). Parties submitting arguments in this proceeding are requested to submit with the argument: (1) A statement of the issue, (2) a brief summary of the argument, and (3) a table of authorities, in accordance with 19 CFR 351.309(d)(2). Case and rebuttal briefs must be served on interested parties in accordance with 19 CFR 351.303(f).

An interested party may request a hearing within 30 days of publication of these preliminary results. *See* 19 CFR 351.310(c). Any hearing, if requested, ordinarily will be held two days after the due date of the rebuttal briefs in accordance with 19 CFR 351.310(d)(1). 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, or at a hearing, if requested, within 120 days of publication of these preliminary results, unless extended. *See* section 751(a)(3)(A) of the Act, and 19 CFR 351.213(h).

Assessment Rate

Upon completion of the final results of this administrative review, the Department shall determine, and CBP shall assess, antidumping duties on all appropriate entries. Pursuant to 19 CFR 351.212(b)(1), the Department will calculate importer-specific assessment rates for each respondent based on the ratio of the total amount of antidumping duties calculated for the examined sales to the total entered value of those sales. Where the respondent did not report the entered value for U.S. sales, we have calculated importer-specific assessment rates for the merchandise in question by aggregating the dumping margins calculated for all U.S. sales to each importer and dividing this amount by the total quantity of those sales. To determine whether the duty assessment

[8] *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, 61732–33 (November 19, 1997).

rates were *de minimis,* in accordance with the requirement set forth in 19 CFR 351.106(c)(2), we calculated importer-specific *ad valorem* rates based on the estimated entered value. Where the assessment rate is above *de minimis,* we will instruct CBP to assess duties on all entries of subject merchandise by that importer. Pursuant to 19 CFR 351.106(c)(2), we will instruct CBP to liquidate without regard to antidumping duties any entries for which the assessment rate is *de minimis* (*i.e.,* less than 0.50 percent). The Department intends to issue assessment instructions directly to CBP 15 days after publication of the final results of this review.

The Department clarified its ''automatic assessment'' regulation on May 6, 2003. *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003). This clarification will apply to entries of subject merchandise during the POR produced by the respondent subject to this review for which the reviewed company did not know that the merchandise which it sold to an intermediary (*e.g.* a reseller, trading company, or exporter) was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediary involved in the transaction. For a full discussion of this clarification, *see id.*

Cash Deposit Requirements

To calculate the cash deposit rate for Koehler, we divided its total dumping margin by the total net value of its sales during the review period. The following deposit rates will be effective upon publication of the final results of this administrative review for all shipments of lightweight thermal paper from Germany entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for companies subject to this review 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,* no cash deposit will be required; (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 final results for a review in which that manufacturer or exporter participated; (3) if the exporter is not a firm covered in this review, a prior review, or the original less-than-fair-value (LTFV) investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent final results for the manufacturer of the merchandise; and (4) if neither the exporter nor the manufacturer is a firm covered in this review, the cash deposit rate will be 6.50 percent, the all-others rate established in the LTFV investigation. *See Antidumping Duty Orders: Lightweight Thermal Paper from Germany and the People's Republic of China,* 73 FR 70959 (November 24, 2008). These cash deposit requirements, when imposed, shall remain in effect until further notice.

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.

These preliminary results of administrative review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

Dated: November 30, 2011.

Paul Piquado,

Assistant Secretary for Import Administration.

[FR Doc. 2011–31440 Filed 12–6–11; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–520–803]

Polyethylene Terephthalate Film, Sheet, and Strip From the United Arab Emirates: Preliminary Results of Antidumping Duty Administrative Review

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

SUMMARY: 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 the United Arab Emirates (UAE). This review covers the respondent, JBF RAK LLC (JBF), a producer and exporter of PET Film from the UAE. The Department preliminarily determines that sales of PET Film from the UAE have been made below normal value (NV) during the November 1, 2009, through October 31, 2010, period of review. The preliminary results are listed below in the section titled ''Preliminary Results of Review.'' Interested parties are invited to comment on these preliminary results.

DATES: *Effective Date:* December 7, 2011.

FOR FURTHER INFORMATION CONTACT: Andrew Huston, or Jun Jack Zhao, AD/CVD Operations, Office 6, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; *telephone:* (202) 482–4261 or (202) 482–1396, respectively.

SUPPLEMENTARY INFORMATION:

Background

On November 10, 2008, the Department published in the **Federal Register** the antidumping duty order on PET Film from the UAE. *See Polyethylene Terephthalate Film, Sheet, and Strip From Brazil, the People's Republic of China and the United Arab Emirates: Antidumping Duty Orders and Amended Final Determination of Sales at Less Than Fair Value for the United Arab Emirates,* 73 FR 66595 (November 10, 2008) (*Order*). On November 1, 2010, the Department published a notice of opportunity to request an administrative review of the Order. *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 75 FR 67079 (November 1, 2010). In response, on November 29, 2010, JBF requested that the Department conduct an administrative review of its sales of PET Film in the U.S. market.

On December 28, 2010, the Department initiated an administrative review of JBF. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part,* 75 FR 81565, 81570 (December 28, 2010). On January 27, 2011, the Department issued an antidumping duty questionnaire to JBF. On April 6, 2011, JBF requested a 10 day extension to submit reconciliation information required by Sections B, C, and D of the initial questionnaire, which the Department approved by letter on the same date. JBF timely submitted its response to Section A of the questionnaire on March 10, 2011, its response to Sections B, C, and D on April 11, 2011, and the reconciliation information on April 21, 2011. On May 20, 2011, the Department issued a supplemental questionnaire to JBF, to which JBF timely responded on June 3, 2011.

On June 20, 2011, JBF submitted information requested by the

Department regarding its submissions to United States Customs and Border Protection (CBP). On July 22, 2011, the Department issued a second supplemental questionnaire. JBF submitted its timely response to the second supplemental questionnaire on August 22, 2011. On July 29, 2011, the Department extended the time period for issuing the preliminary results of this administrative review. *See Polyethylene Terephthalate Film, Sheet and Strip From the United Arab Emirates: Extension of Time Limit for Preliminary Results of Antidumping Duty Administrative Review,* 76 FR 45508 (July 29, 2011). On September 23, 2011, the Department issued a third supplemental questionnaire, to which JBF submitted its timely response on October 11, 2011.

Scope of the Order

The products covered by the order are all gauges of raw, pre-treated, or primed polyethylene terephthalate film, whether extruded or co-extruded. 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. Also excluded is roller transport cleaning film which has at least one of its surfaces modified by application of 0.5 micrometers of SBR latex. Tracing and drafting film is also excluded. PET Film is classifiable under subheading 3920.62.00.90 of the Harmonized Tariff Schedule of the United States (HTSUS). While HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of the order is dispositive.

Period of Review

The period of review (POR) is November 1, 2009, through October 31, 2010.

Comparisons to Normal Value

To determine whether sales of PET Film were made at less than NV, we compared JBF's sales, which were all export price (EP) sales, made to unaffiliated customers in the United States to NV, as described below in the ''Normal Value'' section of this notice. In accordance with section 777A(d)(2) of the Act, we compared the EP of individual transactions to monthly weighted-average NVs.

Product Comparisons

Pursuant to section 771(16) of the Act, we determined products sold by JBF, as described in the ''Scope of the Order'' section, above, and sold in the UAE during the POR, to be foreign like products for purposes of determining appropriate product comparisons to U.S. sales. We have relied on five criteria to match U.S. sales of subject merchandise to comparison-market sales: Grade, specification, thickness, thickness category, and surface treatment. 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 most similar foreign like product on the basis of the characteristics listed above.

In its first questionnaire response, JBF recommended two changes to our model matching criteria based on surface treatment. First, JBF proposed that the ranking values for surface treatment should be weighted to ensure that certain surface treatments are matched. We have not adopted this suggestion in the preliminary results. As a result of surface treatment being the least important characteristic in the ranking, the proposed change makes no difference in the matching, given that the preceding four factors (grade, specification, thickness, and thickness category) determine all matches. The Department, therefore, will not adopt this change, which would contradict the matching methodology used in the investigation, the previous review, and other PET Film cases. If JBF can demonstrate, subsequent to these preliminary results, that this change is justified based on the physical properties of surface treatments and that it would also affect matching, we will reexamine the suggested change to model matching criteria in the final results. We note in this regard that even if JBF's proposed change affected our calculations, the current basis for its proposal is not detailed and relies only on a few brief assertions. Second, JBF recommended changing the ranking of values for surface treatment to account for a new surface treatment which was not listed in the original questionnaire. JBF suggested this surface treatment be ranked between two existing categories with which it is most physically similar. Based on our analysis of the similarity of surface treatments, we have adopted JBF's suggestion to change the ranking of surface treatment values so that this new type of surface treatment will be matched to products with the most similar surface treatment, if identical matches are not available. *See* Memorandum to Mark Hoadley, ''Preliminary Analysis for JBF RAK LLC,'' dated November 30, 2011, (*JBF Analysis Memo*) and attached SAS programs.

Arm's-Length Test

In this proceeding, JBF did not report sales to affiliates in the home market; therefore the arms length test was not necessary.

Level of Trade

To determine whether NV sales are at a different level of trade (LOT) than U.S. sales, we examine selling functions along the chain of distribution between the respondent and the unaffiliated customer for EP sales and between the respondent and the affiliated U.S. importer for CEP sales. 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 pursuant to section 773(a)(7)(A) of the Act.

In implementing these principles, we examined information provided by JBF regarding the selling functions involved in its home market and U.S. sales, including a description of these selling functions, listed in Exhibit A–5 of JBF's March 10, 2011 submission. Our analysis revealed that there were not any significant differences in selling functions between different channels of distribution or customer types in either the home or U.S. markets. Therefore, we preliminarily determine that JBF made all home-market sales at one level of trade. Moreover, we preliminarily determine that all home-market sales by JBF were made at the same level of trade as its U.S. sales. Accordingly, a LOT adjustment is not warranted.

Date of Sale

The Department will normally use invoice date, as recorded in the exporter's or producer's records kept in the ordinary course of business, as the date of sale, but may use a date other than the invoice date if it better reflects the date on which the material terms of sale are established. *See* 19 CFR 351.401(i). For JBF, we preliminarily determine that no departure from our standard practice is warranted. JBF reported invoice date as date of sale, and the record does not indicate that material terms of sale are established at a later date or earlier date in the sales process.

Margin Calculation

Export Price

The Department based the price of all U.S. sales of subject merchandise by JBF on EP as defined in section 772(a) of the Act because the merchandise was sold

by JBF to an unaffiliated purchaser in the United States before importation. We calculated EP based on the packed price to unaffiliated purchasers in the United States. *See* section 772(c) of the Act. We made adjustments to price for billing adjustments, where applicable, and deducted all movement expenses reported by JBF.

Normal Value

A. Selection of Comparison Market

To determine whether there was a sufficient volume of sales of PET Film in the home market to serve as a viable basis for calculating NV, we compared the volume of respondent's home market sales of the foreign like product to the volume of its U.S. sales of the subject merchandise, in accordance with section 773(a)(1) of the Act. In accordance with section 773(a)(1)(B) of the Act, and 19 CFR 351.404(b), because JBF's aggregate volume of home market sales of the foreign like product was greater than five percent of its aggregate volume of U.S. sales of the subject merchandise, we find that the home market was viable for comparison purposes.

B. Calculation of Cost of Production (COP)

In accordance with section 773(b)(3) of the Act, we calculated COP based on the sum of JBF's cost of materials and fabrication for the foreign like product, plus amounts for selling, general and administrative expenses, interest expenses, and home market packing costs. Details regarding calculation of COP, as well as other calculation detail can be found in the *JBF Analysis Memo,* and attached SAS programs.

C. Cost of Production Test

On a product-specific basis, we compared the revised COP figures to home market prices, net of applicable billing adjustments, discounts and rebates, movement charges, selling expenses, and packing, to determine whether home market sales had been made at prices below COP. In determining whether to disregard home market sales made at prices below COP, we examined, in accordance with sections 773(b)(1)(A) and (B) of the Act, whether, within an extended period of time, such sales were made in substantial quantities, and whether such sales were made at prices which did not permit the recovery of all costs within a reasonable period of time in the normal course of trade.

In accordance with section 773(b) of the Act, where less than 20 percent of a given product was sold at prices less than COP, we did not disregard any below-cost sales of that product, because the below-cost sales were not made in ''substantial quantities.'' However, we disregarded the below-cost sales that: (1) Have been made within an extended period of time (within six months to one year) in substantial quantities (20 percent or more), as defined by section 773(b)(2)(B) and (C) of the Act; and (2) were not made at prices which permit recovery of all costs within a reasonable period of time, as prescribed by section 773(b)(2)(D) of the Act. Accordingly, we determined to disregard certain of JBF's sales in the determination of NV because (1) 20 percent or more of a given product was sold at prices less than COP and (2) based on our comparison of prices to weighted-average COP figured for the POR, they were made at prices that would not permit recovery of all costs within a reasonable period of time. We used the remaining home market sales as the basis for determining NV, in accordance with section 773(b)(1) of the Act.

D. Constructed Value

After disregarding certain sales as below cost, as described above, home market sales of contemporaneous identical and similar products existed that allowed for price-to-price comparisons for all margin calculations. Therefore, the Department did not need to rely on constructed value for any calculations for these preliminary results.

E. Price-to-Price Comparisons

We calculated NV based on packed prices to unaffiliated customers in the home market. We used JBF's adjustments and deductions as reported. We made deductions, where appropriate, for foreign inland freight pursuant to section 773(a)(6)(B) of the Act. We also made adjustments for differences in circumstances of sale (COS) in accordance with section 773(a)(6)(C)(iii) of the Act and 19 CFR 351.410. In so doing, we made COS adjustments for the cost of providing samples to customers. Finally, we added U.S. packing costs and deducted home market packing costs, in accordance with sections 773(a)(6)(A) and (B) of the Act, respectively.

Currency Conversions

Pursuant to section 773(A) of the Act and 19 CFR 351.415, we made currency conversions for JBF's sales based on the daily exchange rates in effect on the dates of the relevant U.S. sales as certified by the Federal Reserve Bank of New York.

Preliminary Results of Review

As a result of our review, we preliminarily determine the following weighted-average dumping margin exists for the period November 1, 2009, through October 31, 2010.

Manufacturer/exporter	Weighted-average margin (percent)
JBF RAK LLC	3.46

Assessment Rates

The Department shall determine, and CBP shall assess, antidumping duties on all appropriate entries. The Department intends to issue assessment instructions to CBP 15 days after the date of publication of the final results of review. For assessment purposes, where JBF reported the entered value for its sales, we calculated importer-specific (or customer-specific) *ad valorem* assessment rates based on the ratio of the total amount of the antidumping duties calculated for the examined sales to the total entered value of those same sales. *See* 19 CFR 351.212(b). However, where JBF did not report the entered value for its sales, we will calculate importer-specific (or customer-specific) per unit duty assessment rates.[1] We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review if any assessment rate calculated in the final results of this review is above *de minimis.*

Cash Deposit Requirements

The following deposit requirements will be effective for all shipments of PET Film from the UAE entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review, as provided for by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for the company under review will be the rate established in the final results of this review (except, if the rate is zero or *de minimis, i.e.,* less than 0.5 percent, no cash deposit will be required); (2) for previously reviewed or investigated companies not listed above, the cash

[1] JBF notified CBP in a ''prior disclosure'' letter that some entries of subject merchandise were misidentified as ''free and dutiable'' entries at the time of entry. These entries were not corrected by CBP as they had already been liquidated. JBF states in its letter to CBP that it will pay the entire amount of antidumping duties due on both correctly and incorrectly classified entries at the time the Department issues its liquidation instructions. A ''prior disclosure'' letter is provided for in CBP's regulations (19 CFR 162.74). The letter allows importers to correct mistakes made during the entry process on their initiative, thus avoiding possible sanctions or penalties.

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 less-than-fair-value 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, the cash deposit rate will be the all others rate for this proceeding, 4.05 percent.[2] These deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure and Public Comment

We will disclose the calculations used in our analysis to parties in this review within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). Any interested party may request a hearing within 30 days of the publication of this notice in the **Federal Register.**[3] If a hearing is requested, the Department will notify interested parties of the hearing schedule.

Interested parties are invited to comment on the preliminary results of this review. Unless extended by the Department, interested parties must 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, must be filed not later than five days after the time limit for filing case briefs. *See* 19 CFR 351.309(c) and (d) (additional discussion on case briefs and rebuttal briefs, respectively). Parties who submit case briefs or rebuttal briefs in this review 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. Executive summaries should be limited to five pages total, including footnotes.

We intend to issue the final results of this administrative review, including the results of our analysis of issues raised in the written comments, within 120 days of publication of these preliminary results in the **Federal Register,** unless otherwise extended. *See* section 751(a)(3)(A) of the Act.

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 Department's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

These preliminary results of administrative review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: November 30, 2011.

Paul Piquado,

Assistant Secretary for Import Administration.

[FR Doc. 2011–31428 Filed 12–6–11; 8:45 am]

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[2] *See Order,* 73 FR at 66597.

[3] *See* 19 CFR 351.309(c); Parties submitting written comments must submit them pursuant to the Department's e-filing regulations. *See https://iaaccess.trade.gov/help/IA%20ACCESS%20User%20Guide.pdf.*

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–947]

Certain Steel Grating From the People's Republic of China: Notice of Rescission of the 2010–2011 Antidumping Duty Administrative Review

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

SUMMARY: The Department of Commerce (''the Department'') is rescinding the administrative review of the antidumping duty order on certain steel grating from the People's Republic of China (''PRC'') for the period of review (''POR'') of January 6, 2010, through June 30, 2011, with respect to Ningbo Haitian International Co., Ltd. (''Ningbo Haitian''), Shanghai Minmetals Materials & Products Co., Ltd. (''Shanghai Minmetals''), Yantai Xinke Steel Structure Co., Ltd. (''Yantai Xinke''), Sinosteel Yantai Steel Grating Co., Ltd. (''Sinosteel Yantai''), Ningbo Jiulong Machinery Manufacturing Co., Ltd. (''Ningbo Jiulong''), Accurate Screen, Ltd. (''Accurate Screen''), Wuxi Juhua Import/Export Co., Ltd. (''Wuxi Juhua''), and Well Forge Industries (''Well Forge''). This rescission is based on the timely withdrawal of the requests for review by the only interested party that requested the review of these companies.

DATES: *Effective Date:* December 7, 2011.

FOR FURTHER INFORMATION CONTACT: Thomas Martin or Robert Bolling, AD/CVD Operations, Office 4, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone (202) 482–3936 or (202) 482–3434, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 1, 2011, the Department published in the **Federal Register** a notice of opportunity to request an administrative review of the antidumping duty order on certain steel grating from the PRC. *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review,* 76 FR 38609, 38610 (July 1, 2011). In response, on August 1, 2011, Fisher & Ludlow and Alabama Metal Industries Corporation (hereafter referred to as ''Petitioners'') timely requested an administrative review of entries of the subject merchandise during the POR from Ningbo Haitian, Shanghai Minmetals, Yantai Xinke, Sinosteel Yantai, Ningbo Jiulong, Accurate Screen, Wuxi Juhua, and Well Forge. On August 26, 2011, the Department initiated a review of these companies. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocation in Part,* 76 FR 53404 (August 26, 2011).

In a letter dated September 21, 2011, Petitioners withdrew their request for review of the aforementioned companies, and requested that the Department rescind the review with respect to these companies. No other parties requested a review.

Rescission of Administrative Review

Pursuant to 19 CFR 351.213(d)(1), the Secretary will rescind an administrative review, in whole or in part, if the party who requested the review withdraws the request within 90 days of the date of publication of the notice of initiation of the requested review. Accordingly, given that Petitioners' withdrawal requests were timely, and because no other party requested a review, pursuant to 19 CFR 351.213(d)(1), the Department is rescinding the entire administrative review of the antidumping duty order on certain steel grating from the PRC for the period January 6, 2010, through June 30, 2011.

Assessment

The Department will instruct U.S. Customs and Border Protection (''CBP'') to assess antidumping duties on all appropriate entries. Antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19

CFR 351.212(c)(1)(i). The Department intends to issue appropriate assessment instructions directly to CBP 15 days after the date of publication of this notice in the **Federal Register**.

Notification to Importers

This notice serves as a 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 antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective orders (''APO'') of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This notice is published in accordance with sections 751(a) and 777(i) of the Act, and 19 CFR 351.213(d)(4).

Dated: December 1, 2011.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2011–31447 Filed 12–6–11; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–809]

Circular Welded Non-Alloy Steel Pipe From the Republic of Korea: Preliminary Results of the Antidumping Duty Administrative Review

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

SUMMARY: In response to requests from interested parties, the Department of Commerce (''the Department'') is conducting an administrative review of the antidumping duty order on circular welded non-alloy steel pipe (''CWP'') from the Republic of Korea (''Korea''), covering the period November 1, 2009, through October 31, 2010. We preliminarily determine the exporters/producers covered by this review made sales of the subject merchandise at prices below normal value (''NV''). If these preliminary results are adopted in our final results, we will instruct U.S. Customs and Border Protection (''CBP'') to assess antidumping duties on all appropriate entries. Interested parties are invited to comment on these preliminary results.

DATES: *Effective Date:* December 7, 2011.

FOR FURTHER INFORMATION CONTACT: Mary Kolberg, or Jennifer Meek, AD/CVD Operations, Office 1, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone (202) 482–1785 or (202) 482–2778, respectively.

SUPPLEMENTARY INFORMATION:

Background

On November 2, 1992, the Department published an antidumping duty order on CWP from Korea. *See Notice of Antidumping Duty Orders: Certain Circular Welded Non-Alloy Steel Pipe from Brazil, the Republic of Korea (Korea), Mexico, and Venezuela, and Amendment to Final Determination of Sales at Less Than Fair Value: Certain Circular Welded Non-Alloy Steel Pipe from Korea,* 57 FR 49453 (November 2, 1992) (''*CWP Order*'').

On November 30, 2010, both Hyundai HYSCO (''HYSCO'') and SeAH Steel Corporation (''SeAH'') timely requested an administrative review of this order for the period November 1, 2009, through October 31, 2010. Also, on November 30, 2010, United States Steel Corporation (''U.S. Steel''), a manufacturer of the domestic like product, requested a review of the following producers/exporters of subject merchandise: SeAH; HYSCO; Husteel Co., Ltd. (''Husteel''); Nexteel Co., Ltd. (''Nexteel''); Kumkang Industrial Co., Ltd. (''Kumkang''); and A–JU Besteel Co., Ltd. (''Besteel''). Likewise, on November 30, 2010, Wheatland Tube Company, a domestic producer of circular welded pipe, requested a review of the subject merchandise sales made by SeAH, HYSCO, Husteel, Nexteel, Dongbu Steel Co., Ltd. (''Dongbu''), and Kumkang. On December 28, 2010, we initiated an administrative review. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part,* 75 FR 81565 (December 28, 2010) (''*Initiation Notice*'').

In our initiation notice, we indicated that we would select mandatory respondents for review based upon CBP data, and that we would limit the respondents selected for individual review in accordance with section 777A(c)(2) of the Tariff Act of 1930, as amended (''the Act''). *See Initiation Notice,* 75 FR at 81565. On January 10, 2011, we received comments on the issue of respondent selection from HYSCO.

On February 4, 2011, after considering the resources available to the Department, we determined that it was not practicable to examine all producers/exporters of subject merchandise for which a review was requested. As a result, we selected the two largest producers/exporters of CWP from Korea during the POR for individual review in this segment of this proceeding, pursuant to section 777A(c)(2)(B) of the Act. These mandatory respondents were HYSCO and SeAH. *See* Memorandum from Mary Kolberg and Jennifer Meek, International Trade Analysts, AD/CVD Operations, Office 1, to Susan H. Kuhbach, Director, AD/CVD Operations, Office 1, ''Respondent Selection: Antidumping Duty Administrative Review: Certain Circular Welded Non-Alloy Steel Pipe from the Republic of Korea,'' dated February 4, 2011.

On January 25, 2011, Wheatland submitted a request for a duty absorption determination for a number of producers or exporters subject to this review, including SeAH, HYSCO, Husteel, Nexteel, Dongbu, Kumkang, and Besteel. The Court of Appeals for the Federal Circuit found that the Department lacks authority to conduct two-and four-year duty absorption inquiries for transitional orders (orders in effect before January 1, 1995). *See FAG Italia S.p.A.* v. *United States,* 291 F.3d 806, 819 (Fed. Cir. 2002). Since the order for this case is from 1992, we have not conducted a duty absorption inquiry in this proceeding.

On February 9, 2011, we issued the antidumping questionnaire to HYSCO and SeAH.

On July 11, 2011, we published in the **Federal Register** an extension of the time limit for the completion of the preliminary results of this review until no later than November 30, 2011, in accordance with section 751(a)(3)(A) of the Act, and 19 CFR 351.213(h)(2). *See Circular Welded Non-Alloy Steel Pipe From the Republic of Korea: Extension of Time Limit for Preliminary Results of*

the Antidumping Duty Administrative Review, 76 FR 40689 (July 11, 2011).

On July 13, 2011, Wheatland withdrew its request for review of Husteel, Nexteel, Kumkang, and Dongbu. U.S. Steel also withdrew its request for review of Husteel, Nexteel, Kumkang, and Besteel on July 13, 2011. On August 16, 2011, we rescinded the administrative review for Husteel, Nexteel, Kumkang, Dongbu, and Besteel for November 1, 2009, through October 31, 2010. *See Circular Welded Non-Alloy Steel Pipe From the Republic of Korea:*

Partial Rescission of Antidumping Duty Administrative Review, 76 FR 52636 (August 23, 2011).

Scope of the Order

The merchandise subject to this review is circular welded non-alloy steel pipe and tube, of circular cross-section, not more than 406.4mm (16 inches) in outside diameter, regardless of wall thickness, surface finish (black, galvanized, or painted), or end finish (plain end, beveled end, threaded, or threaded and coupled). These pipes and tubes are generally known as standard pipes and tubes and are intended for the low-pressure conveyance of water, steam, natural gas, air, and other liquids and gases in plumbing and heating systems, air-conditioning units, automatic sprinkler systems, and other related uses. Standard pipe may also be used for light load-bearing applications, such as for fence tubing, and as structural pipe tubing used for framing and as support members for reconstruction or load-bearing purposes in the construction, shipbuilding, trucking, farm equipment, and other related industries. Unfinished conduit pipe is also included in this review.

All carbon-steel pipes and tubes within the physical description outlined above are included within the scope of this review except line pipe, oil-country tubular goods, boiler tubing, mechanical tubing, pipe and tube hollows for redraws, finished scaffolding, and finished conduit.[1]

Imports of these products are currently classifiable under the following Harmonized Tariff Schedule (''HTS'') subheadings: 7306.30.10.00, 7306.30.50.25, 7306.30.50.32, 7306.30.50.40, 7306.30.50.55, 7306.30.50.85, and 7306.30.50.90. Although the HTS subheadings are provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

Date of Sale

The Department normally will use the date of invoice, as recorded in the producer's or exporter's records kept in the ordinary course of business, as the date of sale, but may use a date other than the invoice date if the Department is satisfied that a different date better reflects the date on which the material terms of sale are established. *See* 19 CFR 351.401(i).

(A) SeAH

For its home market sales, SeAH has reported the date the billing document is created in its accounting system as the date of sale. This is the date when the final price and quantity are set and is, in most cases, the same as the date of the shipping invoice.

For its U.S. sales, SeAH reported the earlier of the date of shipment from Korea or the date of Pusan Pipe America Inc.'s (''PPA'') (SeAH's U.S. affiliate) invoice to the unaffiliated U.S. customer as the date of sale. SeAH explained that all U.S. sales are produced to order and, while the price is set with the customer's order, the quantity is subject to change between order and shipment. We are relying on the sale dates reported by SeAH for both home market and U.S. sales.

(B) HYSCO

For its home market sales, HYSCO reported the date of sale as the earlier of the date of shipment from HYSCO's factory or the date on which HYSCO issued its tax and commercial invoice. HYSCO noted that quantity can change up until shipment from HYSCO's factory, and price can change up until HYSCO's issuance of its tax and commercial invoice.

For its U.S. sales, HYSCO reported the date of shipment from Korea as the date of sale because the quantity and price for its U.S. sales can change up until the date of shipment from its factory in Korea. (Invoicing to the unaffiliated customer always occurs after shipment from Korea.) In support of its claimed date of sale for the U.S. market, HYSCO provided sales documentation regarding changes to the material terms of sale after order date and its quantity allowances. We intend to seek further information regarding HYSCO's U.S. date of sale for the final results, but are relying on the sale dates reported by HYSCO for these preliminary results.

Comparisons to Normal Value

To determine whether SeAH's and HYSCO's sales of CWP from Korea to the United States were made at less than normal value (''NV''), we compared constructed export price (''CEP'') to NV, as described in the ''Constructed Export Price'' and ''Normal Value'' sections of this notice below.

Product Comparisons

In accordance with section 771(16) of the Act, we considered all products produced by SeAH and HYSCO that are covered by the description contained in the ''Scope of the Order'' section above and were sold in the home market during the POR to be the foreign like product for purposes of determining appropriate product comparisons to U.S. sales.

We have relied on five criteria to match U.S. sales of subject merchandise to comparison market sales of the foreign like product: (1) Grade; (2) nominal pipe size; (3) wall thickness; (4) surface finish; and (5) end-finish. For SeAH, we used actual pipe size in millimeters instead of nominal pipe size because SeAH works with actual outside diameter measurements in the ordinary course of business. Where there were no sales of identical merchandise in the comparison market made in the ordinary course of trade 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.

Level of Trade/Constructed Export Price Offset

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 level of trade (''LOT'') as the EP or CEP transaction. The LOT in the comparison market is the LOT of the starting-price sales or, when NV is based on CV, the LOT of the sales from which we derive selling, general and administrative (''SG&A'') expenses and profit. For CEP, the LOT is that of the constructed sale from the exporter to the affiliated importer. *See* 19 CFR 351.412(c)(ii). *See also Micron Technology, Inc.* v. *United States,* 243 F.3d 1301, 1314 (Fed. Cir. 2001).

Where it is not possible to make comparisons at the same LOT, the statute permits the Department to account for the different levels. *See* section 773(a)(7)(A) of the Act. Specifically, if the comparison market sales are made at multiple LOTs, and

[1] *See Final Negative Determination of Scope Inquiry on Certain Circular Welded Non-Alloy Steel Pipe and Tube From Brazil, the Republic of Korea, Mexico, and Venezuela,* 61 FR 11608 (March 21, 1996). In accordance with this determination, pipe certified to the API 5L line-pipe specification and pipe certified to both the API 5L line-pipe specifications and the less-stringent ASTM A–53 standard-pipe specifications, which falls within the physical parameters as outlined above, and entered as line pipe of a kind used for oil and gas pipelines is outside of the scope of the antidumping duty order.

the difference in LOTs 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, the Department makes an upward or downward LOT adjustment in accordance with section 773(a)(7)(A) of the Act. *See Notice of Preliminary Determination of Sales at Less Than Fair Value: Light-Walled Rectangular Pipe and Tube From Mexico,* 73 FR 5515, 5522 (January 30, 2008) (''*LWR Pipe from Mexico''*). Alternatively, for CEP sales, if the NV LOT is at a more advanced stage of distribution than the LOT of the CEP, but the data available do not provide an appropriate basis to determine a LOT adjustment, we reduce NV by the amount of indirect selling expenses incurred in the foreign comparison market on sales of the foreign like product, but by no more than the amount of the indirect selling expenses incurred for CEP sales. *See* section 773(a)(7)(B) of the Act (the CEP offset provision) and *LWR Pipe from Mexico,* 73 FR at 5522.

To determine whether sales are made at different LOTs, we examine stages in the marketing process and selling functions along the chain of distribution between the producer and the unaffiliated customer. *See, e.g., Notice of Preliminary Determination of Sales at Not Less Than Fair Value: Polyethylene Terephthalate Film, Sheet, and Strip from Thailand,* 73 FR 24565 (May 5, 2008); and *LWR Pipe from Mexico,* unchanged in *Notice of Final Determination of Sales at Less Than Fair Value: Light-Walled Rectangular Pipe and Tube from Mexico,* 73 FR 35649 (June 24, 2008). In particular, we analyze whether different selling activities are performed, and whether any price differences (other than those for which other allowances are made under the Act) are shown to be wholly or partly due to a difference in LOT between the CEP and NV. In analyzing differences in selling functions, we determine whether the LOTs identified by the respondent are meaningful. *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27371 (May 19, 1997). If the claimed LOTs are the same, we expect that 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. *See Porcelain-on-Steel Cookware From Mexico: Final Results of Antidumping Duty Administrative Review,* 65 FR 30068 (May 10, 2000), and accompanying Issues and Decision Memorandum at Comment 6.

(A) SeAH

SeAH reported two channels of distribution in the comparison market, Korea: (1) Direct sales to unaffiliated end-users and distributors; and (2) sales to affiliated companies. In the U.S. market, SeAH reported one channel of distribution corresponding to the CEP sales made through its affiliated company in the United States, PPA. SeAH stated that its U.S. sales were made at a different, less advanced LOT than its comparison market sales. Because it had no comparison market sales that were at the same LOT as the U.S. CEP sales, SeAH is not seeking a LOT adjustment. Instead, it claims that a CEP offset is warranted.

In evaluating SeAH's claim, we examined its activities in each channel of distribution relating to four different types of selling functions: sales process and marketing support, freight and delivery, inventory maintenance and warehousing, and warranty and technical services. Based on our analysis, we preliminarily determine that SeAH's selling activities in the comparison market did not vary significantly by channel of distribution. Therefore, we preliminary determine that SeAH sold at one LOT in the comparison market. We further determine preliminarily that SeAH sold at one LOT in the U.S. market since there is only one channel of distribution in this market, and the marketing process and selling functions are the same for all of SeAH's cutomers in the United States.

We then compared the selling functions performed by SeAH for its U.S. sales to the selling functions performed for the single LOT in the comparison market. Record evidence indicates that SeAH undertakes significant activities in the comparison market related to the sales process and marketing support, as well as warehousing and warranty services that it does not undertake for its U.S. CEP sales. *See* Memorandum from Jennifer Meek to the File, Re: Preliminary Results Calculation Memorandum, dated November 30, 2011 (''SeAH Preliminary Sales Calculation Memo''). These differences in selling functions performed for comparison and U.S. market transactions indicate that SeAH's comparison market sales are made at a more advanced stage of distribution than its U.S. sales. Consequently, we preliminarily determine that SeAH's comparison and U.S. market sales are at different LOTs.

(B) HYSCO

HYSCO reported one channel of distribution in the comparison market, Korea: sales directly to customers, which were unaffiliated distributors and both affiliated and unaffiliated end users. In the U.S. market, HYSCO reported two channels of distribution: (1) Sales to affiliate Hyundai HYSCO USA, Inc. (''HHU''), which, in turn sold the merchandise to unaffiliated customers in the United States; and (2) sales through another party to unaffiliated U.S. customers. HYSCO reported that the home market LOT was more advanced than the LOT for its U.S. sales. HYSCO is not seeking a LOT adjustment. Instead, it claims that a CEP offset is warranted. *See* HYSCO's Section A Questionnaire Response at A–19.

In evaluating HYSCO's claim, we examined its activities in each channel of distribution relating to 24 different types of selling functions. Based on our analysis, we preliminarily determine that HYSCO's selling activities in the U.S. market did not vary significantly by channel of distribution. Therefore, we preliminarily determine that HYSCO sold at one LOT in the U.S. market. We further determine preliminarily that HYSCO sold at one LOT in the comparison market since there is only one channel of distribution in this market, and the marketing process and selling functions are the same for all of HYSCO's customers in the home market.

We then compared the selling functions performed by HYSCO for its U.S. sales to the selling functions performed for the single LOT in the comparison market. Record evidence indicates that HYSCO undertakes significant activities in the comparison market in 10 of the 24 selling functions, including sales forecasting, strategic/economic planning, packing, sales/marketing support, etc. *See* Memorandum from Mary Kolberg to the File, Re: Preliminary Results Calculation Memorandum, dated November 30, 2011 (''HYSCO Preliminary Sales Calculation Memo''). These differences in selling functions performed for the comparison and U.S. markets indicate that HYSCO's comparison market sales are made at a more advanced stage of distribution than its U.S. sales. Consequently, we preliminarily determine that HYSCO's comparison market and U.S. sales are at different LOTs.

As discussed above, the Department will make a LOT adjustment in these circumstances when the information exists to do so. We have found different

LOTs between the comparison and U.S. markets for SeAH and HYSCO. However, since there is only one LOT in the comparison market for each company, there is no basis upon which to determine whether there is a pattern of consistent price differences between LOTs in the comparison market. Further, we do not have information that would allow us to examine the price patterns of SeAH's and HYSCO's sales of other similar products, and there is no other record evidence upon which a LOT adjustment could be based. Therefore, we have not made a LOT adjustment for either company.

Instead, in accordance with section 773(a)(7)(B) of the Act, we preliminarily determine that a CEP offset is appropriate for SeAH and HYSCO to reflect that their comparison market sales are at a more advanced stage than the LOT of their respective U.S. sales. We based the amount of the CEP offset on comparison market indirect selling expenses and limited the deduction to the amount of the indirect selling expenses deducted from CEP under section 772(d)(1)(D) of the Act. For a detailed discussion, *see* SeAH Preliminary Sales Calculation Memo and HYSCO Preliminary Sales Calculation Memo.

Constructed Export Price

In accordance with section 772(b) of the Act, CEP is the price at which the subject merchandise is first sold (or agreed to be sold) in the United States before or after the date of importation by or for the account of the producer or exporter of such merchandise, or by a seller affiliated with the producer or exporter, to a purchaser not affiliated with the producer or exporter.

(A) SeAH

For purposes of this review, SeAH classified all of its sales of CWP to the United States as CEP sales. During the POR, SeAH made sales in the United States through its U.S. affiliate, PPA, which then resold the merchandise to unaffiliated customers in the United States. We calculated CEP based on the packed, delivered prices to unaffiliated purchasers in the United States, net of billing adjustment and discounts. We adjusted these prices for movement expenses, including foreign inland freight, international freight, marine insurance, foreign and U.S. brokerage and handling, bill of lading charges, and U.S. customs duties, in accordance with section 772(c)(2)(A) of the Act.

In accordance with section 772(d)(1) of the Act, we deducted from the starting price those selling expenses that were incurred in selling the subject merchandise in the United States, including imputed credit expenses, warranty expenses, and indirect selling expenses. We also made an adjustment for profit in accordance with section 772(d)(3) of the Act. *See* SeAH's Preliminary Sales Calculation Memo.

(B) HYSCO

For purposes of this review, HYSCO classified all of its export sales of CWP to the United States as CEP sales. During the POR, HYSCO made sales in the United States through two channels, including through affiliate HHU and another party, which then resold the merchandise to unaffiliated customers in the United States. We calculated CEP based on the packed, delivered price to unaffiliated purchasers in the United States. We adjusted these prices for movement expenses, including foreign inland freight, international freight, marine insurance, foreign and U.S. brokerage and handling, and U.S. customs duties, in accordance with section 772(c)(2)(A) of the Act.

In accordance with section 772(d)(1) of the Act, we deducted from the starting price those selling expenses that were incurred in selling the subject merchandise in the United States, including warranty expenses, imputed credit expenses, and indirect selling expenses. We also made an adjustment for profit in accordance with section 772(d)(3) of the Act. *See* HYSCO Preliminary Sales Calculation Memo.

Normal Value

A. Selection of Comparison Market

To determine whether there was a sufficient volume of sales in Korea to serve as a viable basis for calculating NV, we compared SeAH's and HYSCO's volume of home market sales of the foreign like product to their respective U.S. sales volumes of the subject merchandise, in accordance with section 773(a)(1)(B) of the Act. Because the aggregate home market sales volumes of the foreign like product were greater than five percent of their aggregate U.S. sales volumes of the subject merchandise, we determine that the home market was viable for comparison purposes for both SeAH and HYSCO.

B. Affiliated Party Transactions and Arm's Length Test

SeAH and HYSCO reported sales of the foreign like product to affiliated and unaffiliated customers in the comparison market. The Department calculates NV based on a sale to an affiliated party only if it is satisfied that the price to the affiliated party is comparable to the price at which sales are made to parties not affiliated with the producer or exporter, *i.e.,* sales at ''arm's length.'' *See* 19 CFR 351.403(c). To test whether the sales to affiliates were made at arm's length prices, we compared on a model-specific basis, the starting prices of sales to affiliated and unaffiliated customers net of all movement charges, direct selling expenses, and packing. In accordance with the Department's current practice, if the prices charged to an affiliated party were, on average, between 98 and 102 percent of the prices charged to unaffiliated parties for merchandise identical or most similar to that sold to the affiliated party, we considered the sales to be at arm's length and included such sales in the calculation of NV. *See* 19 CFR 351.403(c). Conversely, where sales to the affiliated party did not pass the arm's length test, all sales to that affiliated party were excluded from the NV calculation. *See Antidumping Proceedings: Affiliated Party Sales in the Ordinary Course of Trade,* 67 FR 69186, 69194 (November 15, 2002).

C. Cost of Production Analysis

The Department disregarded sales below the COP in the last completed reviews in which SeAH and HYSCO participated. *See Circular Welded Non-Alloy Steel Pipe from the Republic Korea: Final Results of the Antidumping Duty Administrative Review,* 75 FR 34980 (June 21, 2010) and *Circular Welded Non-Alloy Steel Pipe from Korea: Final Results of Antidumping Duty Administrative Review,* 69 FR 32492 (June 10, 2004), respectively. Thus, in accordance with section 773(b)(2)(A)(ii) of the Act, there are reasonable grounds to believe or suspect that SeAH and HYSCO made sales of the subject merchandise in their comparison market at prices below the COP in the current review period. Pursuant to section 773(b)(1) of the Act, we initiated a COP investigation of sales by SeAH and HYSCO.

1. Calculation of Cost of Production

We calculated the COP based on the sum of the cost of materials and fabrication for the foreign like product, plus amounts for selling, general and administrative (''SG&A'') expenses, in accordance with section 773(b)(3) of the Act.

Except as noted below, we relied on the COP data submitted by HYSCO and SeAH in their questionnaire responses for the COP calculation.

During the POR, HYSCO purchased hot-rolled coil from its affiliates. We analyzed HYSCO's affiliated transactions in accordance with section

773(f)(3) of the Act, and adjusted HYSCO's cost of manufacturing to reflect the higher of market or transfer price, or the affiliate's COP. *See* Memorandum from Ji Young Oh to Neal M. Halper, Director of Office of Accounting, ''Cost of Production and Constructed Value Calculation Adjustments for the Preliminary Results—Hyundai HYSCO,'' dated November 30, 2011.

Based on our review of the record evidence, neither HYSCO nor SeAH appeared to experience significant changes in the cost of manufacturing during the POR. Therefore, we followed our normal methodology of calculating an annual weighted-average cost.

2. Test of Comparison Market Sales Prices

As required under section 773(b)(2) of the Act, we compared the POR weighted-average COP to the per-unit price of 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. We determined the net comparison market prices for the below cost test by subtracting from the gross unit price any applicable movement charges, discounts, rebates, direct and indirect selling expenses (also subtracted from the COP), and packing expenses.

3. Results of the COP Test

Pursuant to section 773(b)(2)(C)(i) of the Act, where less than 20 percent of 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.'' Where 20 percent or more of a respondent's home market sales of a given model were at prices less than the COP, we disregarded the below-cost sales because: (1) They 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 our comparison of prices to the weighted-average COPs, they were at prices which would not permit the recovery of all costs within a reasonable period of time, in accordance with section 773(b)(2)(D) of the Act.

Our cost test for HYSCO and SeAH indicated that for home market sales of certain models, more than 20 percent were sold at prices below the COP within an extended period of time and were at prices which would not permit the recovery of all costs within a reasonable period of time. Thus, in accordance with section 773(b)(1) of the Act, we excluded these below-cost sales from our analysis and used the remaining above-cost sales to determine NV.

D. Constructed Value

In accordance with section 773(e) of the Act, we calculated CV based on the sum of SeAH's and HYSCO's respective material and fabrication costs, SG&A expenses, profit, and U.S. packing costs. We calculated the COP component of CV as described above in the ''Cost of Production Analysis'' section of this notice. In accordance with section 773(e)(2)(A) of the Act, we based SG&A expenses and profit on the amounts incurred and realized by the respondents in connection with the production and sale of the foreign like product in the ordinary course of trade, for consumption in the foreign country.

E. Calculation of Normal Value Based on Comparison Market Prices

We found the method that HYSCO used to calculate the rate of its home market short-term borrowing during the period of review did not properly reflect the actual rates it received in borrowing. In a supplemental response, HYSCO submitted an alternative calculation for its home market short-term borrowing rate. We have used the rate calculated by this alternative method to recalculate HYSCO's reported home market credit expenses and home market inventory carrying costs.

For those comparison products for which there were sales at prices above the COP for HYSCO and SeAH, we based NV on home market prices. We calculated NV based on packed prices to unaffiliated customers in Korea, or prices to affiliated customers which were determined to be at arm's length (*see* discussion above on the arm's length test). We adjusted the starting price for billing adjustments and interest revenue (both HYSCO only) and by deducting for foreign inland freight, including warehousing (HYSCO only) pursuant to section 773(a)(6)(B)(ii) of the Act. We made adjustments for differences in packing, in accordance with section 773(a)(6)(A) and 773(a)(6)(B)(i) of the Act, and in circumstances of sale (for imputed credit and warranty expenses (HYSCO only)) under section 773(a)(6)(c)(iii) of the Act and 19 CFR 351.410.

When comparing U.S. sales with comparison market sales of similar, but not identical, merchandise, we also made adjustments for physical differences in the merchandise in accordance with section 773(a)(6)(C)(ii) of the Act and 19 CFR 351.411. We based this adjustment on the difference in the variable cost of manufacturing for the foreign like products and subject merchandise. *See* 19 CFR 351.411(b).

F. Price-to-CV Comparison

Where we were unable to find a home market match of such or similar merchandise, in accordance with section 773(a)(4) of the Act, we based NV on CV. Where appropriate, we made adjustments to CV in accordance with section 773(a)(8) of the Act.

Currency Conversion

Pursuant to 19 CFR 351.415 and section 773A of the Act, we made currency conversions based on the exchange rates in effect on the date of the U.S. sale, as certified by the Federal Reserve Bank. *See* Import Administration Web site at: *http://ia.ita.doc.gov/exchange/index.html.*

Preliminary Results of the Review

We preliminarily determine that a weighted-average dumping margin exists for the respondents for the period November 1, 2009, through October 31, 2010.

Manufacturer/exporter	Weighted-average margin (percent)
SeAH Steel Corporation	2.31
Hyundai HYSCO	0.59

Public Comment

The Department will disclose calculations performed within five days of the date of publication of this notice to the parties to this proceeding in accordance with 19 CFR 351.224(b). Any interested party may request a hearing within 30 days of the publication of this notice in the **Federal Register.** *See* 19 CFR 351.310. If a hearing is requested, the Department will notify interested parties of the hearing schedule. Issues raised in the hearing will be limited to those raised in the case briefs.

Interested parties are invited to comment on the preliminary results of this review. The Department will consider case briefs filed by interested parties within 30 days after the date of publication of this notice in the **Federal Register**. *See* 19 CFR 351.309(c). Interested parties may file rebuttal briefs, limited to issues raised in the case briefs. *See* 19 CFR 351.309(d). The Department will consider rebuttal briefs filed not later than five days after the time limit for filing case briefs. Parties

submitting arguments in this proceeding are requested to submit with the argument: (1) A statement of the issue, (2) a brief summary of the argument, and (3) a table of authorities, in accordance with 19 CFR 351.309(d)(2). Further, parties submitting case and/or rebuttal briefs are requested to provide the Department with an additional electronic copy of the public version of any such comments on a computer diskette. Case and rebuttal briefs must be served on interested parties in accordance with 19 CFR 351.303(f).

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 these preliminary results, unless extended. *See* section 751(a)(3)(A) of the Act, and 19 CFR 351.213(h).

Assessment Rates

The Department shall determine, and CBP shall assess, antidumping duties on all appropriate entries, in accordance with 19 CFR 351.212(b)(1). The Department will issue appropriate appraisement instructions for the companies subject to this review directly to CBP 15 days after the date of publication of the final results of this review.

For HYSCO and SeAH, we will calculate importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of antidumping duties calculated for the examined sales to the total entered value of the sales, as reported by HYSCO and SeAH. *See* 19 CFR 351.212(b)(1). Pursuant to 19 CFR 351.106(c)(2), we will instruct CBP to liquidate without regard to antidumping duties any entries for which the assessment rate is *de minimis* (*i.e.,* less than 0.50 percent).

The Department clarified its ''automatic assessment'' regulation on May 6, 2003. *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003) (''*Assessment Policy Notice*''). This clarification will apply to entries of subject merchandise during the period of review produced by companies included in these final results of review for which the reviewed companies did not know that the merchandise they sold to the intermediary (*e.g.,* a reseller, trading company, or exporter) was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediary involved in the transaction. *See Assessment Policy Notice* for a full discussion of this clarification.

Cash Deposit Requirements

The following deposit rates will be effective upon publication of the final results of this administrative review for all shipments of CWP from Korea entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rates for the companies listed above will be the rates 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 final results in which that manufacturer or exporter participated; (3) if the exporter is not a firm covered in this review, a prior review, or the original less-than-fair-value (''LTFV'') investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent final results 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 conducted by the Department, the cash deposit rate will be 4.80 percent, the ''all others'' rate established in the LTFV investigation. *See CWP Order.* These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice 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 antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

This notice serves as the only reminder to parties subject to administrative protective order (''APO'') of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

These preliminary results of review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: November 30, 2011.

Paul Piquado,

Assistant Secretary for Import Administration.

[FR Doc. 2011–31432 Filed 12–6–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–357–812]

Honey From Argentina: Notice of Extension of Time Limit for Preliminary Results

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

SUMMARY: The Department of Commerce (the Department) is extending the preliminary results of this administrative review to no later than December 15, 2011.

DATES: *Effective Date:* December 7, 2011.

FOR FURTHER INFORMATION CONTACT: John Drury or Angelica Mendoza, AD/CVD Operations, Office 7, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Room 7850, Washington, DC 20230; *telephone:* (202) 482–0195, or (202) 482–3019, respectively.

SUPPLEMENTARY INFORMATION:

Background

On January 28, 2011, the Department initiated a review of the 20 companies for which an administrative review was requested. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 76 FR 5137 (January 28, 2011) (*Initiation Notice*).[1]

On September 7, 2011, the Department extended the time limit for the preliminary results until December

[1] On February 24, 2011, the Department published a subsequent initiation notice which included corrections to the *Initiation Notice* with respect to honey from Argentina. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part,* 76 FR 10329 (February 24, 2011) (*Second Initiation Notice*). In the review request for Nexco S.A. (Nexco), it also requested revocation from the antidumping duty order on honey from Argentina (in part). However, Nexco's request for revocation in part from the order was inadvertently omitted from the *Initiation Notice.* Furthermore, certain company names were misspelled in the same *Initiation Notice.* All errors were corrected in the *Second Initiation Notice.*

1, 2011, and rescinded the administrative review with respect to ten companies: (1) Alimentos Naturales-Natural Foods Lavalle, (2) Alma Pura, (3) Apidouro Comercial Exportadora E Importadora Ltda., (4) Bomare S.A., (5) HoneyMax, (6) Interrupcion S.A., (7) Miel Ceta SRL, (8) Nexco, (9) Productos Afer S.A., and (10) Seabird Argentina S.A. *See Notice of Extension of Time Limit for Preliminary Results and Partial Rescission of Antidumping Duty Administrative Review,* 76 FR 55349 (September 7, 2011). This review covers the following companies: TransHoney S.A. (TransHoney), Compañía Inversora Platense S.A. (CIPSA), AGLH S.A., Algodonera Avellaneda S.A.,.Compania Apicola Argentina S.A., El Mana S.A., Industrial Haedo S.A., Mielar S.A., Patagonik S.A., and Villamora S.A. We selected TransHoney and CIPSA for individual examination. *See* Memorandum to Richard O. Weible, ''Administrative Review of the Antidumping Duty Order on Honey from Argentina: Respondent Selection Memorandum,'' dated May 9, 2011.

Extension of Time Limit for Preliminary Results

Section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), requires the Department to complete the preliminary results of an administrative review within 245 days after the last day of the anniversary month of an order for which a review is requested. However, if it is not practicable to complete the review within this time period, section 751(a)(3)(A) of the Act allows the Department to extend the time limit for the preliminary results to a maximum of 365 days after the last day of the anniversary month of an order for which a review is requested.

The Department has determined it is not practicable to complete this review within the statutory time limit due to the selection of two new mandatory respondents for this review after the requests for review for the original respondents were withdrawn. The Department requires additional time to analyze sufficiently information submitted by the current respondents in this administrative review. Accordingly, the Department is further extending the time limit for completion of the preliminary results of this administrative review by 14 days (*i.e.,* to December 15, 2011).

This notice is issued and published in accordance with section 351.213(d)(4) of the Department's regulations and sections 751(a)(3)(A) and 777(i)(1) of the Act.

Dated: December 1, 2011

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2011–31442 Filed 12–6–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–831]

Fresh Garlic From the People's Republic of China: Preliminary Results of the 2009–2010 Antidumping Duty Administrative Review

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

SUMMARY: In response to requests from interested parties, the Department of Commerce (Department) is conducting an administrative review of the antidumping duty order on fresh garlic from People's Republic of China (PRC) covering the period of review (POR) of November 1, 2009, through October 31, 2010.

The Department preliminarily finds that two fully participating mandatory respondents have demonstrated their eligibility for a separate rate, and sold subject merchandise to the United States at prices below normal value (NV). The Department preliminarily grants a separate rate to five additional companies which demonstrated eligibility for separate rate status; the rates assigned to each of these seven companies can be found in the ''Preliminary Results'' section.

The Department invites interested parties to comment on these preliminary results. If these preliminary results are adopted in the final results, the Department will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on entries of subject merchandise during the POR for which assessment rates are above *de minimis.*

DATES: *Effective Date:* December 7, 2011.

FOR FURTHER INFORMATION CONTACT: Scott Lindsay or Lingjun Wang, AD/CVD Operations, Office 6, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; *telephone:* (202) 482–0780 and (202) 482–2316.

SUPPLEMENTARY INFORMATION:

Background

On November 16, 1994, the Department published in the **Federal Register** the antidumping duty order on fresh garlic from the PRC.[1] On November 1, 2010, the Department published a notice of opportunity to request an administrative review of the antidumping duty order on fresh garlic from the PRC for the period November 1, 2009 through October 31, 2010.[2] On December 28, 2010, the Department published a notice of initiation of administrative review with respect to 112 companies.[3] On October 20, 2011, the Department published partial preliminary results, rescission of, and intent to rescind, in part, the administrative review.[4]

In February 2011, each of the following five companies timely submitted a separate rate status certification: (1) Hebei Golden Bird Trading Co., Ltd. (Golden Bird); (2) Shenzhen Xinboda Industrial Co., Ltd. (Xinboda); (3) Henan Weite Industrial Co., Ltd. (Henan Weite); (4) Jinan Farmlady Trading Co., Ltd. (Farmlady); (5) Qingdao Xintianfeng Foods Co., Ltd. (QXF). On March 4, 2011, Chengwu County Yuanxiang Industry & Commerce Co., Ltd. (Yuanxiang) submitted a separate rate status certification and explained that its submission was delayed due to a medical issue with one of its attorneys. The Department found this explanation to be reasonable and therefore accepted the certificate. On August 17, 2011, the Department moved documents related to Yantai Jinyan Trading Inc.'s (Jinyan) separate rate status, submitted by Jinyan during the most recently complete new shipper review, to the record of this administrative review.[5]

On March 4, 2011, the Department selected the five largest exporters by volume as mandatory respondents: (1)

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[1] *See Antidumping Duty Order: Fresh Garlic From the People's Republic of China,* 59 FR 59209 (November 16, 1994) (*Order*).

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation: Opportunity to Request Administrative Review,* 75 FR 67079 (November 1, 2010).

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part,* 75 FR 81565, 81568–81569 (December 28, 2010) (*Initiation Notice*). The Department also initiated a review of Zhengzhou Dadi. However, the responses of Shenzhen Xinboda, a mandatory respondent, indicate that Zhengzhou Dadi is its affiliated producer. As such, we will address Zhenghou Dadi in the context of our analysis of Shenzhen Xinboda. We do not include Zhengzhou Dadi in our company counts in this notice.

[4] *See Fresh Garlic From the People's Republic of China: Partial Preliminary Results, Rescission of, and Intent To Rescind, in Part, the 2009–2010 Administrative Review,* 76 FR 65172 (October 20, 2011) (*Partial Preliminary Results*).

[5] *See* Memorandum to The File, Through Dana S. Mermelstein, From Jacqueline Arrowsmith, Re: Moving Yantai Jinyan's Separate Rates Application to the November 1, 2009 through October 31, 2010 (16th) Administrative Review (August 17, 2011).

Shandong Longtai Fruits and Vegetables Co., Ltd. (Longtai); (2) Weifang Hongqiao International Logistic Co., Ltd. (Hongqiao); (3) Golden Bird; (4) Xinboda; (5) Harmoni.[6] On March 14, 2011, the Department issued a Non-Market Economy Antidumping Duty Questionnaire (Initial Questionnaire) to each of the five mandatory respondents. Golden Bird and Xinboda submitted their responses on April 25 and May 18, 2011, respectively.[7] Petitioners[8] commented on these responses on July 6, 2011; and Golden Bird responded to Petitioners' comments on July 20, 2011. On July 29, 2011, the Department issued its first supplemental questionnaires to Golden Bird and Xinboda, and received responses from both on August 19, 2011. On August 29, 2011, Petitioners made their initial comments on the supplemental questionnaire responses and renewed their request to conduct verification. On September 19, 2011, Petitioners commented on Xinboda's supplemental questionnaire response. On October 5, 2011, Petitioners commented on Golden Bird's supplemental questionnaire response, and Golden Bird rebutted these comments on October 17, 2011. On October 20, 2011, consistent with 19 CFR 351.213(d)(1), the Department rescinded the review with respect to Harmoni because both Petitioners and Harmoni had withdrawn their respective requests for a review of Harmoni within the 90 day period provided by the regulations.[9] Also on October 20, 2011, the Department determined that Hongqiao and Longtai are subject to the PRC-wide entity rate.[10] On October 28, 2011, the Department issued second supplemental questionnaires to Golden Bird and Xinboda. Golden Bird submitted its supplemental response on November 14, 2011, and Xinboda submitted its supplemental response on November 16, 2011. The Department notes that these questionnaire responses were received too late to be considered for this preliminary determination. The Department will therefore consider these submissions in its analysis for the final results.

On March 31, 2011, the Department issued a letter to interested parties soliciting comments on selecting surrogate country and surrogate values (SV). On July 12, 2011, Petitioners submitted SV information. On July 29, 2011, Petitioners provided additional SV information which was rebutted by Golden Bird in a submission dated August 8, 2011 and commented on by Yuanxiang in a submission dated August 11, 2011. Also on July 29, 2011, Golden Bird provided SV information which was rebutted by Petitioners in a submission dated August 5, 2011, and that submission was rebutted by Golden Bird on August 15, 2011 (sur-rebuttal); Petitioners commented on the sur-rebuttal on September 15, 2011, and those sur-rebuttal comments were commented on by Golden Bird on October 11, 2011. On October 5, 2011, Xinboda asked the Department to clarify and revise the surrogate country list in the Department's letter issued on March 31, 2011; Petitioners responded to Xinboda's request on October 13, 2011. On October 26, 2011, Petitioners provided comments in advance of the preliminary results.

Scope of the Order

The products covered by the order are all grades of garlic, whole or separated into constituent cloves, whether or not peeled, fresh, chilled, frozen, provisionally preserved, or packed in water or other neutral substance, but not prepared or preserved by the addition of other ingredients or heat processing. The differences between grades are based on color, size, sheathing, and level of decay. The scope of the order does not include the following: (a) Garlic that has been mechanically harvested and that is primarily, but not exclusively, destined for non-fresh use; or (b) garlic that has been specially prepared and cultivated prior to planting and then harvested and otherwise prepared for use as seed. The subject merchandise is used principally as a food product and for seasoning. The subject garlic is currently classifiable under subheadings 0703.20.0010, 0703.20.0020, 0703.20.0090, 0710.80.7060, 0710.80.9750, 0711.90.6000, and 2005.90.9700 of the Harmonized Tariff Schedule of the United States (HTSUS).

Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of the order is dispositive. In order to be excluded from the order, garlic entered under the HTSUS subheadings listed above that is (1) Mechanically harvested and primarily, but not exclusively, destined for non-fresh use or (2) specially prepared and cultivated prior to planting and then harvested and otherwise prepared for use as seed must be accompanied by declarations to U.S. Customs and Border Protection to that effect.

Non-Market Economy Country Status

The Department has treated the PRC as a non-market economy (NME) country in all past antidumping duty investigations and administrative reviews.[11] A designation as an NME country remains in effect until it is revoked by the Department pursuant to section 771(18)(C)(i) of the Tariff Act of 1930, as amended (the Act). No interested party to this proceeding has contested such treatment. Hence, the Department calculated NV using factors of production (FOPs) methodology in accordance with section 773(C) of the Act.

Market-Oriented Industry

On July 29, 2011 and August 15, 2011, Golden Bird informed the Department that it should consider granting the PRC garlic industry market economy (ME) treatment. The Department has interpreted this as a request that the Department conduct a market oriented industry (MOI) examination for the PRC garlic industry. On August 5, 2011, Petitioners submitted a letter to the Department stating that the Department should reject this MOI request as being without merit.

As a threshold matter, the Department requires that any MOI claim be submitted such that it provides sufficient time to consider the claim.[12] As the Department made clear in the *Coated Paper Preliminary Results,* respondents that request MOI treatment should submit a complete MOI claim no later than two months after the initiation of a segment of a proceeding. This ensures that there is sufficient time to analyze the request and in the event the Department makes an affirmative MOI determination, there would be

[6] *See* Memorandum to Barbara E. Tillman, Through Thomas Gilgunn, From Nicholas Czajkowski, Re: Antidumping Administrative Review of Fresh Garlic From the People's Republic of China: Respondent Selection Memorandum (March 4, 2011).

[7] The Department granted several extensions (in April through November 2011) for various sections of the Initial Questionnaire.

[8] The Petitioners are the Fresh Garlic Producers Association, its individual members being Christopher Ranch L.L.C., The Garlic Company, Valley Garlic, and Vessey and Company, Inc.

[9] *See Partial Preliminary Results.*

[10] *See Partial Preliminary Results.*

[11] *See* Memorandum from the Office of Policy to David M. Spooner, Assistant Secretary for Import Administration, The People's Republic of China (PRC) Status as a Non-Market Economy (NME), dated May 15, 2006. This document is available online at *http://ia.ita.doc.gov/download/prc-nme-status/prc-nme-status-memo.pdf.*

[12] *See, e.g., Certain Coated Paper Suitable for High-Quality Print Graphics Using Sheet-Fed Presses From the People's Republic of China: Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination,* 75 FR 24892 (May 6, 2010) (*Coated Paper Preliminary Results*).

sufficient time in a proceeding to obtain home market prices and/or cost data.[13]

In order to consider a timely submitted MOI claim, the Department requires information on each of the three prongs of the MOI test regarding the situation and experience of the PRC garlic industry as a whole. Specifically, the Department requires information in support of the party's claims that: (1) There is virtually no government involvement in production or prices for the industry; (2) the industry is marked by private or collective ownership that behaves in a manner consistent with market considerations; and (3) producers pay market-determined prices for all major inputs and for all but an insignificant proportion of minor inputs. Even in those cases where the Department limits the number of firms it investigates, an MOI claim must cover all (or virtually all) of the producers in the industry in question.[14]

The Department finds that Golden Bird's request that the Department consider granting the PRC garlic industry ME treatment is an untimely and deficient MOI request. As an initial matter, Golden Bird's request was not received by the Department until July 29, 2011, seven months after the initiation of this review, well beyond any reasonable time in which to properly consider and act on a claim, and well beyond the two month-period following initiation to make a claim that the Department specified in *Coated Paper Preliminary Results.*

In addition to being untimely, Golden Bird's request is deficient as an MOI claim because Golden Bird failed to demonstrate that it represents ''all or virtually all of the producers'' in the garlic industry.[15] Meeting this initial threshold is necessary to ensure that the Department's MOI analysis is based on evidence that reflects the experience of the garlic industry.[16] Moreover, Golden Bird's request does not meaningfully attempt to address any of prongs of the MOI test regarding ownership and market-determined inputs.[17] For all of the reasons noted above, the Department determines that the MOI claim does not warrant further consideration in this review.

Surrogate Country

Section 773(c)(1) of the Act directs the Department to base NV on the NME producer's FOPs, valued in a surrogate ME country or countries considered to be appropriate by the Department. In accordance with section 773(c)(4) of the Act, in valuing the FOPs, the Department shall use, to the extent possible, the prices or costs of the FOPs in one or more ME countries that are: (1) At a level of economic development comparable to that of the NME country; and (2) significant producers of comparable merchandise. Moreover, it is the Department's practice to select an appropriate surrogate country based on the availability and reliability of data from the countries.[18]

The Department determined that India, the Philippines, Indonesia, Thailand, Ukraine and Peru are countries comparable to the PRC in terms of economic development.[19] Once the Department has identified the countries that are economically comparable to the PRC, the Department selects an appropriate surrogate country by determining whether an economically comparable country is a significant producer of comparable merchandise and whether the data for valuing FOPs are both available and reliable.

For the preliminary results, Golden Bird, Yuanxiang, and Petitioners submitted data for valuing FOPs, and these data are sourced from India. On October 5, 2011, Xinboda argued for the first time that India is not the appropriate surrogate country for this review because its economic comparability was determined based on the data which is not contemporaneous with the POR. Responding to Xinboda's argument, on October 13, 2011, Petitioners argued that India is the only appropriate surrogate for comparable merchandise.

The Department issued its list of potential surrogate countries on March 31, 2011, providing parties four months, until July 29, 2011,[20] in which to comment on the selection. On October 5, 2011, more than two months after the deadline, Xinboda argued against the selection of India and provided no explanation for the delay or data in support of an alternative surrogate country. In light of the untimeliness of Xinboda's argument and the lack of any alternative SV data to consider, the Department declines to reject India as the surrogate country for the preliminary results.

Accordingly, the Department has determined that India is the appropriate surrogate country for use in this review, based on the following facts: (1) India is at a level of economic development comparable to that of the PRC; (2) India is a significant producer of comparable merchandise; and (3) India provides the best opportunity to use quality, publicly available data to value the FOPs.[21] Therefore, the Department has selected India as the surrogate country and, accordingly, has calculated NV using Indian prices to value the respondent's FOPs, when available and appropriate. The Department has obtained and relied upon publicly available information wherever possible.

Normal Value

A. Methodology

We compared NV to individual EP transactions in accordance with section 777A(d)(2) of the Act, as appropriate. Section 773(c)(1)(B) of the Act provides that the Department shall determine NV using an FOPs methodology if: (1) The merchandise is exported from an NME country; and (2) the information does not permit the calculation of NV using home market prices, third-country prices, or constructed value under section 773(a) of the Act. When determining NV in an NME context, the Department will base NV on FOPs

[13] *See Notice of Final Determination of Sales at Less Than Fair Value: Freshwater Crawfish Tail Meat From the People's Republic of China,* 62 FR 41347, 41353 (August 1, 1997) (*Crawfish LTFV Final*).

[14] *See Notice of Final Determination of Sales at Less Than Fair Value and Negative Final Determination of Critical Circumstances: Certain Color Television Receivers From the People's Republic of China,* 69 FR 20594 (April 16, 2004) (*TV Receivers LTFV Final*), and accompanying Issues and Decision Memorandum at Comment 1. *See also Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination: Synthetic Indigo from the People's Republic of China,* 64 FR 69723, 59725 (December 14, 1999) (*Indigo Preliminary Results*). *See also Crawfish LTFV Final,* 62 FR at 41353.

[15] *See TV Receivers LTFV Final* and accompanying Issues and Decision Memorandum at Comment 1 (an MOI allegation must cover all (or virtually all) of the producers in the industry in question). *See Indigo Preliminary Results,* 64 FR at 69725. *See also Crawfish LTFV Final,* 62 FR at 41353.

[16] Golden Bird's request is unclear as to the garlic industry for which it claims ''market economy treatment.'' Golden Bird is a trading company who sells fresh garlic produced by a non-integrated processor.

[17] We note that Golden Bird's request provided no information to substantiate the claims regarding the first prong of the MOI test regarding the ''independence'' of garlic farmers and the absence of government regulation of ''garlic production and market''.

[18] *See* Department Policy Bulletin No. 04.1: Non-Market Economy Surrogate Country Selection Process (March 1, 2004) (Policy Bulletin).

[19] *See* Letter to All Interested Parties, Re: 16th Administrative Review of the Antidumping Duty Order on Fresh Garlic from the People's Republic of China (March 31, 2011).

[20] *See* Memorandum to All Interested Parties, Through Thomas Gilgunn, From David Lindgren, Subject: Request for Extension to Submission of Comments and Information related to Surrogate Country and Values Selection (June 28, 2011).

[21] *See* Memorandum to The File, Through Thomas Gilgunn, From Lingjun Wang, Re: Fresh Garlic from the People's Republic of China—2009–2010 Administrative Review—Surrogate Values for the Preliminary Results (November 30, 2011) (SV Memorandum).

because the presence of government controls on various aspects of these economies renders price comparisons and the calculation of production costs invalid under our normal methodologies.[22] However, there are circumstances in which the Department will modify its standard FOP methodology, choosing to apply SVs to an intermediate input instead of the individual FOPs used to produce that intermediate input. In some cases, a respondent may report factors used to produce an intermediate input that accounts for an insignificant share of total output. When the potential increase in accuracy to the overall calculation that results from valuing each of the FOPs is outweighed by the resources, time, and burden such an analysis would place on all parties to the proceeding, the Department has valued the intermediate input directly using SVs.[23]

For the final results of several prior administrative reviews and new shipper reviews under the garlic order,[24] the Department found that garlic industry producers in the PRC do not generally track actual labor hours incurred for growing, tending, and harvesting activities and, thus, do not maintain appropriate records which would allow most, if not all, respondents to quantify, report, and substantiate this information. In the preliminary results of *Garlic 11, Garlic 12, Garlic 13,* and *Garlic 15,* the Department also stated that ''should a respondent be able to provide sufficient factual evidence that it maintains the necessary information in its internal books and records that would allow us to establish the completeness and accuracy of the reported FOPs, we will revisit this issue and consider whether to use its reported FOPs in the calculation of NV.[25]''

For the preliminary results, the Department is applying an ''intermediate-input product valuation methodology'' to calculate NV for Golden Bird and Xinboda.[26]

B. Factor Valuations

In accordance with section 773(c) of the Act, the Department calculated NV based on the FOPs data reported by Golden Bird and Xinboda for the POR. We relied on the factor-specific data submitted by Golden Bird and Xinboda for the production inputs in their questionnaire responses, where applicable, for purposes of selecting SVs. To calculate NV, the Department multiplied the reported per-unit factor consumption rates by publicly available India SVs.

In selecting the SVs, consistent with our past practice, the Department considered the quality, specificity, and contemporaneity of the data.[27] As appropriate, the Department adjusted input prices by including freight costs to make them delivered prices. Specifically, the Department added to the SVs, as appropriate, a surrogate freight cost using the shorter of the reported distance from the domestic suppliers to the factory or the distance from the nearest seaport to the factory. This adjustment is in accordance with the decision of the U.S. Court of Appeals for the Federal Circuit (CAFC). *See Sigma Corp.* v. *United States,* 117 F.3d 1401, 1408 (Fed. Cir. 1997). Where necessary, we adjusted the SVs for inflation/deflation using the Wholesale Price Index (WPI) as published in the International Monetary Fund's International Financial Statistics, available at *http://ifs.apdi.net/imf.* For more information regarding the Department's valuation for the various FOPs, *see* SV Memorandum.

Garlic Bulb Valuation

The Department's practice when selecting the ''best available information'' for valuing FOPs, in accordance with section 773(c)(1) of the Act,[28] is to select, to the extent practicable, SVs which are publicly available, product-specific, representative of a broad market average, tax-exclusive and contemporaneous with the POR.[29]

As discussed above, the Department is applying an intermediate input methodology for Golden Bird and Xinboda. Therefore, the Department sought to identify the best available SV for the garlic bulb input into production. For the preliminary results, the Department finds that data from the Azadpur APMC's ''Market Information Bulletin'' are the most appropriate information available to value the garlic bulb input. Consistent with the findings in the *Garlic 12, Garlic 13,* and *Garlic 15,* the Department continues to find that garlic bulb sizes that range from 55 mm and above are Grade Super-A, and garlic bulb sizes that range between 40 mm and 55 mm are Grade A and Grade Super-A. The Department has used Grade A and Grade Super A for garlic bulb valuation. Because the Grade Super-A prices reported by the APMC which are on the record of this review are from 2007–2008, the Department applied a garlic-specific Wholesale Price Index to the non-contemporaneous data to make them contemporaneous to the POR.

Other Factors of Production

The Department has obtained import statistics from the Global Trade Atlas

[22] *See, e.g., Preliminary Determination of Sales at Less Than Fair Value, Affirmative Critical Circumstances, In Part, and Postponement of Final Determination: Certain Lined Paper Products From the People's Republic of China,* 71 FR 19695, 19703 (April 17, 2006) (unchanged in *Notice of Final Determination of Sales at Less Than Fair Value, and Affirmative Critical Circumstances, In Part: Certain Lined Paper Products From the People's Republic of China*), 71 FR 53079 (September 8, 2006)).

[23] *See, e.g., Notice of Final Determination of Sales at Less Than Fair Value: Polyvinyl Alcohol from the People's Republic of China,* 68 FR 47538 (August 11, 2003), and accompanying Issues and Decision Memorandum at Comment 1 (PVA) (citing *Final Results of First New Shipper Review and First Antidumping Duty Administrative Review: Certain Preserved Mushrooms From the People's Republic of China,* 66 FR 31204 (June 11, 2001)).

[24] *See, e.g., Fresh Garlic from the People's Republic of China: Final Results and Partial Rescission of the Eleventh Administrative Review and New Shipper Reviews,* 72 FR 34438 (June 22, 2007) (*Garlic 11*); *Fresh Garlic from the People's Republic of China: Final Results and Partial Rescission of the 12th Administrative Review,* 73 FR 34251 (June 17, 2008) (*Garlic 12*); *Fresh Garlic from the People's Republic of China: Final Results and Rescission, In Part, of Twelfth New Shipper Reviews,* 73 FR 56550 (September 29, 2008); and *Fresh Garlic From the People's Republic of China: Final Results and Partial Rescission of the 13th Antidumping Duty Administrative Review and New Shipper Reviews,* 74 FR 29174 (June 19, 2009) (*Garlic 13*); and *Fresh Garlic From the People's Republic of China: Final Results and Final Rescission, in Part, of the 2008–2009 Antidumping Duty Administrative Review,* 76 FR 37321 (June 27, 2011) (*Garlic 15*).

[25] *See Fresh Garlic from the People's Republic of China: Partial Rescission and Preliminary Results of the Eleventh Administrative Review and New Shipper Reviews,* 71 FR 71510, 71520 (December 11, 2006); *Fresh Garlic from the People's Republic of China: Notice of Preliminary Results and Preliminary Partial Rescission of the Twelfth Administrative Review,* 72 FR 69652 (December 10, 2007); *Fresh Garlic from the People's Republic of China: Preliminary Results of the Antidumping Duty Administrative and New Shipper Reviews and Intent to Rescind, In Part, the Antidumping Duty Administrative and New Shipper Reviews,* 73 FR 74462 (December 8, 2008); and *Fresh Garlic from the People's Republic of China: Preliminary Results of, Partial Rescission of, and Intent to Rescind, in Part, the 15th Antidumping Duty Administrative Review,* 75 FR 80458 (December 22, 2010). All were unchanged in their respective final results.

[26] *See* Memorandum to Thomas Gilgunn, From Lingjun Wang, Re: Fresh Garlic from the People's Republic of China 2009–2010 Administrative Review—Intermediate Input Methodology (November 30, 2011).

[27] *See, e.g., Folding Metal Tables and Chairs from the People's Republic of China; Final Results of Antidumping Duty Administrative Review,* 71 FR 71509 (December 11, 2006), and accompanying Issues and Decision Memorandum at Comment 9.

[28] Section 773(c)(1)(B) of the Act states that ''the valuation of the factors of production shall be based on the best available information regarding the values of such factors in a market economy country or countries considered to be appropriate by the administering authority.''

[29] *See, e.g., Final Determination of Sales at Less Than Fair Value: Certain Artist Canvas from the People's Republic of China,* 71 FR 16116 (March 30, 2006) and accompanying Issues and Decision Memorandum at Comment 2.

(GTA) for valuing various FOPs. The data reported in the GTA published by the Global Trade Information Services, such as those from India, are in original currency and correspond to the original currency value reported by each country. Additionally, these data are reported to the nearest digit which has the same level of accuracy as the original data released.

Furthermore, with regard to the GTA Indian import-based SVs, in accordance with the Omnibus Trade and Competitiveness Act of 1988 legislative history, the Department continues to apply its long-standing practice of disregarding SVs if it has a reason to believe or suspect the source data may be subsidized.[30] In this regard, the Department has previously found that it is appropriate to disregard such prices from Indonesia, South Korea and Thailand, because the Department has determined that these countries maintain broadly available, non-industry specific export subsidies.[31] Based on the existence of these subsidy programs that were generally available to all exporters and producers in Indonesia, South Korea, and Thailand at the time of the POR, the Department finds that it is reasonable to infer that all exporters from these countries may have benefitted from these subsidies. The Department also disregarded prices from NME countries [32] and those imports that were labeled as originating from an ''unspecified'' country from the average Indian import values, because we could not be certain that they were not from either an NME or a country with general export subsidies.

The Department valued the packing material inputs using weighted-average unit import values derived from the Monthly Statistics of the Foreign Trade of India, as published by the Directorate General of Commercial Intelligence and Statistics of the Ministry of Commerce and Industry, Government of India, and compiled by the GTA.

The Department valued truck freight cost using a per-unit average rate calculated from monthly data published on *http://www.infobanc.com/logistics/logtruck.htm* [33] for the POR.

The Department valued electricity using March 2009 electricity price rates from Electricity Tariff & Duty and Average Rates of Electricity Supply in India, published by the Central Electricity Authority of the Government of India.

The Department valued brokerage and handling expenses using a price list of export procedures necessary to export a standardized cargo of goods in India. The price list is compiled based on a survey case study of the procedural requirements for trading a standard shipment of goods by ocean transport in India that is published in *Doing Business 2010: India,* published by the World Bank.

Previously, the Department used regression-based wages that captured the worldwide relationship between *per capita* GNI and hourly manufacturing wages, pursuant to 19 CFR 351.408(c)(3), to value the respondents' cost of labor in NME cases. However, on May 14, 2010, the Court of Appeals for the Federal Circuit (CAFC), in *Dorbest Ltd.* v. *United States,* 604 F.3d 1363, 1372 (Fed. Cir. 2010) (*Dorbest*), invalidated 19 CFR 351.408(c)(3). As a consequence of the CAFC's ruling in *Dorbest,* the Department no longer relies on the regression-based wage rate methodology described in its regulations.

On June 21, 2011, the Department revised its methodology for valuing the labor input in NME antidumping proceedings.[34] In *Labor Methodologies,* the Department determined that the best methodology to value the labor input is to use industry-specific labor rates from the primary surrogate country. Additionally, the Department determined that the best data source for industry-specific labor rates is Chapter 6A: Labor Cost in Manufacturing, from the International Labor Organization (ILO) Yearbook of Labor Statistics (Yearbook).

In these preliminary results, the Department calculated the labor input using the wage method described in *Labor Methodologies.* To value Golden Bird and Xinboda's labor input, the Department relied on data reported by India to the ILO in Chapter 6A of the Yearbook. The Department further finds the two-digit description under ISIC-Revision 3 (15-Manufacture of Food Products and Beverages) to be the best available information on the record because it is specific to the industry being examined, and is therefore derived from industries that produce comparable merchandise. Accordingly, relying on Chapter 6A of the Yearbook, the Department calculated the labor input using labor data reported by India to the ILO under Sub-Classification 15 of the ISIC-Revision 3 standard, in accordance with section 773(c)(4) of the Act. For these preliminary results, the calculated industry-specific wage rate is 33.028 Rs per hour.

Financial Ratios

The Department is using Tata Tea Ltd.'s (Tata Tea) unconsolidated 2010/2011 financial statements as the basis for the surrogate financial ratios. Since the 2002–2003 administrative review, the Department has considered tea processing to be sufficiently similar to garlic processing in that neither product is highly processed or preserved prior to sale.[35] Accordingly, the Department finds that non-integrated tea processors to be a comparable industry to fresh garlic. Tata Tea's unconsolidated financial statement indicates that it has not received subsidies under programs the Department has found countervailable in Indian countervailing duty proceedings [36] and Tata' Tea's unconsolidated 2010/2011 financial statements cover seven months of the instant POR. The Department has not used Golden Bird's suggested financial data from Limtex Tea Limited, Garlico, REI Agro Limited and LT Foods Limited because, in *Garlic 15,* the Department found that the 09/10 financial statements of Limtex Tea Limited, REI Agro Limited and LT Foods Limited

[30] Omnibus Trade and Competitiveness Act of 1988, Conf. Report to Accompany H.R. 3, H.R. Rep. No. 576, 100th Cong., 2nd Sess. (1988) at 590.

[31] *See, e.g., Certain Cut-to-Length Carbon-Quality Steel Plate from Indonesia: Final Results of Expedited Sunset Review,* 70 FR 45692 (August 8, 2005), and accompanying Issues and Decision Memorandum at 4; *Corrosion-Resistant Carbon Steel Flat Products from the Republic of Korea: Final Results of Countervailing Duty Administrative Review,* 74 FR 2512 (January 15, 2009), and accompanying Issues and Decision Memorandum at 17, 19–20; and *Final Affirmative Countervailing Duty Determination: Certain Hot-Rolled Carbon Steel Flat Products From Thailand,* 66 FR 50410 (October 3, 2001), and accompanying Issues and Decision Memorandum at 23.

[32] The NME countries are Armenia, Azerbaijan, Belarus, Georgia, Kyrgyz Republic, Moldova, North Korea, the People's Republic of China, Tajikistan, Turkmenistan, Uzbekistan, and the Socialist Republic of Vietnam.

[33] *See Polyethylene Retail Carrier Bags From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review,* 73 FR 52282, 52286 (September 9, 2008) (unchanged in *Polyethylene Retail Carrier Bags from the People's Republic of China: Final Results of Antidumping Duty Administrative Review,* 74 FR 6857 (February 11, 2009)); and SV Memorandum at Attachment 9.

[34] *See Antidumping Methodologies in Proceedings Involving Non-Market Economies: Valuing the Factor of Production: Labor,* 76 FR 36092 (June 21, 2011) (*Labor Methodologies*).

[35] *See Fresh Garlic from the People's Republic of China: Final Results of Antidumping Duty Administrative Review,* 70 FR 34082 (June 13, 2005) (*Garlic 9*), and accompanying Issues and Decision Memorandum at 34–35.

[36] In *Certain New Pneumatic Off-The-Road Tires from the People's Republic of China: Final Affirmative Determination of Sales at Less Than Fair Value and Partial Affirmative Determination of Critical Circumstances,* 73 FR 40485 (July 15, 2008) and accompanying Issues and Decision Memorandum at Comment 17.A, the Department stated that its practice is to disregard financial statements where we have reason to suspect that the company has received actionable subsidies, and where there is other usable data on the record.

indicated that each company received subsidies under programs the Department found to be countervailable. Moreover, Garlico's 09/10 financial statements indicate that it operates as a trading company (rather than a processor) for nearly one quarter of its sales. Although parties have argued that Tata Tea has received subsidies the Department has found countervailable, in our analysis of Tata Tea's 09/10 financial statement, we did not find evidence of these subsidies.

For these reasons, the Department finds that Tata Tea's unconsolidated financial statement is the best information on the record and provides complete and usable financial data for a non-integrated producer and seller of tea.

U.S. Price

In accordance with section 772(a) of the Act, we calculated export prices (EP) for Golden Bird's and Xinboda's sales to the United States because they were made to unaffiliated parties before the date of importation. We calculated Golden Bird's and Xinboda's EP based on their price to unaffiliated purchasers in the United States. In accordance with section 772(c) of the Act, where appropriate, we deducted movement expenses (*e.g.* foreign inland freight, international freight, brokerage and handling, marine insurance, warehousing, and U.S. customs duties) from the starting price to unaffiliated purchasers. For the expenses that were either provided by an NME vendor or paid for with an NME currency, we used SVs as appropriate.

Separate Rate

In proceedings involving NME countries, the Department has a rebuttable presumption that all companies within the country are subject to government control and thus should be assessed a single antidumping duty rate.[37] It is the Department's policy to assign all exporters of subject merchandise in an NME country this single rate unless an exporter can demonstrate that it is sufficiently independent so as to be entitled to a separate rate. Exporters can demonstrate this independence through the absence of both *de jure* and *de facto* governmental control over export activities. The Department analyzes each entity exporting the subject merchandise under a test arising from 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 further developed 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*). However, if the Department determines that a company is wholly foreign-owned or located in an ME, then a separate rate analysis is not necessary to determine whether it is independent from government control.

Separate Rate Recipients

In the *Initiation Notice,* the Department explained the process by which exporters and producers not being individually reviewed may obtain separate rate status in NME reviews. The process requires exporters and producers to submit a separate rate status application or separate rate status certification. However, the standard for eligibility for a separate rate (which is whether a firm can demonstrate an absence of both *de jure* and *de facto* government control over its export activities) has not changed.

Golden Bird, Xinboda, Henan Weite, Farmlady, QXF, and Yuanxiang each certified its eligibility for separate rate status with a Separate Rate Certification. The Department moved Jinyan's Initial Questionnaire response and supplemental questionnaire responses from a new shipper review to this review.[38] Jinyan's new shipper review sale was found to be outside of the POR of the new shipper review, so the Department rescinded that review.[39] However, as Jinyan's sale was within the POR of this administrative review, the Department transferred the documents from Jinyan's questionnaire responses from the new shipper review that related to its eligibility for a separate rate to the instant review for consideration here. These documents serve as the basis for the Department to consider Jinyan's for eligibility for separate rate status. Each company reported that it is a wholly Chinese-owned company. Therefore, the Department must analyze whether each company can demonstrate the absence of both *de jure* and *de facto* government control over export activities.

a. Absence of *De Jure* Control

The Department considers the following *de jure* criteria in determining whether an individual company may be granted a separate rate: (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) other formal measures by the government decentralizing control of companies.[40]

Golden Bird, Henan Weite, Xinboda, Farmlady, QFX, Yuanxiang and Jinyan each certified that, consistent with the most recently complete segment of this proceeding in which it participated and was granted a separate rate, there is an absence of *de jure* government control of its exports.[41] Each of these companies certified to its separate rate status, and stated, where applicable, that the company had no relationship with any level of the PRC government with respect to ownership, internal management, and business operations. In this segment, we have no new information on the record that would cause us to reconsider the previous *de jure* control determinations with regard to these companies. Thus, the Department finds that evidence on the record supports a preliminary finding of an absence of *de jure* government control with regard to the export activities of these companies.

b. Absence of *De Facto* Control

As stated in previous cases, there is evidence that certain enactments of the PRC central government have not been implemented uniformly among different sectors and/or jurisdictions in the PRC.[42] Therefore, the Department has determined that an analysis of *de facto* control is critical in determining whether the respondents are, in fact, subject to a degree of government control which would preclude the

[37] *See* Policy Bulletin 05.1: Separate Rates Practice and Application of Combination Rates in Antidumping Investigations involving Non-Market Economy Countries, available at *http://ia.ita.doc.gov/policy/bull05-1.pdf.*

[38] *See* Memorandum to The File, Through Dana S. Mermelstein, From Jacqueline Arrowsmith, Re: Moving Yantai Jinyan's Separate Rates Application to the November 1, 2009 through October 31, 2010 (16th) Administrative Review.

[39] *See Fresh Garlic From the People's Republic of China: Final Rescission of New Shipper Reviews of Jining Yifa Garlic Produce Co., Ltd., Shenzhen Bainong Co., Ltd., and Yantai Jinyan Trading Inc.,* 76 FR 52315 (August 22, 2011).

[40] *See Sparklers.*

[41] The most recently complete segment of this proceeding in which Golden Bird participated and was granted a separate rate was *Fresh Garlic from the People's Republic of China: Final Results and Rescission, In Part, of Twelfth New Shipper Reviews,* 73 FR 56550 (September 29, 2008). The most recently complete segment of this proceeding in which Henan Weite participated and was granted a separate rate was *Fresh Garlic from the People's Republic of China: Final Results and Partial Rescission of the 14th Antidumping Duty Administrative Review,* 75 FR 34976 (June 21, 2010). The most recently complete segment of this proceeding in which Xinboda, Farmlady, and QXF participated and were granted a separate rate was *Garlic 15.* The most recently complete segment of this proceeding in which Yuanxiang participated and was granted a separate rate was *Fresh Garlic from the People's Republic of China: Final Results and Final Rescission, In Part, of New Shipper Reviews,* 74 FR 50952 (October 2, 2009).

[42] *See Silicon Carbide,* 59 FR at 22586–87.

Department from assigning separate rates.

The absence of *de facto* government control over exports is based on whether a company: (1) Sets its own export prices independent 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.[43]

Each company certified that there is an absence of *de facto* government control of its exports in the most recently complete segment of proceeding in which it was granted a separate rate. Their separate rate certifications, stated, where applicable, that they had no relationship with any level of the PRC government with respect to ownership, internal management, and business operations. In this segment, we have no new information on the record that would cause us to reconsider the previous period's *de facto* control determinations with regard to these companies. Therefore, the Department preliminarily finds that these companies have established, *prima facie,* that they qualify for separate rates under the criteria established by *Silicon Carbide* and *Sparklers.*

Margin for the Separate Rate Recipients

As discussed above, the Department has preliminarily determined that Golden Bird, Xinboda, Henan Weite, Farmlady, QXF, Yuanxiang, and Jinyan have demonstrated their eligibility for separate rate status. The statute and the Department's regulations do not address the establishment of a rate to be applied to individual companies not selected for examination where the Department limited its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, we have looked to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance when calculating the rate for respondents we did not examine in an administrative review. For the exporters subject to a review that were determined to be eligible for separate rate status, but were not selected as mandatory respondents, the Department generally weight-averages the rates calculated for the mandatory respondents, excluding any rates that are zero, *de minimis,* or based entirely on facts available.[44] However, the Department has calculated a positive margin for the two fully participating mandatory respondents, Golden Bird and Xinboda. Accordingly, for the preliminary results, consistent with our practice, the Department has preliminarily determined that the margin to be assigned to the separate rate recipients should be a simple average of these two margins.[45]

Currency Conversion

We made currency conversions into U.S. dollars, in accordance with section 773A(a) of the Act, based on the exchange rates in effect on the dates of the U.S. sales, as certified by the Federal Reserve Bank. *See http://www.ia.ita.doc.gov/exchange/index.html.*

Preliminary Results

As a result of the review, the Department preliminarily determines that the following margins exist for the period November 1, 2009 through October 31, 2010:

Companies	Weighted-average margin (dollars per kilogram)
Hebei Golden Bird Trading Co., Ltd	$0.20/kg.
Shenzhen Xinboda Industrial Co., Ltd	$0.75/kg.
Henan Weite Industrial Co., Ltd	$0.48/kg.
Jinan Farmlady Trading Co., Ltd	$0.48/kg.
Qingdao Xintianfeng Foods Co., Ltd	$0.48/kg.
Chengwu County Yuanxiang Industry & Commerce Co., Ltd	$0.48/kg.
Yantai Jinyan Trading Co., Ltd	$0.48/kg.
PRC–Wide Rate	$4.71/kg.

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Act and 19 CFR 351.212(b), the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. The Department will direct CBP to assess importer-specific assessment rates based on the resulting per-unit (*i.e.,* per kilogram) amount on each entry of the subject merchandise during the POR. The Department intends to issue appropriate assessment instructions for such companies directly to CBP 15 days after the publication of this notice in the **Federal Register**.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For the exporters listed above, the cash deposit rate will be the rate established in these final results of review (except, if the rate is zero or *de minimis, i.e.,* less than 0.5 percent, a zero cash deposit rate will be required for that company); (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (3) for all PRC exporters of subject merchandise which have not been found to be entitled to a separate rate, the cash deposit rate will be the PRC-wide rate of $4.71 per kilogram; and (4) for all non-PRC exporters of subject merchandise which

[43] *See, e.g., Silicon Carbide,* 59 FR at 22587, and *Sparklers,* 56 FR at 20589; *see also Notice of Final Determination of Sales at Less Than Fair Value: Furfuryl Alcohol From the People's Republic of China,* 60 FR 22544, 22545 (May 8, 1995).

[44] *See, e.g., Wooden Bedroom Furniture From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review, Preliminary Results of New Shipper Review and Partial Rescission of Administrative Review,* 73 FR 8273, 8279 (February 13, 2008) (unchanged in *Wooden Bedroom Furniture from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and New Shipper Review,* 73 FR 49162 (August 20, 2008)).

[45] *See Multilayered Wood Flooring From the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 76 FR 64318 (October 18, 2011).

have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporter that supplied that non-PRC exporter. These requirements, when imposed, shall remain in effect until further notice.

Disclosure and Public Comment

The Department will disclose calculations performed for these preliminary results to the parties within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). Interested parties may submit written comments no later than 30 days after the date of publication of these preliminary results of review.[46] Rebuttals to written comments may be filed no later than five days after the written comments are filed.[47]

Any interested party may request a hearing within 30 days of publication of this notice.[48] Hearing requests should contain the following information: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. Oral presentations will be limited to issues raised in the briefs. If a request for a hearing is made, parties will be notified of the time and date for the hearing to be held at the U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.[49]

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 these preliminary results, pursuant to section 751(a)(3)(A) of the Act.

Notification to Importers

This notice 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 antidumping duties occurred and the subsequent assessment of double antidumping duties.

We are issuing and publishing these preliminary results in accordance with sections 751(a)(2)(B) and 777(i) of the Act, and 19 CFR 351.214(h) and 351.221(b)(4).

Dated: November 30, 2011.

Paul Piquado,

Assistant Secretary for Import Administration.

[FR Doc. 2011–31436 Filed 12–6–11; 8:45 am]

BILLING CODE 3510–DS–P

[46] *See* 19 CFR 351.309(c); Parties submitting written comments must submit them pursuant to the Department's e-filing regulations. *See https://iaaccess.trade.gov/help/IA%20ACCESS%20User%20Guide.pdf.*

[47] *See* 19 CFR 351.309(d).

[48] See 19 CFR 351.310(c).

[49] *See* 19 CFR 351.310(d).

DEPARTMENT OF COMMERCE

International Trade Administration

Executive-Led Business Development Mission to Kabul, Afghanistan; February 2012* Dates Are Withheld

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice.

Mission Description

The United States Department of Commerce's International Trade Administration is organizing a business development trade mission to Kabul, Afghanistan in February 2012. This mission will be led by a Senior Commerce Department official. Targeted sectors include: Construction (including engineering, architecture, transportation and logistics, and infrastructure); mining (including equipment, technology, and services); agribusiness; and information and communications technology. The mission's goal is to help U.S. companies explore long-term business opportunities in Afghanistan and enhance U.S.-Afghan commercial relations by providing U.S. participants with first-hand market information, access to government decision makers as well as one-on-one meetings with business contacts, including potential agents, distributors, and partners, to position themselves to enter or expand their presence in the targeted sectors.

Commercial Setting

The Government of the Islamic Republic of Afghanistan (GIRoA) is taking steps to develop its market economy and increase both domestic and foreign private investment. GIRoA continues to develop legal and administrative regulatory frameworks that will lead to a market more conducive to trade, investment and private sector development. For example, Afghanistan adopted an investment law that allows investments to be 100% foreign-owned. Additionally, on October 28, 2010, Afghanistan and Pakistan signed the Afghanistan Pakistan Transit Trade Agreement (APTTA), allowing Afghan container trucks to drive through Pakistan to the Indian border, and also to port cities such as Karachi.

After 30 years of war require reconstruction and development efforts are required to grow and stabilize Afghanistan's economy. The GIRoA is committed to promoting economic development, increasing production and earnings, promoting technology transfer, improving national prosperity and advancing Afghans' standard of living in partnership with international donor agencies. GIRoA recognizes that U.S. services, equipment and technology would enhance development of Afghanistan's industrial sector and lead to increased productivity and greater technical skills for Afghan citizens. International donors continue to support Afghanistan's development; however, long-term sustainable growth will take place through private sector development.

To support Afghanistan's private sector and promote reconstruction efforts, GIRoA has identified domestic priority sectors needing investment and development in both equipment and services. These priority sectors are: Construction and infrastructure, logistics and transportation, mining, agribusiness, and information and communications technology providers.

The economy is beginning to move from one based on state owned enterprises and the informal economy to a more formal market economy. A notable sign of this transition for the U.S. business community is the establishment of an American Chamber of Commerce in Kabul in 2010.

Kabul is the capital of Afghanistan, situated in Kabul Province. With a total metropolitan population of 2.6 million, it is also the largest city in Afghanistan. It is the commercial center for the country, with national Afghan businesses, associations, and GIRoA ministries maintaining a presence in Kabul. Afghanistan's GDP per capita is approximately $500, and has experienced double digit growth in recent years.

The Commerce Department has supported commercial and private sector development in Afghanistan since 2002, and posted a Senior Commercial Officer in Kabul in June 2010.

Mission Goals

The goal of the mission is to provide U.S. participants with first-hand market information, access to government decision makers and one-on-one meetings with business contacts, including potential agents, distributors, and partners, so that they can position themselves to enter the Afghan market

or expand their business presence in Afghanistan. Thus, the mission seeks to:

- Improve U.S. companies' understanding of commercial opportunities in Afghanistan.
- Facilitate business meetings between U.S. and Afghan businesses to promote the development of U.S. commercial opportunities in Afghanistan.
- Introduce U.S. industry to the Afghan business community and government leaders.
- Provide GIRoA policymakers with U.S. industry feedback on the direction of its commercial reforms.

Mission Scenario

The business development mission will take place in Kabul, Afghanistan. Participants will meet with Afghan leaders in the public and private sector, learn about the market by participating in Embassy briefings, and explore additional opportunities at networking receptions. Activities will include one-on-one meetings with pre-screened business prospects. (Note that the regular workweek in Afghanistan is Sunday through Thursday.)

PROPOSED TIMETABLE

[The State Department will follow RSO procedure in reference to security within and around the mission event.]

Day One (weekend)	Travel Day—Depart U.S. on evening flight.
Day Two	Travel Day—Participants arrive in transit city (tbd) and overnight in pre-arranged departure from transit city.
Day Three	Travel Day. Arrive in Kabul, Afghanistan (afternoon). Evening Event.
Day Four	Security Briefing. Market Briefing. One-on-One Business Appointments. Reception.
Day Five	Market Briefing. Industry Sector Briefing. Meetings with Government and Industry Officials. One-on-One Business Appointments. Reception.
Day Six	One-on-One Business Appointments (optional). Travel Day—Depart for the U.S. (evening).
Day Seven	Travel Day—Arrive in U.S. (morning).

Participation Requirements

This business development mission is designed for a minimum of 15 qualified companies and can accommodate a maximum of 20 participants from the companies accepted. All parties interested in participating in this business development mission to Kabul, Afghanistan, must submit a completed application package for consideration by the U.S. Department of Commerce. All applicants will be evaluated on their ability to meet certain conditions and to best satisfy the selection criteria as outlined below. U.S. companies already doing business in the target sectors as well as U.S. companies seeking to enter this market for the first time are encouraged to apply.

Fees and Expenses

After a company has been selected to participate in the mission, a payment to the U.S. Department of Commerce in the form of a participation fee is required. The participation fee is $4,800 for a single participant for a small- or medium-sized enterprise (SME) [1] and $5,245 for a single participant for a large firm. Participants per company will be limited due to space constraints. The fee for each additional participant is $1,500. Applicants are encouraged to provide a clear business purpose and clarification of role of any additional participants proposed to participate in the mission.

Interpretation services for official activities are included in the fee. Expenses for travel, lodging, meals, and incidentals will be the responsibility of each mission participant. Lodging and meals for each participant will cost approximately $150 USD per day.

Conditions for Participation

- An applicant must submit a completed and signed mission application and supplemental application materials, including information on the company's products and/or services, primary market objectives, and goals for participation. If the U.S. Department of Commerce receives an incomplete application, the Department may reject the application, request additional information, or take the lack of information into account when evaluating the application.
- Each applicant must also certify that the products and services it seeks to export through the mission are either produced in the United States, or, if not, marketed under the name of a U.S. firm and have at least fifty-one percent U.S. content.

Selection Criteria for Participation

Selection will be based on the following criteria:

- Suitability of the company's products or services to the mission goals.
- Applicant's potential for business in Afghanistan.
- Consistency of the applicant's goals and objectives with the stated scope of the mission.

(Additional factors, such as diversity of company, size, type and location may be considered during the selection process.)

Referrals from political organizations and any documents containing references to partisan political activities (including political contributions) will be removed from an applicant's submission and will not be considered during the selection process.

Timeframe for Recruitment and Applications

Mission recruitment will be conducted in an open and public manner, including posting on the U.S. Department of Commerce trade missions calendar—*http://www.trade.gov/trade-missions/*—and other Internet Web sites, publication in domestic trade publications and association

[1] An SME is defined as a firm with 500 or fewer employees or that otherwise qualifies as a small business under SBA regulations. *See http://www.sba.gov/contractingopportunities/owners/basics/whatismallbusiness/index.html.* Parent companies, affiliates, and subsidiaries will be considered when determining business size. The dual pricing reflects the Commercial Service's user fee schedule that became effective May 1, 2008. *See http://www.export.gov/newsletter/march2008/initiatives.html.*

newsletters, direct outreach to the Department's clients and distribution lists, publication in the **Federal Register**, and announcements at industry meetings, symposia, conferences, and trade shows.

Recruitment for the mission will begin immediately and conclude no later than January 3, 2012, by the close of business. Applications received after January 3, 2012, will be considered only if space and scheduling constraints permit.

Disclaimer, Security, and Transportation

Business development mission members participate in the mission and undertake related travel at their own risk and are advised to obtain insurance accordingly. Any question regarding insurance coverage must be resolved by the participant. The U.S. Government does not make any representations or guarantees as to the safety or security of participants. Companies should consult the State Department's travel warning for Afghanistan: *http://travel.state.gov/travel/cis_pa_tw/tw/tw_2121.html. http://travel.state.gov/travel/cis_pa_tw/tw/tw_2121.html.*

ITA will coordinate with the U.S. Embassy in Kabul to arrange for transportation of the mission participants to and from the airport and lodging facilities. The primary venue for the mission has security measures in place.

For More Information and an Application Packet Contact

U.S. Commercial Service Domestic Contact

Jessica Arnold, International Trade Specialist, U.S. Commercial Service, Washington, DC, *Tel.:* (202) 482–2026, *Email: afghanmission2011@trade.gov.*

Afghanistan Investment and Reconstruction Task Force Contact

Ariana Marshall, International Trade Specialist, Afghanistan Investment and Reconstruction Task Force, *Tel:* (202) 482–3754, *Email: afghanmission2011@trade.gov.*

Elnora Moye,

Trade Program Assistant.

[FR Doc. 2011–31424 Filed 12–6–11; 8:45 am]

BILLING CODE 3510–FP–P

DEPARTMENT OF COMMERCE

International Trade Administration

U.S. Education Mission to Poland and Czech Republic Warsaw, Poland and Prague, Czech Republic, April 15–19, 2012

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice.

Mission Description

The United States Department of Commerce, International Trade Administration, U.S. & Foreign Commercial Service, is coordinating and sponsoring an education industry trade mission to Warsaw, Poland and Prague, Czech Republic from April 15 to 19, 2012. This mission will include representatives from regionally accredited graduate programs and 4-year undergraduate educational institutions. This mission will seek to connect United States education institutions to potential students, university/institution partners and education consultants in Poland and the Czech Republic. The mission will include one-on-one appointments with potential partners, embassy briefings, student fairs and networking events in Warsaw and Prague, which represent the largest cities in two dynamic and growing countries that hold high potential for U.S. educational institutions interested in students from this region.

Commercial Setting

Poland

Poland is a prime target from which U.S. educational institutions can successfully recruit both graduate and undergraduate students. This market is not only the sixth largest country in the European Union in terms of population, but from a demographics standpoint, the population is heavily skewed towards young students with keen interest in higher education per the Ministry of Education. Poland's total population of 38 million includes over 5.5 million young people from 15 to 24 years of age, including 1.9 million students.

Polish students are well-disposed toward the United States, as exemplified by their foreign language curriculum. English is the first choice for a second language in this market and is used by almost all high school and university students. Since 2004, when Poland joined the European Union, Polish young adults have been participating in the European Union educational programs. Increasingly, young Polish students are also interested in expanding their experiences beyond the European Union. There is thus a strong core group of students who are very interested in studying in the United States per recent trends and sources.

Over 450 institutions of higher education exist in Poland, including 132 of public origin. Poland is currently undergoing a higher education reform. The legislation became effective October 1, 2011 and is expected to better organize and streamline the education process. The changes are expected to raise the standards for access to free-of-charge study programs, a side effect which may result in increased interest in studying abroad.

The Polish Ministry of Education and other higher education authorities strongly encourage Polish students to study abroad, and welcome foreign students to study in Poland as well. While most Polish students choose to study abroad in Europe, the interest in studying in the United States is still quite high. As in other European countries, the number of students studying in the United States has slightly declined over the last few years, mainly due to the global fiscal crisis. For the 2009/2010 academic year, there were 2,264 Polish students studying in the United States, compared to 2,772 in 2008. With the Polish economy continuing to experience positive growth and with stronger interest on the part of U.S. educational institutions to focus on the market, the trend is expected to reverse. It should be well noted that currently a balanced interest exists in both undergraduate as well as graduate studies.

Czech Republic

Study abroad programs are popular in the Czech Republic, as Czechs discovered travel and study abroad in the 1990s after the fall of communism. Though the number of Czechs studying in the United States experienced a decline in recent years, to about 1,000 students, current exchange rates and the visa waiver program are making U.S. education more attractive. The majority of university students are interested in economic and humanities subjects while technical areas rank as their third choice.

English is the standard second language in the Czech Republic, providing a large pool of candidates for both undergraduate and graduate studies in the U.S. A recent government decision that will make English language mandatory for primary school students should improve the ability of Czech students to study at U.S. universities and colleges. Many U.S.

higher education institutions have under-targeted this market and can take reap extra student recruitment opportunities in a country that has not been saturated with overseas student recruitment fairs.

Mission Goals

The goals of the U.S. Education Mission to the Czech Republic and Poland are:

(1) To gain market exposure and introduce participants to two growing student markets in the region, taking advantage of the United States' strong ties and positive reputation in these countries.

(2) To develop market knowledge and relationships that can enhance future recruitment of students as well as potential partnerships with local educational institutions

Mission Scenario

Participation in the mission will include the following:

- Pre-travel briefings/webinars;
- Embassy/consulate and industry briefings;
- Networking reception at Ambassador's Residence in Warsaw;
- Pre-scheduled meetings with university heads and educational consultants in Warsaw and Prague;
- Student recruitment fairs in Warsaw and Prague;
- Airport transfers to hotels and sites in Warsaw and Prague .

The precise schedule will depend on the specific goals and objectives of the mission participants.

PROPOSED TIMETABLE—APRIL 15–19 2012

Sunday, April 15, 2012	Arrive Warsaw.
Evening	Individual transfer to the hotel.
Monday, April 16.	
8:30 a.m.	Embassy briefing.
10:00 a.m.	Meeting at the Ministry of Higher Education or with one of the universities/schools.
11:30–1:00 p.m.	Set-up the venue and lunch on your own.
1:30–5:30 p.m.	Event.
5:30 p.m.	Closing down.
6:30–8:00 p.m.	Reception at the Residence.
9:00 p.m.	Return to hotel
Tuesday, April 17.	
8:30AM–12:00 p.m.	Individual meetings with Polish educational institutions, agents and other partners.
Afternoon	Plane Departure to Prague.
Wednesday, April 18.	
8:30–11:00AM	Breakfast and School Participant Meetings with Prospective Partners (Optional).
11:30–1:00 p.m.	Set-up the venue and lunch on your own.
2:00 p.m.	Embassy briefing.
3:00 p.m.	Event.
7:00 p.m.	Close down.
8:00 p.m.	Return to hotel.

Participation Requirements

All parties interested in participating in the Mission to the Czech Republic and Poland must complete and submit an application for consideration by the U.S. Department of Commerce. All applicants will be evaluated on their ability to meet certain conditions and best satisfy the selection criteria as outlined below. The mission will include a minimum of 15 and maximum of 20 qualified, regionally accredited U.S. education institutions.

Fees and Expenses

After an educational institution has been selected to participate on the mission, a payment to the U.S. Department of Commerce in the form of a participation fee is required. The participation fee is $1,995 for one principal representative from each regionally accredited educational institution.[1] The fee for each additional representative is $500. Expenses for lodging, some meals, incidentals, and all travel (except for transportation to and from airports in-country, previously noted) will be the responsibility of each mission participant.

Conditions for Participation

An applicant must submit a timely, completed and signed mission application and supplemental application materials, including adequate information on courses offerings, primary market objectives, and goals for participation.

Selection Criteria for Participation

Selection will be based on the following criteria:

- Suitability of a company's products or services to the mission's goals;
- Applicant's potential for business in Mexico, including likelihood of exports resulting from the trade mission;
- Consistency of the applicant's goals and objectives with the stated scope of the trade mission (*i.e.,* the sectors indicated in the mission description).

Referrals from political organizations and any documents containing references to partisan political activities (including political contributions) will be removed from an applicant's submission and not considered during the selection process.

Selection Timeline

Mission recruitment will be conducted in an open and public manner, including publication in the **Federal Register**, posting on the U.S. Department of Commerce trade mission calendar (*http://www.trade.gov/trade-missions*) and other Internet Web sites, press releases to general and trade media, direct mail, notices by industry trade associations and other multiplier groups, and publicity at industry meetings, symposia, conferences, and trade shows. Recruitment for the mission will begin immediately and conclude no later than January 31, 2012. The mission will be open on a first-

[1] An SME is defined as a firm with 500 or fewer employees or that otherwise qualifies as a small business under SBA regulations (see *http://www.sba.gov/services/contracting opportunities/sizestandardstopics/index.html*). Parent companies, affiliates, and subsidiaries will be considered when determining business size. The dual pricing reflects the Commercial Service's user fee schedule that became effective May 1, 2008 (see *http://www.export.gov/newsletter/march2008/initiatives.html* for additional information).

come, first-serve basis. Applications received after that date will be considered only if space and scheduling constraints permit.

Contacts

Mr. James Paul, Director, CS Boston, MA, *Phone:* (617) 565–4304/*Fax:* (617) 565–4313, *Email: jpaul@trade.gov.*

Gabriela Zelaya, International Trade Specialist, CS San Jose, CA, *Phone:* (408) 535–2757, Ext. 107/*Fax:* (408) 535–2758, *Gabriela.Zelaya@trade.gov.*

Elnora Moye,

Trade Program Assistant.

[FR Doc. 2011–31422 Filed 12–6–11; 8:45 am]

BILLING CODE 3510–FP–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XA852

Endangered and Threatened Species; 5-Year Reviews for 4 Distinct Population Segments of Steelhead in California

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of availability of 5-year reviews.

SUMMARY: We, the National Marine Fisheries Service (NMFS) Southwest Region, announce the availability of 5-year reviews for four DPSs of steelhead (*Oncorhynchus mykiss*) in California, as required by the Endangered Species Act (ESA). Information about the 5-year review process, including copies of the 5-year review reports, may be obtained by visiting the NMFS Southwest Regional Office Web site at *http://swr.nmfs.noaa.gov/.*

ADDRESSES: Additional information about the 5-year review process, including copies of the 5-year review reports, may be obtained by visiting the NMFS Southwest Regional Office Web site at *http://swr.nmfs.noaa.gov/* or by writing to us at: NMFS Southwest Region, 501 W. Ocean Blvd., Suite 4200, Long Beach, CA 90802; *Attn:* Craig Wingert.

FOR FURTHER INFORMATION CONTACT: Craig Wingert at the above address or at (562) 980–4021.

SUPPLEMENTARY INFORMATION:

Background

Under the ESA, a list of endangered and threatened wildlife and plant species must be maintained. The list is published at 50 CFR 17.11 (for animals) and 17.12 (for plants). Section 4(c)(2)(A) of the ESA requires that NMFS conduct a review of listed species under its jurisdiction at least once every 5 years (''5-year reviews''). In conducting 5-year reviews, we consider the best scientific and commercial data, including new information that has become available since the last listing determination or most recent status review of a species.

On March 18, 2010, NMFS announced the initiation of 5-year reviews for listed Pacific salmon ESUs and steelhead DPSs in California, Oregon, Washington, and Idaho (75 FR 13082). Both ESUs and DPSs are treated as ''species'' under the ESA and we use the term ''species'' to refer to both in the remainder of this notice. In the March 18, 2010 announcement, we requested new information regarding the biological status of these ESUs and DPSs and the factors that affect them from the public, concerned governmental agencies, Tribes, the scientific community, environmental entities, and other interested parties.

This notice of availability addresses our completed 5-year reviews for: (1) Northern California steelhead; (2) Central California Coast steelhead; (3) South-Central California Coast steelhead; and (4) Southern California steelhead. We used a two-step process to complete the reviews. First, we asked scientists from our Southwest Fisheries Science Center to collect and analyze new information about each species' viability. To evaluate each species' viability, our scientists applied the agency's Viable Salmonid Population framework, which relies on evaluating four key population parameters (abundance, productivity, spatial structure, and diversity). Using this framework, they compiled and evaluated all new relevant information on these four parameters and then updated the overall viability status of each species. They also considered new genetic and biogeographic information related to each species' freshwater and estuarine geographic boundaries. At the end of this process, the Center prepared a report detailing the results and conclusions from their analyses. To complete the review, fishery biologists from the Southwest Region and its field offices evaluated all information that has become available on the species since 2005, the date of its last biological status review.

The 5-year review reports prepared by the Southwest Region, the Southwest Science Center's updated status assessment, and additional information concerning these species are available on the Southwest Region's Web site: *http://swr.nmfs.noaa.gov/.* NMFS concludes that the 5-year review meets the requirements of the ESA.

Authority: 16 U.S.C. 1531 *et seq.*

Dated: November 30, 2011.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2011–31433 Filed 12–6–11; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XO45

Marine Mammals; File No. 14241, Correction

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; receipt of application for permit amendment; correction.

SUMMARY: Notice is hereby given that Dr. Peter Tyack, Woods Hole Oceanographic Institution, Woods Hole, MA has applied for an amendment to Permit No. 14241–02 to conduct research on marine mammals. This document makes a correction to a previously published document (December 2, 2011) in which the **DATES** section was inadvertently omitted.

DATES: Written, telefaxed, or email comments must be received on or before January 3, 2012.

ADDRESSES: The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the *Features* box on the Applications and Permits for Protected Species home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 14241 from the list of available applications.

These documents are also available upon written request or by appointment in the following office(s):

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376;

Northeast Region, NMFS, 55 Great Republic Drive, Gloucester, MA 01930; phone (978) 281–9300; fax (978) 281–9333; and

Southeast Region, NMFS, 263 13th Avenue South, Saint Petersburg, Florida 33701; phone (727) 824–5312; fax (727) 824–5309.

FOR FURTHER INFORMATION CONTACT: Tammy Adams or Carrie Hubard, (301) 713–2289.

SUPPLEMENTARY INFORMATION:

Need for Correction

On December 2, 2011 (76 FR 75524) notice of receipt of an application to amend Permit No. 14241–02 was inadvertently published without specifying the date on which comments are due. Applications are available for comment for 30 days from publication of the notice of receipt. The comment deadline is specified in the **DATES** section of this correction notice.

Dated: December 2, 2011.

Tammy C. Adams,

Acting Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2011–31435 Filed 12–6–11; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XA856

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of a public meeting.

SUMMARY: The Pacific Fishery Management Council's (Council) Highly Migratory Species Management Team (HMSMT) will a hold work session, which is open to the public.

DATES: The work session will be held January 10, 2012 through January 12, 2012. The HMSMT work session will begin each day at 8:30 a.m. and continue until business is completed.

ADDRESSES: The work sessions will be held at Large Conference Room, Torrey Pines Court, National Marine Fisheries Service Southwest Fisheries Science Center, 3333 North Torrey Pines Court, La Jolla, CA 92037; *telephone:* (858) 546–7000.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Dr. Kit Dahl, Pacific Fishery Management Council; *telephone:* (503) 820–2280.

SUPPLEMENTARY INFORMATION: The HMSMT will discuss work assignments to be delivered at the March 2012 Council meeting in Sacramento, CA. The first assignment is the development of recommendations for a management framework for North Pacific albacore tuna fisheries. This will help inform the Council in relation to the development of such a framework planned by the Western and Central Pacific Fisheries Commission Northern Committee. The second assignment is to provide information to the Council about future management of the U.S. west coast swordfish fishery. The HMSMT will also begin work on the next SAFE (Stock Assessment and Fishery Evaluation) document, which is prepared annually, summarizing information from the previous year. Informational topics may also be discussed, time permitting.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during these meetings. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt at (503) 820–2280 at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 1, 2011.

Tracey L. Thompson,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2011–31326 Filed 12–6–11; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Submission for OMB Review; Comment Request

The United States Patent and Trademark Office (USPTO) will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. 35).

Agency: United States Patent and Trademark Office (USPTO).

Title: Statutory Invention Registration.

Form Number(s): PTO/SB/94.

Agency Approval Number: 0651–0036.

Type of Request: Revision of a currently approved collection.

Burden: 4 hours annually.

Number of Respondents: 8 responses per year.

Avg. Hours per Response: The USPTO expects that it will take the public approximately 24 minutes (0.40 hours) to gather the necessary information, create the document, and submit the completed request.

Needs and Uses: 35 U.S.C. 157, administered by the USPTO through 37 CFR 1.293–1.297, authorizes the USPTO to publish a statutory invention registration containing the specifications and drawings of a regularly filed application for a patent without examination, providing the applicant meets all the requirements for printing, waives the right to receive a United States patent on the invention claimed in the identified patent application within a certain period of time prescribed by the USPTO, and pays all application, publication, and other processing fees.

The America Invents Act, Public Law 112–29, was enacted September 16, 2011. It calls for the repeal of Statutory Invention Registration 18 months after the enactment of the Act. The USPTO, therefore, will request renewal for this collection based upon the impending requirement for discontinuation in early 2013.

Affected Public: Businesses or other for-profits.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Nicholas A. Fraser, email: *Nicholas_A._Fraser@omb.eop.gov.*

Once submitted, the request will be publicly available in electronic format through the Information Collection Review page at *http://www.reginfo.gov.*

Paper copies can be obtained by:

- *Email: InformationCollection@uspto.gov.* Include ''0651–0036 copy request'' in the subject line of the message.
- *Mail:* Susan K. Fawcett, Records Officer, Office of the Chief Information Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

Written comments and recommendations for the proposed information collection should be sent on or before January 6, 2012 to Nicholas A. Fraser, OMB Desk Officer, via email to *Nicholas_A._Fraser@omb.eop.gov,* or by fax to (202) 395–5167, marked to the attention of Nicholas A. Fraser.

Dated: December 2, 2011.

Susan K. Fawcett,

Records Officer, USPTO, Office of the Chief Information Officer.

[FR Doc. 2011–31353 Filed 12–6–11; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

National Medal of Technology and Innovation Nomination Application

ACTION: Proposed collection; comment request.

SUMMARY: The United States Patent and Trademark Office (USPTO), 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 the extension of a continuing information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before February 6, 2012.

ADDRESSES: You may submit comments by any of the following methods:

- *Email: InformationCollection@uspto.gov.* Include ''0651–0060 comment'' in the subject line of the message.
- *Mail:* Susan K. Fawcett, Records Officer, Office of the Chief Information Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.
- *Federal Rulemaking Portal: http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to the attention of Steven Berk, Program Manager, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450, by telephone at (571) 272–8400, or by email to *nmti@uspto.gov.* with ''Paperwork'' in the subject line. Additional information about this collection is also available at *http://www.reginfo.gov* under ''Information Collection Review.''

SUPPLEMENTARY INFORMATION:

I. Abstract

The National Medal of Technology and Innovation is the highest honor for technological achievement bestowed by the President of the United States on America's leading innovators. Established by an Act of Congress in 1980, the Medal of Technology was first awarded in 1985. The Medal is awarded annually to individuals, teams (up to four individuals), companies or divisions of companies for their outstanding contributions to the Nation's economic, environmental and social well-being through the development and commercialization of technology products, processes and concepts, technological innovation, and development of the Nation's technological manpower.

The purpose of the National Medal of Technology and Innovation is to recognize those who have made lasting contributions to America's competitiveness, standard of living, and quality of life through technological innovation, and to recognize those who have made substantial contributions to strengthening the Nation's technological workforce. By highlighting the national importance of technological innovation, the Medal also seeks to inspire future generations of Americans to prepare for and pursue technical careers to keep America at the forefront of global technology and economic leadership.

The National Medal of Technology and Innovation Nomination Evaluation Committee, a distinguished independent committee appointed by the Secretary of Commerce, reviews and evaluates the merit of all candidates nominated through an open, competitive solicitation process. The committee makes its recommendations for Medal candidates to the Secretary of Commerce who, in turn, makes recommendations to the President for final selection. The National Medal of Technology and Innovation Laureates are announced by the White House and the Department of Commerce once the Medalists are notified of their selection.

The public uses the National Medal of Technology and Innovation Nomination Application to recognize through nomination an individual's, team's or company's extraordinary leadership and innovation in technological achievement. The application must be accompanied by six letters of recommendation or support from individuals who have first-hand knowledge of the cited achievement(s).

II. Method of Collection

The nomination application and instructions can be downloaded from the USPTO Web site. Nomination files should be submitted by electronic mail to *NMTI@USPTO.gov.* Alternatively, letters of recommendation may be sent by electronic mail, fax, or overnight delivery.

III. Data

OMB Number: 0651–0060.

Form Number(s): None.

Type of Review: Extension of a currently approved collection.

Affected Public: Primarily business or other for-profit organizations; not-for-profit institutions; individuals or households.

Estimated Number of Respondents: 40 responses per year.

Estimated Time per Response: The USPTO estimates that it will take approximately 40 hours to gather the necessary information, prepare the nomination form, write the recommendations, and submit the request for the nomination to the USPTO.

Estimated Total Annual Respondent Burden Hours: 1,600 hours.

Estimated Total Annual Respondent Cost Burden: $60,000. The USPTO expects that private sector individuals of various occupations and professions will complete this information. The hourly rate for these individuals is estimated to be $37.50.

Item	Estimated time for response (hours)	Estimated annual responses	Estimated annual burden hours
National Medal of Technology and Innovation Nomination Form	40	40	1,600
TOTALS		40	1,600

Estimated Total Annual (Non-Hour) Respondent Cost Burden: $0.

Although it is possible for the public to submit the nominations through regular or express mail, to date no submissions have been received in this manner. The majority of recent submissions have been through electronic mail. The USPTO, therefore, is not calculating an estimate of postage costs associated with this information collection.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, *e.g.,* the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection; they will also become a matter of public record.

Dated: December 2, 2011.

Susan K. Fawcett,

Records Officer, USPTO, Office of the Chief Information Officer.

[FR Doc. 2011–31356 Filed 12–6–11; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No. PTO–C–2011–0081]

Extension of Comment Period Regarding Comments on Intellectual Property Enforcement in China

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of extension of public comment period.

SUMMARY: To provide interested parties with the opportunity to comment further to the original request for public comment (see *http://www.gpo.gov/fdsys/pkg/FR–2011–10–17/pdf/2011–26757.pdf*), The United States Patent and Trademark Office (''USPTO'') is extending the period for public comment regarding any challenges that U.S. inventors and companies are facing with the judicial and/or administrative patent enforcement systems of the People's Republic of China.

USPTO invites any member of the public to submit written comments on China's patent enforcement system, including, but not limited to, the following five topics: acquisition and enforcement of utility model and design patents; evidence collection and preservation in Chinese courts; obtaining damages and injunctions; enforceability of court orders and judgments; and administrative patent enforcement. The USPTO would like to resolve rights holders' concerns by working with them to identify problems regarding these and other areas of China's patent enforcement system so that it can then address these issues with the Chinese Government. To help the USPTO address these issues, it encourages interested members of the public to respond to this request.

DATES: Written comments must be received on or before December 21, 2011.

ADDRESSES: Written comments should be sent by electronic mail message via the Internet addressed to *IP.Policy@uspto.gov.* Comments may also be submitted by mail addressed to: Mail Stop OPEA, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450, *Attn:* Elizabeth Shaw. Although comments may be submitted by mail, the USPTO prefers to receive comments via the Internet. If you would like to submit confidential business information that supports your comments, please contact Elizabeth Shaw at *elizabeth.shaw2@uspto.gov,* or 571–272–8494.

The written comments will be available for public inspection by appointment only at the Office of Policy and External Affairs in the Executive Library located in the Madison West Building, Tenth Floor, 600 Dulany Street, Alexandria, Virginia, 22314. *Contact:* Elizabeth Shaw at *elizabeth.shaw2@uspto.gov,* or 571–272– 8494.

Because comments will be made available for public inspection, information that is not desired to be made public, such as an address or phone number should not be included in the comments.

FOR FURTHER INFORMATION CONTACT: Elizabeth Shaw, Office of Policy and External Affairs, by phone 571–272–8494, by facsimile to 571–273–0123, by email at *elizabeth.shaw2@uspto.gov,* or by mail addressed to: Mail Stop OPEA, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, Virginia 22313–1450, *Attn:* Elizabeth Shaw.

SUPPLEMENTARY INFORMATION: On October 17, 2011, the USPTO published a Request for Comments on Intellectual Property Enforcement in China. *See* 76 FR 64075, Oct. 17, 2011. More specifically, the USPTO invited members of the public to comment on their patent enforcement experiences in China. Of concern were the two primary avenues of patent enforcement in China: the judiciary; and the State Intellectual Property Office (SIPO). In regard to the former, concerns over China's judiciary (such as lack of adequate discovery powers, evidentiary burdens, and low damages rewards) have been cited as reasons why U.S. and foreign companies do not file more patent suits in Chinese courts. In regard to the latter, limited investigative powers of the agency and ineffectual penalties for infringement have been cited as reasons for the weakness of this enforcement route.

The notice invited the public to submit written comments on China's patent enforcement system, including, but not limited to, the following five topics: (1) Acquisition and enforcement of utility model and design patents; (2) evidence collection and preservation in Chinese courts; (3) obtaining damages and injunctions; (4) enforceability of court orders; and (5) administrative patent enforcement. The USPTO is now extending the period for submission of public comments until *December 21, 2011.*

Dated: November 30, 2011.

David J. Kappos,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2011–31305 Filed 12–6–11; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Public Meeting on the Draft Environmental Impact Statement for Basewide Water Infrastructure and Stuart Mesa Bridge Replacement at Marine Corps Base Camp Pendleton, CA

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: Pursuant to Section (102)(2)(c) of the National Environmental Policy Act of 1969 (NEPA) (42 United States Code [U.S.C.] Sections 4321–4370h); the Council on Environmental Quality (CEQ) regulations for implementing the procedural provisions of NEPA (Title 40 Code of Federal Regulations (CFR) parts 1500–1508); Department of the Navy Procedures for Implementing NEPA (32 CFR part 775); and Marine Corps NEPA directives (Marine Corps Order P5090.2A), the Marine Corps (USMC) has prepared and filed with the U.S. Environmental Protection Agency (EPA) a Draft Environmental Impact Statement

(EIS) that evaluates the potential environmental consequences that may result from implementing the Basewide Water Infrastructure and Stuart Mesa Bridge Replacement projects at Marine Corps Base Camp Pendleton (MCBCP). The proposed action would involve the construction, operation, and maintenance of infrastructure upgrades, expansions, and improvements to the Basewide water system and replacement of a critical link in the Base roadway system. The projects would include a northern Advanced Water Treatment (AWT) plant and associated facilities, connection of the Base's northern and southern water systems, and replacement of the bridge on Stuart Mesa Road over the Santa Margarita River (Stuart Mesa Bridge). A Notice of Intent to prepare this EIS was published in the **Federal Register** on March 31, 2010 (Vol. 75, No. 61, p. 16080).

With the filing of the Draft EIS, the Department of the Navy (DoN) is initiating a 45-day public comment period and has scheduled a public open house meeting to receive oral and written comments on the Draft EIS. Federal, State, and local agencies and interested individuals are invited to be present or represented at the public meeting. This notice announces the date and location of the public meeting, and supplementary information about the environmental planning effort.

DATES: The Draft (EIS) public review period will begin December 2, 2011, and end on January 17, 2012. The USMC is holding an informational open house style public meeting to inform the public about the proposed action and the alternatives under consideration, and to provide an opportunity for the public to comment on the Draft EIS. USMC and DoN representatives will be on hand to discuss the proposed action, the NEPA process and the findings presented in the Draft EIS. The meeting will be held from 5:30 p.m. to 8:30 p.m. in the Ole Hanson Fireside Room at the San Clemente Community Center, 100 North Calle Seville, San Clemente, California 92672 on January 5, 2012. The Draft EIS was distributed to Federal, State, and local agencies, elected officials, and other interested parties and individuals on December 2, 2011. The document can be viewed online and downloaded from *www.marines.mil/unit/basecamppendleton/Pages/BaseStaffandAgencies/Environmental/EAEIS/Home.aspx.*

Copies of the Draft EIS are available for public review at the following public libraries: Oceanside Civic Center Library, 330 North Coast Highway, Oceanside, California 92054; San Clemente Library, 242 Avenida del Mar, San Clemente, California 92672; and Fallbrook Branch, San Diego County Public Library, 124 S. Mission Road, Fallbrook, California 92028.

A copy of the Draft EIS will be made available upon written request to Mr. Jesse Martinez, Naval Facilities Engineering Command (NAVFAC) Southwest, 1220 Pacific Highway, San Diego, CA 92132–5190, (619) 532–3844.

Comments

Attendees will be able to submit written comments at the public meeting; a stenographer will also be present to transcribe oral comments. Equal weight will be given to oral and written statements. Comments may be mailed to Mr. Jesse Martinez, NAVFAC Southwest, 1220 Pacific Highway, San Diego, CA 92132–5190. Comments may be submitted during the 45-day public review period. All comments must be postmarked or electronically dated on or before January 17, 2012, to be sure they become part of the public record. All statements, oral transcription and written, submitted during the public review period will become part of the public record on the Draft EIS and will be responded to in the Final EIS.

FOR FURTHER INFORMATION CONTACT: Mr. Jesse Martinez, NAVFAC Southwest, (619) 532–3844. Please submit requests for special assistance, sign language interpretation for the hearing impaired, or other auxiliary aids at the public meeting to Mr. Martinez.

SUPPLEMENTARY INFORMATION: The proposed action evaluated in the Draft EIS is the construction and operation, including maintenance, of three infrastructure projects entirely within MCBCP and funded by Military Construction (MILCON) program appropriation. These projects include an advanced water treatment plant and associated facilities in the northern part of the Base (MILCON Project Number P–1044); connection of the Base's northern and southern water systems (P–1045); and replacement of the Stuart Mesa Bridge over the Santa Margarita River and associated roadway/flood control improvements (P–1039). Each project is a separate, distinct, and independently complete and usable action. Full environmental analyses for four action alternatives, and a No Action Alternative are presented in the Draft EIS.

Purpose and Need

The proposed action is needed to modernize and expand the capacity and capability of MCBCP's aging (1960s era) potable water system and roadway infrastructure.

The current potable water piping and treatment system is outdated and undersized. Higher quality drinking water through advanced water treatment is needed in the northern portion of the Base because the current water treatment processes do not meet the secondary drinking water standards for total dissolved solids and may not meet the pending Federal Safe Drinking Water Act Stage 2 Disinfectant Byproducts Rule. In addition, the two Base water systems, the northern system and the southern system, are not connected. The independent systems have resulted in service interruptions to portions of the Base during maintenance and natural disasters.

In the case of the roadway system, the Stuart Mesa Bridge, together with nearby roadway segments and the adjacent intersection of Stuart Mesa Road and Vandegrift Boulevard, represents a critical roadway connection on the main internal north-south connector in the southern and western portions of MCBCP. The roadway link has been severed in the past by flooding, underscoring the need for an all-weather solution.

The purpose of the proposed action is to enhance the ability of MCBCP to efficiently meet its mission by developing new or upgraded, reliable, and compliant infrastructure systems necessary to sustain military training and operations and quality of life services on MCBCP. The purpose is to provide: (1) Improved water treatment capabilities, capacity, and drinking water system redundancy to deliver higher quality water in the north; (2) water security and a connected, more comprehensive system for the delivery of Basewide water services during periods of scheduled, unscheduled, and emergency system interruption; and (3) improved traffic flow and efficient all-weather traffic accessibility to key training and non-training areas in the southern portion of MCBCP that are now severed during periodic flooding in the vicinity of the Stuart Mesa Bridge.

Alternatives

The EIS evaluates three MILCON projects (P–1044, P–1045, and P–1039) and four alternatives for each MILCON for a total of 12 action alternatives. As the environmental and engineering assessment developed for the proposed action, a combination of alternatives were identified as the preferred alternative based on operational, environmental, economic, and military sustainability reasons. The preferred alternatives are P–1044 Alternative 1;

P–1045 Alternative 3; and P–1039 Alternative 4. Each is identified and discussed below.

Advanced Water Treatment (AWT) North and Associated Facilities (MILCON P–1044). Four alternatives involving a combination of two AWT plant sites and two pipeline routes were evaluated. All alternatives include construction of an 8.6 million gallon per day AWT facility, new and replacement water lines, pump stations with emergency generators, connection to existing reservoirs and distribution system, a brine disposal system, and plant access improvements. Raw water, treated water, and brine would be conveyed via new proposed lines. Raw water lines would extend from the existing wells to the AWT facility. Treated water lines would extend from the AWT facility to the west to serve the San Onofre Housing Areas and the 51 Area (San Onofre), 62 Area (San Mateo), 63 Area (Cristianitos), 64 Area (Talega), 52 Area (School of Infantry), and 53 Area (Horno). Trenchless construction to extend lines beneath San Onofre Creek and San Mateo Creek or suspension of the pipelines over the creeks would be incorporated to minimize impacts. Following water treatment at the AWT, brine would be disposed via ocean outfall and injection wells. The ocean outfall disposal would use the existing decommissioned San Onofre Nuclear Generating Station (SONGS) 12-foot-diameter, 3,200-foot-long cooling water intake structure located on the Pacific Ocean floor. Two deep injection well fields (approximately 750 feet deep) would also be used. One would be located at the existing San Onofre percolation ponds and the other would be located northwest of the San Onofre Surf Beach area of San Onofre State Beach. The proposed AWT facility would include micro-filtration and liquid granulated activated carbon/reverse osmosis.

Alternative 1 (Preferred Alternative). Under this alternative the AWT facility would be constructed at a location south of San Onofre Creek. A portion of the conveyance lines would be located within Basilone Road. The brine disposal line would extend from the AWT facility to the south to connect to the proposed injection wells and to the existing SONGS ocean intake pipeline. The line to SONGS would extend beneath Interstate-5 (I–5) via trenchless construction.

Alternative 2. Under this alternative, raw water, treated water, and brine would be conveyed via three proposed new pipelines located primarily in El Camino Real instead of Basilone Road as proposed under Alternative 1.

Alternative 3. Under this alternative, the AWT facility would be located south of Basilone Road. Water conveyance pipelines would be the same as Alternative 1.

Alternative 4. Under this alternative, the AWT facility would be located south of Basilone Road. Water conveyance pipelines would be the same as Alternative 2.

Connection of North and South Water Systems (MILCON P–1045). Four alternatives involving different pipeline routes were evaluated.

Alternative 1. Under this alternative, approximately 188,000 linear feet (LF) of potable water lines sized up to 36 inches in diameter would connect the northern and southern water systems of MCBCP. The water line would start at the new AWT North facility (P–1044) and extend south on an alignment using El Camino Real to Stuart Mesa Road. Dividing at the junction of Stuart Mesa Road and Las Pulgas Road, one branch would run north along Las Pulgas Road to an existing reservoir in the 43 Area (Las Pulgas). This lateral pipeline would be approximately 10 to 14 inches in diameter. The other branch would continue along Stuart Mesa Road before splitting again into two more branches. One of these branches would extend northeast on the west side of the Santa Margarita River along North River Road, passing east of the 32 Area (Marine Air Control Squadron-1) and 33 Area (Margarita) and west of the 23 Area (Marine Corps Air Station Camp Pendleton) to Basilone Road and on to connect to the AWT South facility at Haybarn Canyon as well as several reservoirs along a ridge above the AWT South. The second branch would continue south along Stuart Mesa Road, crossing under or suspending over the Santa Margarita River and then north along Vandegrift Boulevard to an existing pump station and several existing reservoirs in the Wire Mountain area. The construction and operation of a new 4-million-gallon water reservoir in the Wire Mountain area is proposed along with associated water line connections to serve the new Naval Hospital Camp Pendleton (currently under construction) and the 21 Area (Del Mar). The pipelines would use trenchless construction under or suspended over San Onofre Creek, Las Flores Creek, Aliso Canyon drainage, French Creek, and two locations on the Santa Margarita River to avoid impacts to these areas. The project would also include the construction and operation of three pump stations along the alignment. Maintenance access/recreation corridors could also be included.

Alternative 2. The proposed north-south pipeline would start at the new AWT North facility (P–1044) and extend south in El Camino Real to Las Pulgas Road and run north in Las Pulgas Road to Basilone Road. The water line would extend along Basilone Road to Vandegrift Boulevard and run east to connect to the AWT South at Haybarn Canyon as well as several reservoirs along a ridge above the AWT South. This alternative would require an additional pump station and would be approximately 165,000 LF.

Alternative 3 (Preferred Alternative). This alternative would be similar to Alternative 1 except it would not include the segment on the west side of the Santa Margarita River along North River Road. The new 4-million-gallon water reservoir and connections to the new Naval Hospital Camp Pendleton and the 21 Area (Del Mar) would be included. This alternative would be approximately 137,000 LF.

Alternative 4. This alternative would be similar in alignment to Alternative 3, with an additional pipe segment extending further on Vandegrift Boulevard east of the 22 Area (Chappo) before connecting to the AWT South at Haybarn Canyon as well as several reservoirs along a ridge above the AWT South. This alternative would be approximately 179,000 LF.

Stuart Mesa Bridge Replacement and Flood Control Improvements (P–0139). Four alternatives including a combination of two flood control methods and the use of a temporary bridge during construction were evaluated. All alternatives include demolition of the existing Stuart Mesa Bridge and construction of a new four lane bridge and flood protection measures.

Alternative 1. Construction would consist of a new cast-in-place prestressed concrete bridge (approximately 1,200 feet long by 56 feet wide) with pile foundations, new approach road and bridge abutments, earthwork and grading, rock protection and revetment, bridge deck, guard rails, night lighting, asphalt pavement, and pavement marking and signs. The project includes ''100-year storm'' flood protection control measures to protect Stuart Mesa Road and Vandegrift Boulevard. Flood control facilities consist of levees, levee scour protection, and a storm water drain system. Under this alternative, no temporary replacement bridge would be constructed over the Santa Margarita River and traffic would need to utilize alternate existing routes during construction.

Alternative 2. Under this alternative, a temporary use bridge would be constructed to allow vehicular traffic along Stuart Mesa Road to continue to cross the Santa Margarita River. Bridge construction would be the same as Alternative 1.

Alternative 3. Under this alternative, flood walls would be constructed rather than levees. The flood walls, while having a smaller construction footprint, would provide the same flood control protection. No temporary replacement bridge would be constructed over the Santa Margarita River. Bridge construction would be the same as Alternative 1.

Alternative 4 (Preferred Alternative). This alternative would be similar to Alternative 3, with the exception of a construction phase temporary use bridge, which would allow traffic along Stuart Mesa Road to continue to cross the Santa Margarita River during demolition of the existing bridge and construction of the new bridge.

Environmental Issues

The Draft EIS evaluates the potential environmental effects associated with each of the alternatives. Issues addressed include: Geology and soils, hydrology and water quality, biological resources, cultural resources, land use, visual resources, socioeconomics and environmental justice, traffic, air quality, noise, public health and safety, services and utilities, and coastal zone resources, and marine resources. Relevant and reasonable measures that could alleviate environmental effects have been considered.

Schedule

A 45-day public comment period will start upon publication of the EPA Notice of Availability in the **Federal Register**. Comments on the Draft EIS must be received by January 17, 2012. The DoN will consider and respond to all comments received on the Draft EIS when preparing the Final EIS. The DoN expects to issue the Final EIS in June 2012, at which time a Notice of Availability (NOA) will be published in the **Federal Register** and local print media. A Record of Decision is expected in August 2012.

Dated: November 29, 2011

L.R. Almand,

Alternate Federal Register Liaison Officer, Office of the Judge Advocate General, U.S. Navy.

[FR Doc. 2011–31344 Filed 12–6–11; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Comment Request.

SUMMARY: The Department of Education (the Department), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the reporting burden on the public and helps the public understand the Department's information collection requirements and provide the requested data in the desired format. The Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before February 6, 2012.

ADDRESSES: Comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov* or mailed to U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Washington, DC 20202–4537. Please note that written comments received in response to this notice will be considered public records.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35) requires that Federal agencies provide interested parties an early opportunity to comment on information collection requests. The Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management, publishes this notice containing proposed information collection requests at the beginning of the Departmental review of the information collection. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: December 2, 2011.

Darrin King,

Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

Institute of Education Sciences

Type of Review: Revision.

Title of Collection: Integrated Evaluation of ARRA Funding, Implementation and Outcomes.

OMB Control Number: 1850–0877.

Agency Form Number(s): N/A.

Frequency of Responses: Annually; Once.

Affected Public: State, Local or Tribal Government.

Total Estimated Number of Annual Responses: 5,551.

Total Estimated Annual Burden Hours: 5,039.

Abstract: On February 17, 2009, President Obama signed the American Recovery and Reinvestment Act (ARRA) into law (Pub. L. 111–50). ARRA supports investments in innovative strategies that are intended to lead to improved results for students, long-term gains in school and local education agency (LEA) capacity for success, and increased productivity and effectiveness.

This evaluation will focus on answering three sets of policy/research questions:

- To what extent did ARRA funds go to the intended recipients?
- Is ARRA associated with the implementation of the key reform strategies it promoted?
- What implementation supports and challenges are associated with ARRA?

The integrated evaluation will draw on existing data, including ED data collections, ED ARRA program files, ARRA required reporting, and databases of achievement and other outcomes. The evaluation will also collect new information through surveys of (1) The 50 states and the District of Columbia, (2) a nationally representative sample of school districts, and (3) a nationally representative sample of schools within the sampled school districts. Surveys were conducted in spring 2011 and are planned for spring 2012.

A report will be prepared to describe the distribution of funding. A report and state tabulations will be prepared after each annual survey. The first report, based on the 2011 surveys, will focus on early ARRA implementation and strategies. The second report, based on the 2012 surveys, will expand upon strategies implemented under ARRA.

Copies of the proposed information collection request may be accessed from

http://edicsweb.ed.gov, by selecting the ''Browse Pending Collections'' link and by clicking on link number 4754. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to (202) 401–0920. Please specify the complete title of the information collection and OMB Control Number when making your request.

Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–(800) 877–8339.

[FR Doc. 2011–31381 Filed 12–6–11; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Comment request.

SUMMARY: The Department of Education (the Department), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the reporting burden on the public and helps the public understand the Department's information collection requirements and provide the requested data in the desired format. The Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management, Office of Management, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before February 6, 2012.

ADDRESSES: Comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov* or mailed to U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Washington, DC 20202–4537. Please note that written comments received in response to this notice will be considered public records.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35) requires that Federal agencies provide interested parties an early opportunity to comment on information collection requests. The Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management, publishes this notice containing proposed information collection requests at the beginning of the Departmental review of the information collection. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: December 2, 2011.

Darrin King,

Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

Office of Planning, Evaluation and Policy Development

Type of Review: Pending.

Title of Collection: 21st Century Community Learning Centers: Lessons Learned Guides.

OMB Control Number: 1875—NEW.

Agency Form Number(s): N/A.

Total Estimated Number of Annual Responses: 1,020.

Total Estimated Annual Burden Hours: 690.

Abstract: The purpose of this study is to produce guides for the 21st Century Community Learning Centers (21st CCLC) program that will assist the U.S. Department of Education staff in providing technical assistance to grantees on the following four topics: (1) Science, Technology, Engineering, and Math (STEM); (2) English Learners; (3) Career and Technical Education, and (4) structures to increase learning time. The Department will identify 21st CCLC sites that are implementing activities in a manner that builds on scientific evidence, strong management and organizational practice, and data use; conduct site visits to those programs to investigate and document the practices; and write a ''lessons from the field'' guide for practitioners that includes site descriptions and cross-site analyses of good and innovative practice that can help other 21st CCLC grantees implement similar programs.

Copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov,* by selecting the ''Browse Pending Collections'' link and by clicking on link number 4763. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to (202) 401–0920. Please specify the complete title of the information collection and OMB Control Number when making your request.

Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–(800) 877–8339.

[FR Doc. 2011–31390 Filed 12–6–11; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–3972–002.

Applicants: PJM Interconnection, L.L.C.

Description: Compliance Filing per September 15, 2011 Order in ER11–3972 re Order No. 741 to be effective 12/13/2011.

Filed Date: 11/29/11.

Accession Number: 20111129–5150.

Comments Due: 5 p.m. ET 12/20/11.

Docket Numbers: ER11–4459–001.

Applicants: El Paso Electric Company.

Description: Compliance Filing of Revisions to OATT Attachment M to be effective 11/1/2011.

Filed Date: 11/30/11.

Accession Number: 20111130–5185.

Comments Due: 5 p.m. ET 12/21/11.

Docket Numbers: ER11–4498–002; ER11–4499–002; ER11–4500–002; ER11–4507–002; ER11–4501–002.

Applicants: Smoky Hills Wind Farm, LLC, Smoky Hills Wind Project II, LLC, Enel Stillwater, LLC, Caney River Wind Project, LLC, Canastota Windpower, LLC.

Description: Notice of Non-Material Change in Status re Smoky Hills Wind Farm, LLC, et al.

Filed Date: 11/29/11.

Accession Number: 20111129–5201.
Comments Due: 5 p.m. ET 12/20/11.

Docket Numbers: ER12–226–000.
Applicants: Asset and Energy Cost Saving Cooperative, Kipcon, Inc.
Description: Supplemental Information of Kipcon, Inc.
Filed Date: 11/30/2011.
Accession Number: 20111130–5229.
Comment Date: 5 p.m. ET 12/21/11.

Docket Numbers: ER12–378–001.
Applicants: South Carolina Electric & Gas Company.
Description: Revised 3 TAP Agreements—Compliance filing to be effective 11/10/2011.
Filed Date: 11/30/11.
Accession Number: 20111130–5004.
Comments Due: 5 p.m. ET 12/21/11.

Docket Numbers: ER12–421–001.
Applicants: Heritage Garden Wind Farm I, LLC.
Description: Amendment to MBR Application to be effective 12/31/2011.
Filed Date: 11/30/11.
Accession Number: 20111130–5024.
Comments Due: 5 p.m. ET 12/21/11.

Docket Numbers: ER12–481–000.
Applicants: ISO New England Inc.
Description: Amend to Agreements of Phase I/II HVDC to be effective 1/29/2012.
Filed Date: 11/29/11.
Accession Number: 20111129–5038.
Comments Due: 5 p.m. ET 12/20/11.

Docket Numbers: ER12–482–000.
Applicants: Arizona Public Service Company.
Description: Service Agreement No. 311, revision of EPC activities with NTUA to be effective 11/30/2011.
Filed Date: 11/29/11.
Accession Number: 20111129–5147.
Comments Due: 5 p.m. ET 12/20/11.

Docket Numbers: ER12–483–000.
Applicants: The Empire District Electric Company.
Description: Compliance Filing ER10–877: GFR Tariff, SA Nos. 1–4, Rate Schedule Nos. 5–8 to be effective 9/17/2010.
Filed Date: 11/29/11.
Accession Number: 20111129–5174.
Comments Due: 5 p.m. ET 12/20/11.

Docket Numbers: ER12–484–000.
Applicants: PacifiCorp.
Description: DGT ARTSOA Rev 4 to be effective 1/29/2012.
Filed Date: 11/29/11.
Accession Number: 20111129–5180.
Comments Due: 5 p.m. ET 12/20/11.

Docket Numbers: ER12–485–000.
Applicants: PacifiCorp.
Description: Deseret Control Area Services Agreement Cancellation to be effective 1/29/2012.
Filed Date: 11/29/11.
Accession Number: 20111129–5185.
Comments Due: 5 p.m. ET 12/20/11.

Docket Numbers: ER12–486–000.
Applicants: Southern California Edison Company.
Description: LGIA Antelope Valley Solar PV1 Project—Solar Star California XIX, LLC to be effective 12/1/2011.
Filed Date: 11/30/11.
Accession Number: 20111130–5000.
Comments Due: 5 p.m. ET 12/21/11.

Docket Numbers: ER12–487–000.
Applicants: Dairyland Power Cooperative.
Description: Supply and Voltage Control from Generation Sources to be effective 2/1/2012.
Filed Date: 11/30/11.
Accession Number: 20111130–5002.
Comments Due: 5 p.m. ET 12/21/11.

Docket Numbers: ER12–489–000.
Applicants: City of Azusa, California.
Description: City of Azusa TRR & TO Tariff Revisions to be effective 12/1/2011.
Filed Date: 11/30/11.
Accession Number: 20111130–5135.
Comments Due: 5 p.m. ET 12/21/11.

Docket Numbers: ER12–489–000.
Applicants: City of Azusa, California.
Description: Work Paper Filing under City of Azusa, California..
Filed Date: 11/30/11.
Accession Number: 20111130–5186.
Comments Due: 5 p.m. ET 12/21/11.

Docket Numbers: ER12–490–000.
Applicants: PJM Interconnection, L.L.C.
Description: Original Service Agreement No. 3143; Queue No. W4–059 to be effective 11/1/2011.
Filed Date: 11/30/11.
Accession Number: 20111130–5137.
Comments Due: 5 p.m. ET 12/21/11.

Docket Numbers: ER12–491–000
Applicants: Bangor Hydro Electric Company, ISO New England Inc.
Description: BHE and ISO NE Amended and Restated LSA to be effective 11/1/2011.
Filed Date: 11/30/11.
Accession Number: 20111130–5138.
Comments Due: 5 p.m. ET 12/21/11.

Docket Numbers: ER12–492–000.
Applicants: Florida Power Corporation.
Description: Notice of Cancellation of Rate Schedule No. 116 of Florida Power Corporation.
Filed Date: 11/30/11.
Accession Number: 20111130–5189.
Comments Due: 5 p.m. ET 12/21/11.

Docket Numbers: ER12–493–000.
Applicants: Florida Power Corporation.
Description: Notice of Cancellation of Rate Schedule No. 120 of Florida Power Corporation.
Filed Date: 11/30/11.
Accession Number: 20111130–5190.
Comments Due: 5 p.m. ET 12/21/11.

Docket Numbers: ER12–494–000.
Applicants: PJM Interconnection, L.L.C.
Description: PJM Interconnection, L.L.C. submits tariff filing per 35.13(a)(2)(iii: First Revised Service Agreement No. 2389; Queue No. V3–024 to be effective 11/1/2011.
Filed Date: 11/30/11.
Accession Number: 20111130–5211.
Comments Due: 5 p.m. ET 12/21/11.

Take notice that the Commission received the following electric reliability filings:

Docket Numbers: RR12–3–000.
Applicants: North American Electric Reliability Corporation.
Description: Petition for Approval of Revisions to the Rules of Procedure of the North American Electric Reliability Corporation.
Filed Date: 11/29/11.
Accession Number: 20111129–5207.
Comments Due: 5 p.m. ET 12/20/11.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 30, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–31382 Filed 12–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP12–170–000.

Applicants: Gas Transmission Northwest LLC.
Description: Adjustments for Leap Year 2012 to be effective 1/1/2012.
Filed Date: 11/28/11.
Accession Number: 20111128–5060.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–171–000.
Applicants: Natural Gas Pipeline Company of America, LLC.
Description: Secure Energy Negotiated Rate Filing to be effective 11/26/2011.
Filed Date: 11/28/11.
Accession Number: 20111128–5129.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–172–000.
Applicants: Midcontinent Express Pipeline LLC.
Description: Sawgrass Negotiated Rate Filing to be effective 12/1/2011.
Filed Date: 11/28/11.
Accession Number: 20111128–5139.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–173–000.
Applicants: PostRock KPC Pipeline, LLC.
Description: Request for Waiver of Tariff Provision of PostRock KPC Pipeline, LLC.
Filed Date: 11/28/11.
Accession Number: 20111128–5157.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–174–000.
Applicants: Transcontinental Gas Pipe Line Company, LLC.
Description: S–2 Tracker Filing Effective 2011–12–01 to be effective 12/1/2011.
Filed Date: 11/28/11.
Accession Number: 20111128–5183.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–175–000.
Applicants: Natural Gas Pipeline Company of America LLC.
Description: EDF Negotiated Rate Filing to be effective 12/1/2011.
Filed Date: 11/28/11.
Accession Number: 20111128–5210.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–176–000.
Applicants: Alliance Pipeline L.P.
Description: 2012 Rates to be effective 1/1/2012.
Filed Date: 11/29/11.
Accession Number: 20111129–5003.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–177–000.
Applicants: CenterPoint Energy Gas Transmission Company.
Description: CEGT's Annual Sligo Lease LUFG Percentage Tracker Filing.
Filed Date: 11/28/11.
Accession Number: 20111128–5238.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–178–000.
Applicants: Gulf Crossing Pipeline Company LLC.
Description: Antero 2 to Tenaska 225 Capacity Release Negotiated Rate Agreement Filing to be effective 12/1/2011.
Filed Date: 11/29/11.
Accession Number: 20111129–5023.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–179–000.
Applicants: Gulf Crossing Pipeline Company LLC.
Description: Antero 3 to Tenaska 226 Capacity Release Negotiated Rate Agreement Filing to be effective 12/1/2011.
Filed Date: 11/29/11.
Accession Number: 20111129–5024.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–180–000.
Applicants: Natural Gas Pipeline Company of America.
Description: OXY Amended Negotiated Rate Filing to be effective 12/1/2011.
Filed Date: 11/29/11.
Accession Number: 20111129–5073.
Comments Due: 5 p.m. ET 12/12/11.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP11–2594–001.
Applicants: National Fuel Gas Supply Corporation.
Description: Rate Schedule PTR Compliance Filing to be effective 10/27/2011.
Filed Date: 11/28/11.
Accession Number: 20111128–5140.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP11–1670–006.
Applicants: Eastern Shore Natural Gas Company.
Description: eTariff Viewer Correction—RP11–1670 Interim Settlement Rates to be effective 11/1/2011.
Filed Date: 11/29/11.
Accession Number: 20111129–5067.
Comments Due: 5 p.m. ET 12/12/11.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, and service can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf*. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 29, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–31384 Filed 12–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP12–181–000.
Applicants: Southern Star Central Gas Pipeline, Inc.
Description: Southern Star Central Gas Pipeline, Inc. Annual OFO Report.
Filed Date: 11/29/11.
Accession Number: 20111129–5077.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–182–000.
Applicants: Southern Natural Gas Company, L.L.C.
Description: Annual Storage Cost Reconciliation Mechanism Report of Southern Natural Gas Company, L.L.C.
Filed Date: 11/29/11.
Accession Number: 20111129–5156.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–183–000.
Applicants: Midwestern Gas Transmission Company.
Description: Submits tariff filing per 154.204: Amendment to Non-Conforming Agreement FA0916 to be effective 11/19/2011.
Filed Date: 11/29/11.
Accession Number: 20111129–5157.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–184–000.
Applicants: Kinder Morgan Interstate Gas Transmission LLC.
Description: Negotiated Rate 2011–11–29 MGE to be effective 12/1/2011.
Filed Date: 11/29/11.
Accession Number: 20111129–5158.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–185–000.
Applicants: National Fuel Gas Supply Corporation.
Description: TSCA for 2012 to be effective 1/1/2012.
Filed Date: 11/30/11.
Accession Number: 20111130–5044.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–186–000.
Applicants: Southern Star Central Gas Pipeline, Inc.
Description: Southern Star Central Gas Pipeline, Inc. Annual Cash-Out Refund Report.
Filed Date: 11/30/11.
Accession Number: 20111130–5045.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–187–000.
Applicants: Gulf South Pipeline Company, LP.
Description: HK 37731 to Texla 39417 Capacity Release Negotiated Rate Agreement Filing to be effective 12/1/2011.
Filed Date: 11/30/11.
Accession Number: 20111130–5089.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–188–000.
Applicants: Gulf South Pipeline Company, LP.
Description: HK 37731 to Sequent 39419 Capacity Release Negotiated Rate Agreement Filing to be effective 12/1/2011.
Filed Date: 11/30/11.
Accession Number: 20111130–5090.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–189–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: Submits tariff filing per 154.204: ConEd 2011–12–01 Releases #1 to be effective 12/1/2011.
Filed Date: 11/30/11.
Accession Number: 20111130–5111.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–190–000.
Applicants: El Paso Natural Gas Company.
Description: Submits tariff filing per 154.403: Article 11.2 Inflation Filing to be effective 1/1/2012.
Filed Date: 11/30/11.
Accession Number: 20111130–5131.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–191–000.
Applicants: CenterPoint Energy Gas Transmission Company LLC
Description: Submits tariff filing per 154.204: CEGT LLC—Negotiated Rate—December 2011 to be effective 12/1/2011.
Filed Date: 11/30/11.
Accession Number: 20111130–5132.
Comments Due: 5 p.m. ET 12/12/11.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP11–2137–002.
Applicants: Dominion Cove Point LNG, LP.
Description: DCP–2011 Section 4 General Rate Case Motion to be effective 12/1/2011.
Filed Date: 11/21/11.
Accession Number: 20111121–5108.
Comments Due: 5 p.m. ET 12/5/11.

Docket Numbers: RP11–2568–001.
Applicants: Columbia Gas Transmission, LLC.
Description: South Jersey Compliance Filing to be effective 11/1/2011.
Filed Date: 11/21/11.
Accession Number: 20111121–5037.
Comments Due: 5 p.m. ET 12/5/11.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, and service can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 30, 2011.

Nathaniel J. Davis, Sr.

Deputy Secretary

[FR Doc. 2011–31385 Filed 12–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP12–192–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: ConEd 2011–12–01 Releases #2 to be effective 12/1/2011.
Filed Date: 11/30/11.
Accession Number: 20111130–5136.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–193–000.
Applicants: Gulf South Pipeline Company, LP.
Description: QEP 36601–8 Amendment to Negotiated Rate Agreement Filing to be effective 12/1/2011.
Filed Date: 11/30/11.
Accession Number: 20111130–5170.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–194–000.
Applicants: Mojave Pipeline Company, LLC.
Description: Mojave FL&U, to be effective 1/1/2012.
Filed Date: 11/30/11.
Accession Number: 20111130–5235.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–195–000.
Applicants: Colorado Interstate Gas Company LLC.
Description: Spruce Hill—Compliance Filing on Petition to Amend Certificate to be effective 1/1/2012.
Filed Date: 11/30/11.
Accession Number: 20111130–5237.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–196–000.
Applicants: Tennessee Gas Pipeline Company, LLC.
Description: Tennessee Gas Pipeline Company, LLC 2010–2011 Cashout Report.
Filed Date: 11/30/11.
Accession Number: 20111130–5243.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–197–000.
Applicants: Transcontinental Gas Pipe Line Company, LLC.
Description: Change in Gathering Rate to be effective 12/1/2011.
Filed Date: 11/30/11.
Accession Number: 20111130–5264.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–198–000.
Applicants: Chandeleur Pipe Line Company.
Description: Chandeleur Pipe Line Company's FLLA Tariff Filing to be effective 1/1/2012.
Filed Date: 11/30/11.
Accession Number: 20111130–5265.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–199–000.
Applicants: Northwest Pipeline GP.
Description: RP12–199–000 CHUB Non-Conforming Contracts—Marathon & WPX to be effective 1/1/2012.
Filed Date: 11/30/11.
Accession Number: 20111130–5311.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–200–000.
Applicants: Trailblazer Pipeline Company LLC.
Description: MIECO Negotiated Rate Filing to be effective 12/1/2011.
Filed Date: 11/30/11.
Accession Number: 20111130–5324.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–201–000.
Applicants: Kern River Gas Transmission Company.

Description: 2012 Period Two Rates to be effective 5/1/2012.
Filed Date: 12/1/11.
Accession Number: 20111201–5049.
Comments Due: 5 p.m. ET 12/13/11.

Docket Numbers: RP12–202–000.
Applicants: Northern Natural Gas Company.
Description: 20111201 Remove Non-Conforming Tariff Sections to be effective 1/1/2012.
Filed Date: 12/1/11.
Accession Number: 20111201–5070.
Comments Due: 5 p.m. ET 12/13/11.

Docket Numbers: RP12–203–000.
Applicants: Trailblazer Pipeline Company LLC.
Description: Submits tariff filing per 154.204: Negotiated Rate Filing—Concord to be effective 12/1/2011.
Filed Date: 12/1/11.
Accession Number: 20111201–5073.
Comments Due: 5 p.m. ET 12/13/11.

Docket Numbers: RP12–204–000.
Applicants: Trailblazer Pipeline Company LLC.
Description: Submits tariff filing per 154.204: Negotiated Rate Filing—Macquarie to be effective 12/1/2011.
Filed Date: 12/1/11.
Accession Number: 20111201–5074.
Comments Due: 5 p.m. ET 12/13/11.

Docket Numbers: RP12–205–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: Submits tariff filing per 154.204: Negotiated Rates Dec2011 Cleanup to be effective 1/1/2012.
Filed Date: 12/1/11.
Accession Number: 20111201–5075.
Comments Due: 5 p.m. ET 12/13/11.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP11–2001–001.
Applicants: Cameron Interstate Pipeline, LLC.
Description: Cameron Interstate Pipeline Compliance Filing Nov 30 2011 to be effective 11/30/2011.
Filed Date: 11/30/11.
Accession Number: 20111130–5322.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP11–2569–002.
Applicants: Texas Gas Transmission, LLC.
Description: Compliance Filing in RP11–2569, *et al.* to be effective 11/1/2011.
Filed Date: 11/30/11.
Accession Number: 20111130–5169.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP11–2569–003.
Applicants: Texas Gas Transmission, LLC.
Description: Change to Compliance Filing in RP11–2569, *et al.* to be effective 11/1/2011.
Filed Date: 11/30/11.
Accession Number: 20111130–5213.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–175–001.
Applicants: Natural Gas Pipeline Company of America LLC.
Description: Amendment to EDF Trading's Negotiated Rate Filing to be effective 12/1/2011.
Filed Date: 11/30/11.
Accession Number: 20111130–5292.
Comments Due: 5 p.m. ET 12/12/11.

Docket Numbers: RP12–71–001.
Applicants: Williston Basin Interstate Pipeline Company.
Description: Compliance Filing—Negotiated Rate Discount Adjustment to be effective 11/28/2011.
Filed Date: 11/30/11.
Accession Number: 20111130–5156.
Comments Due: 5 p.m. ET 12/12/11.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, and service can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: December 1, 2011.

Nathaniel J. Davis, Sr.

Deputy Secretary

[FR Doc. 2011–31388 Filed 12–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–2895–003.
Applicants: Duke Energy Carolinas, LLC.
Description: Amendment to Compliance Filing to be effective 6/1/2011.
Filed Date: 11/28/11.
Accession Number: 20111128–5219.
Comments Due: 5 p.m. ET 12/19/11.

Docket Numbers: ER12–474–000.
Applicants: PJM Interconnection, L.L.C.
Description: Original Svc Agreement No. 3146; Queue No. V3–052, V4–006, V4–007, V4–030 & V4–031 to be effective 10/28/2011.
Filed Date: 11/28/11.
Accession Number: 20111128–5184.
Comments Due: 5 p.m. ET 12/19/11.

Docket Numbers: ER12–475–000.
Applicants: Duke Energy Ohio, Inc., Duke Energy Indiana, Inc., Duke Energy Kentucky, Inc.
Description: Amendment to Ancillary Services Tariff to be effective 1/1/2012.
Filed Date: 11/28/11.
Accession Number: 20111128–5202.
Comments Due: 5 p.m. ET 12/19/11.

Docket Numbers: ER12–476–000.
Applicants: Duke Energy Kentucky, Inc.
Description: Cancel Reactive Tariff as to Duke Kentucky to be effective 1/1/2012.
Filed Date: 11/28/11.
Accession Number: 20111128–5203.
Comments Due: 5 p.m. ET 12/19/11.

Docket Numbers: ER12–477–000.
Applicants: Duke Energy Kentucky, Inc.
Description: Reactive Power Rate Schedule Filing to be effective 1/1/2012.
Filed Date: 11/28/11.
Accession Number: 20111128–5204.
Comments Due: 5 p.m. ET 12/19/11.

Docket Numbers: ER12–478–000.
Applicants: Duke Energy Ohio, Inc.
Description: Cancel Reactive Tariff as to Duke Ohio to be effective 1/1/2012.
Filed Date: 11/28/11.
Accession Number: 20111128–5208.
Comments Due: 5 p.m. ET 12/19/11.

Docket Numbers: ER12–479–000.
Applicants: Duke Energy Ohio, Inc.
Description: Reactive Power Rate Schedule Filing to be effective 1/1/2012.
Filed Date: 11/28/11.
Accession Number: 20111128–5209.
Comments Due: 5 p.m. ET 12/19/11.

Docket Numbers: ER12–480–000.
Applicants: Midwest Independent Transmission System Operator, Inc.
Description: 11–28–11 Entergy Cost Allocation Filing to be effective 6/1/2013.
Filed Date: 11/28/11.
Accession Number: 20111128–5224.
Comments Due: 5 p.m. ET 12/19/11.

Take notice that the Commission received the following land acquisition reports:

Docket Numbers: LA11–3–000.

Applicants: Iberdrola Renewables, Inc., Atlantic Renewable Projects II LLC, Barton Windpower LLC, Big Horn Wind Project LLC, Big Horn II Wind Project LLC, Blue Creek Wind Farm LLC, Buffalo Ridge I LLC, Buffalo Ridge II LLC, Casselman Windpower LLC, Colorado Green Holdings LLC, Dillon Wind LLC, Dry Lake Wind Power, LLC, Dry Lake Wind Power II LLC, Elk River Windfarm, LLC, Elm Creek Wind, LLC, Elm Creek Wind II LLC, Farmers City Wind, LLC, Flat Rock Windpower LLC, Flat Rock Windpower II LLC, Flying Cloud Power Partners, LLC, Hardscrabble Wind Power LLC, Hay Canyon Wind LLC, Juniper Canyon Wind Power LLC, Klamath Energy LLC, Klamath Generation LLC, Klondike Wind Power LLC, Klondike Wind Power II LLC, Klondike Wind Power III LLC, Leaning Juniper Wind Power II LLC, Lempster Wind, LLC, Locust Ridge Wind Farm, LLC, Locust Ridge Wind Farm II, LLC, MinnDakota Wind LLC, Moraine Wind LLC, Moraine Wind II LLC, Mountain View Power Partners III, LLC, New Harvest Wind Project LLC, Northern Iowa Windpower II LLC, Pebble Springs Wind LLC, Providence Heights Wind, LLC, Rugby Wind LLC, San Luis Solar LLC, Shiloh I Wind Project, LLC, South Chestnut LLC, Star Point Wind Project LLC, Streator-Cayuga Ridge Wind Power LLC, Trimont Wind I LLC, Twin Buttes Wind LLC.

Description: Land Acquisition Report of Atlantic Renewables Projects II LLC, *et. al.*

Filed Date: 11/28/11.

Accession Number: 20111128–5240.

Comments Due: 5 p.m. ET 12/19/11.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 29, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–31387 Filed 12–6–11; 8:45 a.m.]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–4330–002.

Applicants: ISO New England Inc., Vermont Electric Cooperative, Inc.

Description: ISO New England Inc. submits tariff filing per 35.17(b): Second Supplemental Filing to Schedule 21–VEC Revisions to be effective 4/1/2011.

Filed Date: 11/28/2011.

Accession Number: 20111128–5152.

Comment Date: 5 p.m. Eastern Time on Monday, December 19, 2011.

Docket Numbers: ER12–175–001.

Applicants: PJM Interconnection, L.L.C.

Description: PJM Interconnection, L.L.C. submits tariff filing per 35.17(b): Errata to Queue No. X1–072, Original Service Agreement No. 3081 to be effective 9/22/2011.

Filed Date: 11/28/2011.

Accession Number: 20111128–5032.

Comment Date: 5 p.m. Eastern Time on Monday, December 19, 2011.

Docket Numbers: ER12–234–001.

Applicants: Pacific Gas and Electric Company.

Description: Pacific Gas and Electric Company submits tariff filing per 35.17(b): Amendment to Notices of Termination of Cantua and Giffen E&P Agreements to be effective 9/26/2011.

Filed Date: 11/25/2011.

Accession Number: 20111125–5000.

Comment Date: 5 p.m. Eastern Time on Friday, December 16, 2011.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 28, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–31383 Filed 12–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the-Record Communications; Public Notice

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication, and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40

CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. The communications listed are grouped by docket numbers in ascending order. These filings are available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the eLibrary link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, please contact FERC, Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Docket No.	File date	Presenter or requester
Prohibited:		
1. CP11–515–000	11–18–11	William (Ty) Lane.
2. ER10–787–000, *et al.*	11–18–11	Commission Staff.[1]
3. P–12790–001	11–22–11	Commission Staff.[2]
4. P–12790–001	11–22–11	Sean Elwell, *et al.*
5. CP07–444–000	11–22–11	Carolynn Kohout.
6. P–2512–000	11–28–11	Lisa LaRue.
Exempt:		
1. P–459–212	11–10–11	Hon. Darrell Pollock.
2. EL11–39–000	11–17–11	Hon. Charles E. Grassley.
3. P–2144–000	11–17–11	Hon. Cathy McMorris Rodgers.
4. P–459–212	11–17–11	Hon. Chuck Purgason.
5. P–13338–000	11–17–11	Hon. Charles E. Grassley.
6. CP07–44–000	11–17–11	Hon. Jo Bonner.
7. P–459–212	11–21–11	Hon. Kris Franken.[3]
8. P–12715–000	11–21–11	Commission Staff.[4]
9. P–2232–000	11–22–11	Hon. Patrick T. McHenry.
10. P–1267–000	11–23–11	Hon. Jim DeMint.

[1] Material provided in advance of Technical Conference.
[2] Email record.
[3] Notice of Official Record.
[4] Telephone record.

Dated: November 30, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–31386 Filed 12–6–11; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9327–3]

Agency Information Collection Activities; Proposed Renewal of Several Currently Approved Collections; Comment Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit requests to renew several currently approved Information Collection Request (ICR) to the Office of Management and Budget (OMB). The ICRs are specifically identified in this document by their corresponding titles, EPA ICR numbers, OMB Control numbers, and related docket identification (ID) numbers. Before submitting these ICRs to OMB for review and approval, EPA is soliciting comments on specific aspects of the information collection activities.

DATES: Comments must be received on or before February 6, 2012.

ADDRESSES: Submit your comments, identified by the docket ID number for the corresponding ICR as identified in this document, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to the docket ID number for the corresponding ICR as identified in this document. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or email. The regulations.gov Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available in *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is

restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: For questions regarding EPA Docket ID Number EPA–HQ–OPP–2011–0704: Lily G. Negash, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; *telephone number:* (703) 347–8515; *fax number:* (703) 305–5884; *email address:* negash.lily@epa.gov.

For questions regarding EPA Docket ID Number EPA–HQ–OPP–2011–0902: Ryne Yarger, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; *telephone number:* (703) 605–1193; *fax number:* (703) 305–5884; *email address: yarger.ryne@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What information is EPA particularly interested in?

Pursuant to section 3506(c)(2)(A) of PRA, EPA specifically solicits comments and information to enable it to:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.
2. Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
3. Enhance the quality, utility, and clarity of the information to be collected.
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What should I consider when I prepare my comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible and provide specific examples.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the collection activity.
7. Make sure to submit your comments by the deadline identified under **DATES**.
8. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

III. What do I need to know about PRA?

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information subject to PRA approval unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the Code of Federal Regulations (CFR), after appearing in the preamble of the final rule, are further displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instruments or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in a list at 40 CFR 9.1.

Under PRA, *burden* means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or 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 which have subsequently changed; 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.

IV. Which ICRs are being renewed?

EPA is planning to submit a number of currently approved ICRs to OMB for review and approval under PRA. In addition to specifically identifying the ICRs by title and corresponding ICR, OMB and docket ID numbers, this unit provides a brief summary of the information collection activity and the Agency's estimated burden. The Supporting Statement for each ICR, a copy of which is available in the corresponding docket, provides a more detailed explanation.

A. Docket ID Number EPA–HQ–OPP–2011–0704

Title: Submission of Protocols and Study Reports for Environmental Research Involving Human Subjects.

ICR number: EPA ICR No. 2195.04.

OMB control number: OMB Control No. 2070–0169.

ICR status: The approval for this ICR is scheduled to expire on August 31, 2012.

Affected entities: Entities potentially affected by this ICR include anyone who submits protocols and study reports for environmental research involving human subjects under FIFRA and/or FFDCA. Although EPA has only received such third-party research (*i.e.,* research that is not conducted or supported by EPA) in conjunction with FIFRA from pesticide registrants, it is conceivable that other entities could submit such information in the future. Principal respondents to this ICR are employers of physical, engineering, and life scientists in the fields of research and development.

Abstract: The Environmental Protection Agency (EPA or the Agency) is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). In January 2006, EPA issued a final rule to amend the Federal Policy for the Protection of Human Subjects (also known as the Common Rule) at 40 CFR part 26. The information collection activity imposed by this final rule consists of activity-driven reporting and recordkeeping requirements for those who intend to conduct research for submission to EPA under the pesticide laws.

In addition to other protections, if such research involves intentional

dosing of human subjects, these individuals (respondents) are required to submit study protocols to EPA and a cognizant local Human Subjects IRB before such research is initiated so that the scientific design and ethical standards that will be employed during the proposed study may be reviewed and approved. Also, respondents are required to submit information about the ethical conduct of completed research that involved human subjects when such research is submitted to EPA.

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 598 hours per response for research involving intentional exposure of human subjects, and 12 hours per response for all other submitted research with human subjects. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or 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 which have subsequently changed; 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. The information requirements identified in the final rule do not duplicate other federal agency information collections.

The ICR, a copy of which is available in the docket, provides a detailed explanation of this estimate, which is only briefly summarized here:

Estimated total number of potential respondents: 54.

Frequency of response: On occasion.

Estimated total average number of responses for each respondent: 1.

Estimated total annual burden hours: 20,572 hours.

Estimated total annual costs: $1,712,833. This includes an estimated burden cost of $1,712,833 and no additional cost for non-burden hour paperwork costs, *e.g.,* investment or maintenance and operational costs.

Changes in the estimates from the last approval: The renewal of this ICR will not result in a change in the number of hours in the total estimated respondent burden identified in the currently approved ICR.

B. Docket ID Number EPA–HQ–OPP–2011–0902

Title: Consumer Research through Focus Groups to Develop Improved Labeling for Pesticide Products.

ICR number: EPA ICR No. 2367.02.

OMB control number: OMB Control No. 2070–0175.

ICR status: The approval for this ICR is scheduled to expire on August 31, 2012.

Affected entities: Entities potentially affected by this ICR are members of the general public who volunteer to participate in a focus group.

Abstract: EPA intends to renew a voluntary information collection for consumer research involving the use of focus groups to test various versions of pesticide product labels and other informational materials intended for the general public. The purpose of this research is to identify the consumer's understanding of the information on a pesticide product label to assure that the consumer can effectively use this information to select the pesticide product most likely to meet their needs and can readily understand label instructions regarding the safe use, handling, and disposal of the product. The collected information will be used to inform the Agency on the need for and nature of potential revisions to EPA guidance and regulations regarding pesticide product labels and to create other user-friendly consumer information materials.

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 2 hours per response. The ICR, a copy of which is available in the docket, provides a detailed explanation of this estimate, which is only briefly summarized here:

Estimated total number of potential respondents: 300.

Frequency of response: On occasion.

Estimated total average number of responses for each respondent: 1.

Estimated total annual burden hours: 200 hours.

Estimated total annual costs: $6,014. There are no capital expenditures or operational and maintenance costs associated with this collection activity.

Changes in the estimates from the last approval: The renewal of this ICR will result in an overall decrease of 181.34 hours in the total estimated respondent burden identified in the currently approved ICR. This decrease reflects EPA's actual costs of conducting a series of 10 focus groups in 2010. This change is an adjustment.

V. What is the next step in the process for these ICRs?

EPA will consider the comments received and amend the individual ICRs as appropriate. The final ICR packages will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** notice pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of these ICRs to OMB and the opportunity for the public to submit additional comments for OMB consideration. If you have any questions about any of these ICRs or the approval process in general, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

List of Subjects

Environmental protection, Reporting and recordkeeping requirements.

Dated: November 21, 2011.

Stephen A. Owens,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2011–31023 Filed 12–6–11; 8:45 a.m.]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2011–0216; FRL–9501–8]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; NESHAP for Cellulose Products Manufacturing (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. The ICR which is abstracted below describes the nature of the collection and the estimated burden and cost.

DATES: Additional comments may be submitted on or before January 6, 2012.

ADDRESSES: Submit your comments, referencing docket ID number EPA–HQ–OECA–2011–0216, to (1) EPA online using *http://www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center (EPA/DC), Environmental Protection Agency, Enforcement and Compliance Docket and Information Center, mail code 2822IT, 1200

Pennsylvania Avenue NW., Washington, DC 20460; and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Learia Williams, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2223A, Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; *telephone number:* (202) 564–4113; *fax number:* (202) 564–0050; *email address: williams.learia@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On May 9, 2011 (76 *FR* 26900), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments. Any additional comments on this ICR should be submitted to both EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under docket ID number EPA–HQ–OECA–2011–0216, which is available for public viewing online at *http://www.regulations.gov,* or in person viewing at the Enforcement and Compliance Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Avenue NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Enforcement and Compliance Docket is (202) 566–1752.

Use EPA's electronic docket and comment system at *http://www.regulations.gov,* to either submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in the system, select ''docket search,'' then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at *http://www.regulations.gov* as EPA receives them and without change, unless the comment contains copyrighted material, Confidential Business Information (CBI), or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to *http://www.regulations.gov.*

Title: NESHAP for Cellulose Products Manufacturing (Renewal).

ICR Numbers: EPA ICR Number 1974.06, OMB Control Number 2060–0488.

ICR Status: This ICR is scheduled to expire on December 31, 2011. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB.

Abstract: The National Emission Standards for Hazardous Air Pollutants (NESHAP), for Cellulose Products Manufacturing were proposed on August 28, 2000 (65 FR 52166) and promulgated on June 11, 2002 (67 FR 40043). These standards apply to any existing, reconstructed, or new affected sources. These standards apply to each operation that is a major source of hazardous air pollutants (HAP), which includes both the miscellaneous viscose processes source category and the cellulose ethers productions source category. The viscose process includes the cellulose food casing, rayon, cellulosic sponge, and cellophane operations, and the cellulose ethers includes all of the cellulose ether operations. Respondents of affected sources are subject to the requirements of 40 CFR part 63, subpart A, the General Provisions, unless the regulation specifies otherwise.

Owners or operators must submit notification that the facility is subject to the rule; notification of performance test; notification of compliance status (including results of performance tests and other initial compliance demonstrations) and the semiannual compliance report. Owners or operators of cellulose products manufacturing facilities subject to the rule must maintain a file of these measurements, and retain the file for at least five years following the date of such measurements, maintenance reports, and records.

All reports are sent to the delegated state or local authority. In the event that there is no such delegated authority, the reports are sent directly to the EPA regional office. This information is being collected to assure compliance with 40 CFR part 63, subpart UUUU, as authorized in section 112 and 114(a) of the Clean Air Act. The required information consists of emissions data and other information that have been determined to be private.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB Control Number. The OMB Control Numbers for the EPA regulations are listed in 40 CFR part 9 and 48 CFR chapter 15, and are identified on the form and/or instrument, if applicable.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 141 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or 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 which have subsequently changed; 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.

Respondents/Affected Entities: Cellulose products manufacturing.

Estimated Number of Respondents: 13.

Frequency of Response: Weekly, semiannually, and occasionally.

Estimated Total Annual Hour Burden: 12,088.

Estimated Total Annual Cost: $1,258,056, which includes $1,257,042 in labor costs, no capital/startup costs, and $1,014 in operation and maintenance (O&M) costs.

Changes in the Estimates: There is no change in the labor hours in this ICR as compared to the previous ICR. This is due to two considerations: (1) The regulations have not changed over the past three years and are not anticipated to change over the next three years; and (2) the growth rate according to the industry sources is very low, negative, or non-existent, so there is no significant change in the overall burden. There are no new facilities expected to be constructed over the next three years of this ICR.

However, there is an increase in the estimated burden cost as currently identified in the OMB Inventory of Approved Burdens. The increase is not due to any program changes. The change in burden is due to the use of the most updated labor rates.

Dated: November 30, 2011.

John Moses,

Director, Collection Strategies Division.

[FR Doc. 2011–31395 Filed 12–6–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2010–1011; FRL–9500–5]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that the following Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval: Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances; EPA ICR No. 0574.15, OMB No. 2070–0012. The ICR, which is abstracted below, describes the nature of the information collection activity and its expected burden and costs.

DATES: Additional comments may be submitted on or before January 6, 2012.

ADDRESSES: Submit your comments, referencing docket ID Number EPA–HQ–OPPT–2010–1011 to (1) EPA online using *http://www.regulations.gov* (our preferred method), by email to *oppt.ncic@epa.gov* or by mail to: Document Control Office (DCO), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, Mail Code: 7407T, 1200 Pennsylvania Ave. NW., Washington, DC 20460, and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *Attention:* Desk Officer for EPA, 725 17th Street NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Pamela Myrick, Acting Director, Environmental Assistance Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, *Mail code:* 7408–M, 1200 Pennsylvania Ave. NW., Washington, DC 20460; *telephone number:* (202) 554–1404; *email address: TSCA–Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On August 3, 2011 (76 FR 46794), EPA sought comments on this renewal pursuant to 5 CFR 1320.8(d). EPA received no comments during the comment period. Any comments related to this ICR should be submitted to EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under Docket ID No. EPA EPA–HQ–OPPT–2010–1011, which is available for online viewing at *http://www.regulations.gov,* or in person inspection at the OPPT Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Pollution Prevention and Toxics Docket is (202) 566–0280. Use *http://www.regulations.gov* to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket ID number identified above.

EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in *http://www.regulations.gov* as EPA receives them and without change, unless the comment contains copyrighted material, confidential business information (CBI), or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in *http://www.regulations.gov.* The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in *http://www.regulations.gov.* For further information about the electronic docket, go to *http://www.regulations.gov.*

Title: Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances.

ICR Status: This is a request to renew an existing approved collection. This ICR is scheduled to expire on December 31, 2011. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB.

Abstract: Section 5 of the Toxic Substances Control Act (TSCA) requires manufacturers and importers of new chemical substances to submit to EPA notice of intent to manufacture or import a new chemical substance 90 days before manufacture or import begins. EPA reviews the information contained in the notice to evaluate the health and environmental effects of the new chemical substance. On the basis of the review, EPA may take further regulatory action under TSCA, if warranted. If EPA takes no action within 90 days, the submitter is free to manufacture or import the new chemical substance without restriction.

TSCA section 5 also authorizes EPA to issue Significant New Use Rules (SNURs). EPA uses this authority to take follow-up action on new or existing chemicals that may present an unreasonable risk to human health or the environment if used in a manner that may result in different and/or higher exposures of a chemical to humans or the environment. Once a use is determined to be a significant new use, persons must submit a notice to EPA 90 days before beginning manufacture, processing or importation of a chemical substance for that use. Such a notice allows EPA to receive and review information on such a use and, if necessary, regulate the use before it occurs.

Finally, TSCA section 5 also permits applications for exemption from section 5 review under certain circumstances. An applicant must provide information sufficient for EPA to make a determination that the circumstances in question qualify for an exemption. In granting an exemption, EPA may impose appropriate restrictions. This information collection addresses the reporting and recordkeeping requirements associated with TSCA section 5.

Responses to the collection of information are mandatory (see 40 CFR parts 700, 720, 721, 723 and 725). Respondents may claim all or part of a notice as CBI. EPA will disclose information that is covered by a CBI claim only to the extent permitted by, and in accordance with, the procedures in 40 CFR part 2.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register,** are listed in 40 CFR part 9 and included on the related

collection instrument or form, if applicable.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to range between 0.725 hours and 508 hours per response, depending upon the type of response. Burden is defined in 5 CFR 1320.3(b).

Respondents/Affected Entities: Entities potentially affected by this action are manufacturers, processors or importers of chemical substances.

Frequency of Collection: On occasion.

Estimated Average Number of Responses for Each Respondent: 4.8.

Estimated No. of Respondents: 443.

Estimated Total Annual Burden on Respondents: 117,162 hours.

Estimated Total Annual Costs: $34,417,821.

Changes in Burden Estimates: This request reflects a decrease of 350 hours (from 117,512 hours to 117,162 hours) in the total estimated respondent burden from that currently in the OMB inventory. This decrease represents a re-estimate in the number of annual submissions to reflect EPA's experiences since the most recent ICR. The decrease in the number of annual submissions is largely associated with the finalization of the e-PMN rule in 2010. The change is an adjustment.

Dated: November 30, 2011.

John Moses,

Director, Collection Strategies Division.

[FR Doc. 2011–31405 Filed 12–6–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2011–0439; FRL–9500–7]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; Disinfectants/Disinfection Byproducts, Chemical and Radionuclides (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. The ICR, which is abstracted below, describes the nature of the information collection and its estimated burden and cost.

DATES: Additional comments may be submitted on or before January 6, 2012.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OW–2011–0439, to (1) EPA online using *http://www.regulations.gov* (our preferred method), by email to *OW–Docket@epa.gov* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, and (2) OMB by mail to: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Matthew Reed, Drinking Water Protection Division, Office of Ground Water and Drinking Water, (4606M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; *telephone number:* (202) 564–4719; *fax number:* (202) 564–3755; *email address: reed.matthew@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On July 5, 2011 (76 FR 39092), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments during the comment period. Any additional comments on this ICR should be submitted to EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under Docket ID No. EPA–HQ–OW–2011–0439 Notice 2, which is available for online viewing at *http://www.regulations.gov,* or in person viewing at the Water Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Water Docket is (202) 566–2426.

Use EPA's electronic docket and comment system at *http://www.regulations.gov,* to submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in the system, select ''docket search,'' then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at *http://www.regulations.gov* as EPA receives them and without change, unless the comment contains copyrighted material, confidential business information (CBI), or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to *http://www.regulations.gov.*

Title: Disinfectants/Disinfection Byproducts, Chemical and Radionuclides (Renewal).

ICR numbers: EPA ICR No. 1896.09, OMB Control No. 2040–0204.

ICR Status: This ICR is scheduled to expire on December 31, 2011. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the Code of Federal Regulations (CFR), after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: The Disinfectants/Disinfection Byproducts, Chemical and Radionuclides ICR examines Public Water System, primacy agency and EPA burden and costs for recordkeeping and reporting requirements in support of the chemical drinking water regulations. These recordkeeping and reporting requirements are mandatory for compliance with 40 CFR parts 141 and 142. The following chemical regulations are included: Stage 1 Disinfectants and Disinfection Byproducts Rule (Stage 1 DBPR), Stage 2 Disinfectants and Disinfection Byproducts Rule (Stage 2 DBPR), Chemical Phase Rules (Phases II/IIB/V), 1976 Radionuclides Rule and 2000 Radionuclides Rule, Total Trihalomethanes (TTHM) Rule, Disinfectant Residual Monitoring and Associated Activities under the Surface Water Treatment Rule, Arsenic Rule, Lead and Copper Rule (LCR) and revisions. Future chemical-related rulemakings will be added to this consolidated ICR after the regulations are finalized and the initial, rule-specific, ICRs are due to expire.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average .45 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain,

or 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 which have subsequently changed; 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.

Respondents/Affected Entities: Owners/operators of Public Water Systems who must report to their primacy agency. Primacy agencies, which include States. Tribes (if they have been authorized to act as primacy agencies), and EPA Regions that act as primacy agencies in Indian lands and States that do not have primacy.

Estimated Number of Respondents: 153,036.

Frequency of Response: Varies by requirement (*i.e.,* on occasion, monthly, quarterly, semi-annually, annually, biennially, and every 3, 6, and 9 years).

Estimated Total Annual Hour Burden: 5,734,335.

Estimated Total Annual Cost: $435,706,000 includes $230,059,000 annualized capital or O&M costs.

Changes in the Estimates: There is a decrease of 384,924 hours in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens. This decrease is a result of updating relevant baseline information for each rule with the most current and accurate information available (*e.g.,* Public Water System inventories) and updating burden to incorporate the results of consultation with stakeholders. Where appropriate and available, estimated violation, waiver, and other associated rates have also been updated to reflect current information on rule compliance.

Dated: November 30, 2011.

John Moses,

Director, Collection Strategies Division.

[FR Doc. 2011–31402 Filed 12–6–11; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2011–0465; FRL–9500–6]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; Water Quality Standards Regulations (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.,*) this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. The ICR, which is abstracted below, describes the nature of the information collection and its estimated burden and cost.

DATES: Additional comments may be submitted on or before January 6, 2012.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OW–2011–0465, to (1) EPA online using *www.regulations.gov* (our preferred method), by email to *ow-docket@epa.gov* or by mail to: EPA Docket Center, Environmental Protection Agency, Water Docket, Mailcode 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460, and (2) OMB by mail to: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Beth LeaMond, Standards and Health Protection Division, Office of Science and Technology (4305T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; *telephone number:* (202) 566–0444; *fax number:* (202) 566–0409; *email address: leamond.beth@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On June 30, 2011 (76 FR 38384), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments. Any additional comments on this ICR should be submitted to EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under Docket ID No. EPA–HQ–OW–2011–0465, which is available for online viewing at *www.regulations.gov,* or in person viewing at the Water Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The EPA/DC Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Water Docket is (202) 566–2426.

Use EPA's electronic docket and comment system at *www.regulations.gov,* to submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in the system, select ''docket search,'' then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at www.regulations.gov as EPA receives them and without change, unless the comment contains copyrighted material, confidential business information (CBI), or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to *http://www.regulations.gov.*

Title: Water Quality Standards Regulation (Renewal).

ICR numbers: EPA ICR No. 0988.11, OMB Control No. 2040–0049.

ICR Status: This ICR is scheduled to expire on December 31, 2011. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: Water quality standards are provisions of State, Tribal, and Federal law that consist of designated uses for waters of the United States, water quality criteria to protect the designated uses, and an antidegradation policy. Section 303(c) of the Clean Water Act requires States and authorized Tribes to establish water quality standards, and to review and, if appropriate, revise their

water quality standards once every three years. The Act also requires EPA to review and either approve or disapprove the new or revised standards, and to promulgate replacement Federal standards if necessary. Section 118(c)(2) of the Act specifies additional water quality standards requirements for waters of the Great Lakes system.

The Water Quality Standards Regulation (40 CFR part 131 and portions of part 132) governs national implementation of the water quality standards program. The Regulation describes requirements and procedures for States and authorized Tribes to develop, review, and revise their water quality standards, and EPA procedures for reviewing and approving the water quality standards.

The Regulation establishes specific additional requirements for water quality standards and their implementation in the waters of the Great Lakes system, contained in the Water Quality Guidance for the Great Lakes System (40 CFR part 132).

Burden Statement: The public reporting and recordkeeping burden for this collection of information is estimated to average 1,099 hours per response annually. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or 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.

Respondents/Affected Entities: States, Territories and certain authorized Indian tribes that adopt water quality standards under the Clean Water Act; and water dischargers subject to certain requirements related to water quality standards in the Great Lakes system.

Estimated Number of Respondents: 2,415 (56 States and Territories, 36 Tribes; 2,323 Great Lakes dischargers).

Frequency of Response: On occasion.

Estimated Total Annual Hour Burden: 276,981 hours.

Estimated Total Annual Cost: $12,614,040 with no annualized capital or O&M cost.

Changes in the Estimates: There is a decrease of 16,233 hours in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens. This decrease is due to adjustments in EPA's estimates of burden hours to reflect a change in the number of tribes with EPA-approved water quality standards, a change in the estimated number of tribes applying annually to administer standards programs, a revised estimate of the number of Great Lakes dischargers, and updated burden estimates for certain activities required by the Water Quality Guidance for the Great Lakes System.

Dated: November 30, 2011.

John Moses,

Director, Collection Strategies Division.

[FR Doc. 2011–31401 Filed 12–6–11; 8:45 a.m.]

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ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2011–0217; FRL–9500–8]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; NSPS for Sulfuric Acid Plants (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. The ICR which is abstracted below describes the nature of the collection and the estimated burden and cost.

DATES: Additional comments may be submitted on or before January 6, 2012.

ADDRESSES: Submit your comments, referencing docket ID number EPA–HQ–OECA–2011–0217, to: (1) EPA online using *http://www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center (EPA/DC), Environmental Protection Agency, Enforcement and Compliance Docket and Information Center, mail code 2822IT, 1200 Pennsylvania Avenue NW., Washington, DC 20460; and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *Attention:* Desk Officer for EPA, 725 17th Street NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Learia Williams, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2223A, Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; *telephone number:* (202) 564–4113; *fax number:* (202) 564–0050; *email address: williams.learia@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On May 9, 2011 (76 FR 26900), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments. Any additional comments on this ICR should be submitted to both EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under docket ID number EPA–HQ–OECA–2011–0217, which is available for public viewing online at *http://www.regulations.gov,* in person viewing at the Enforcement and Compliance Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Avenue NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Enforcement and Compliance Docket is (202) 566–1752.

Use EPA's electronic docket and comment system at *http://www.regulations.gov* to submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in the system, select ''docket search,'' then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at *http://www.regulations.gov* as EPA receives them and without change, unless the comment contains copyrighted material, Confidential Business Information (CBI), or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to *http://www.regulations.gov.*

Title: NSPS for Sulfuric Acid Plants (Renewal).

ICR Numbers: EPA ICR Number 1057.12, OMB Control Number 2060–0041.

ICR Status: This ICR is scheduled to expire on December 31, 2011. Under OMB regulations, the Agency may continue to conduct or sponsor the

collection of information while this submission is pending at OMB.

Abstract: The New Source Performance Standards (NSPS) for Sulfuric Acid Plants were proposed on August 17, 1971, and promulgated on December 23, 1971. These standards apply to any sulfuric acid facility commencing construction, modification, or reconstruction after the date of proposal. The control of sulfur dioxide (SO_2) and acid mist requires not only the installation of properly designed equipment, but also the proper operation and maintenance of that equipment. Sulfur dioxide and acid mist emissions from sulfuric acid plants result from the burning of sulfur or sulfur-bearing feed-stock to form SO_2, catalytic oxidation of SO_2 to sulfur trioxide, and absorption of SO_2 in a strong acid stream. These standards rely on the capture of SO_2 and acid mist by venting to a control device.

Owners or operators of sulfuric acid plants are required to make the following one-time-only reports, notification of the date of construction or reconstruction, notification of actual startup dates, notification of any physical or operational change to an existing facility, and notification of demonstration of the continuous emissions monitoring system (CEMS). The owners and operators should notify the Administrator of the date of the initial performance test and the results of the test. After the initial recordkeeping and reporting requirements, semiannual reports are required if there has been an exceedance of control device operating parameters. Respondents are also required to maintain records of occurrence and duration of any startup, shutdown, or malfunction, or any period during which the monitoring system is inoperative.

Notifications are to inform the Agency or delegated authority when a source becomes subject to the standard. The reviewing authority may then inspect the source to ensure that the pollution control devices are properly installed and operating and that the standards are being met. Performance test reports are required as these are the Agency's records of a source's initial capability to comply with the emission standards and to serve as a record of the operating conditions under which compliance are to be achieved. The information generated by monitoring, recordkeeping, and reporting requirements described in this ICR are used by the Agency to ensure that facilities that are affected by the standard continue to operate the control equipment and achieve continuous compliance with the regulation.

All reports are sent to the delegated state or local authority. In the event that there is no such delegated authority, the reports are sent directly to the EPA regional office. This information is being collected to assure compliance with 40 CFR part 60, subpart H, as authorized in section 112 and 114(a) of the Clean Air Act. The required information consists of emissions data and other information that have been determined to be private.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB Control Number. The OMB Control Numbers for the EPA regulations are listed in 40 CFR part 9 and 48 CFR chapter 15, and are identified on the form and/or instrument, if applicable.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 81 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or 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 which have subsequently changed; 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.

Respondents/Affected Entities: Sulfuric acid plants.

Estimated Number of Respondents: 53.

Frequency of Response: Initially, occasionally, and semiannually.

Estimated Total Annual Hour Burden: 8,594.

Estimated Total Annual Cost: $1,061,150, which includes $822,650 in labor costs, no capital/startup costs, and $238,500 in operation and maintenance (O&M) costs.

Changes in the Estimates: The adjustment decrease in burden from the most recently approved ICR is due to a more accurate estimate of existing and anticipated new sources. After consulting with the Office of Air Quality Planning and Standards (OAQPS) and a number of trade associations, our data indicates that there are approximately 53 sources subject to the rule, as compared with the active ICR that shows 103 sources. There are no new facilities expected to be constructed over the next three years of this ICR. The decline in the number of sources is partially due to: (1) Plant closures, as the cost to retrofit aging facilities increased due to the down turn in the economy; (2) corporate mergers; and (3) foreign competition. Therefore, there is a net decrease in the burden to industry.

Because there are no new sources with reporting requirements, no capital/startup costs are incurred. The only cost that is incurred is for the O&M of the monitoring equipment.

Dated: November 30, 2011.

John Moses,

Director, Collection Strategies Division.

[FR Doc. 2011–31399 Filed 12–6–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2011–0223; FRL–9501–7]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; NSPS for Bulk Gasoline Terminals (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. The ICR which is abstracted below describes the nature of the collection and the estimated burden and cost.

DATES: Additional comments may be submitted on or before January 6, 2012.

ADDRESSES: Submit your comments, referencing docket ID number EPA–HQ–OECA–2011–0223, to: (1) EPA online using *http://www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov*, or by mail to: EPA Docket Center (EPA/DC), Environmental Protection Agency, Enforcement and Compliance Docket and Information Center, mail code 2822IT, 1200 Pennsylvania Avenue NW., Washington, DC 20460; and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA,

725 17th Street NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Learia Williams, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2223A, Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; *telephone number:* (202) 564–4113; *fax number:* (202) 564–0050; *email address: williams.learia@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On May 9, 2011 (76 FR 26900), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments. Any additional comments on this ICR should be submitted to both EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under docket ID number EPA–HQ–OECA–2011–0223, which is available for public viewing online at *http://www.regulations.gov*, or in person viewing at the Enforcement and Compliance Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Avenue NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Enforcement and Compliance Docket is (202) 566–1752.

Use EPA's electronic docket and comment system at *http://www.regulations.gov* to either submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in the system, select ''docket search,'' then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at *http://www.regulations.gov*, as EPA receives them and without change, unless the comment contains copyrighted material, Confidential Business Information (CBI), or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to *http://www.regulations.gov.*

Title: NSPS for Bulk Gasoline Terminals (Renewal).

ICR Numbers: EPA ICR Number 0664.10, OMB Control Number 2060–0006.

ICR Status: This ICR is scheduled to expire on December 31, 2011. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB.

Abstract: The New Source Performance Standards (NSPS) for Bulk Gasoline Terminals were proposed on December 17, 1980, promulgated on August 18, 1983, and amended on December 22, 1983, February 12, 1999, and December 19, 2003. These standards apply to the total of all loading racks at bulk gasoline terminals that deliver liquid product into gasoline tank trucks and for which construction, modification, or reconstruction commenced after the date of proposal. A bulk gasoline terminal is any gasoline facility that receives gasoline by pipeline, ship, or barge, and has a gasoline throughput greater than 75,700 liters per day. The affected facility includes the loading arms, pumps, meters, shutoff valves, relief valves, and other piping and valves necessary to fill delivery tank trucks. Volatile organic chemicals (VOCs) are the pollutants regulated under this subpart.

Owners or operators of the affected facilities must make the following one-time-only reports: notification of the date of any: (1) Construction or reconstruction; (2) anticipated and actual dates of startup; (3) physical or operational change to an existing facility that may increase the regulated pollutant emission rate; and (4) initial performance test and the results of this initial performance test. Owners or operators are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. In general, these notifications, reports, and records are required of all sources subject to NSPS.

Monitoring requirements specific to bulk gasoline terminals are listed in 40 CFR 60.505. These requirements consist of identifying and documenting vapor tightness for each gasoline tank truck that is loaded at the affected facility, and notifying the owner or operator of each tank truck that is not vapor-tight. The owner or operator must also perform a monthly visual inspection for liquid or vapor leaks, and maintain records of these inspections at the facility.

All reports are sent to the delegated state or local authority. In the event that there is no such delegated authority, the reports are sent directly to the EPA regional office. This information is being collected to assure compliance with 40 CFR part 60, subpart XX, as authorized in section 112 and 114(a) of the Clean Air Act. The required information consists of emissions data and other information that have been determined to be private.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB Control Number. The OMB Control Numbers for the EPA regulations are listed in 40 CFR part 9 and 48 CFR chapter 15, and are identified on the form and/or instrument, if applicable.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 329 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or 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 which have subsequently changed; 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.

Respondents/Affected Entities: Bulk gasoline terminals.

Estimated Number of Respondents: 40.

Frequency of Response: Initially, and occasionally.

Estimated Total Annual Hour Burden: 13,165.

Estimated Total Annual Cost: $1,260,230, which includes $1,260,230 in labor costs exclusively, with neither capital/startup costs nor operation and maintenance (O&M) costs.

Changes in the Estimates: There is no change in the labor hours in this ICR compared to the previous ICR. Consultations with the Office of Air Quality Planning and Standards (OAQPS) and trade associations revealed that there are approximately 40 sources subject to the rule, with no new facilities expected to be constructed over the next three years of this ICR.

However, there is an increase in the estimated burden cost as currently identified in the OMB Inventory of Approved Burdens. The increase is not due to any program changes, but the

change in burden is due to the use of the most updated labor rates.

Dated: November 30, 2011.

John Moses,

Director, Collection Strategies Division.

[FR Doc. 2011–31396 Filed 12–6–11; 8:45 am]

BILLING CODE 6560–50–P

FARM CREDIT SYSTEM INSURANCE CORPORATION

Meeting of the Farm Credit System Insurance Corporation Board

AGENCY: Farm Credit System Insurance Corporation Board; Regular Meeting.

SUMMARY: Notice is hereby given of the regular meeting of the Farm Credit System Insurance Corporation Board (Board).

DATE AND TIME: The meeting of the Board will be held at the offices of the Farm Credit Administration in McLean, Virginia, on December 8, 2011, from 1 p.m. until such time as the Board concludes its business.

FOR FURTHER INFORMATION CONTACT: Dale L. Aultman, Secretary to the Farm Credit System Insurance Corporation Board, (703) 883–4009, TTY (703) 883–4056.

ADDRESSES: Farm Credit System Insurance Corporation, 1501 Farm Credit Drive, McLean, Virginia 22102.

SUPPLEMENTARY INFORMATION: Parts of this meeting of the Board will be open to the public (limited space available) and parts will be closed to the public. In order to increase the accessibility to Board meetings, persons requiring assistance should make arrangements in advance. The matters to be considered at the meeting are:

Open Session

A. Approval of Minutes

- September 8, 2011

B. Business Reports

- September 30, 2011 Financial Reports
- Report on Insured and Other Obligations
- Quarterly Report on Annual Performance Plan

C. New Business

- Policy Statement on Adjustments to Insurance Premiums and Policy Statement on the Secure Base Amount and AIRAs
- Policy on Internal Controls, Audit Coverage and the Audit Committee Charter

Closed Sesson

- Confidential Report on System Performance
- Audit Plan for the Year Ended December 31, 2011

Executive Session

- Executive Session of the FCSIC Board Audit Committee with the External Auditor

Dated: December 1, 2011.

Dale L. Aultman,

Secretary, Farm Credit System Insurance Corporation Board.

[FR Doc. 2011–31323 Filed 12–6–11; 8:45 am]

BILLING CODE 6710–01–P

FEDERAL COMMUNICATIONS COMMISSION

[DA 11–1925]

Notice of Debarment

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: The Enforcement Bureau (the ''Bureau'') debars Mr. Barrett C. White from the schools and libraries universal service support mechanism (or ''E-Rate Program'') for a period of three years. The Bureau takes this action to protect the E-Rate Program from waste, fraud and abuse.

DATES: Debarment commences on the date Mr. Barrett C. White receives the debarment letter or January 6, 2012, whichever date comes first, for a period of three years.

FOR FURTHER INFORMATION CONTACT: Joy Ragsdale, Federal Communications Commission, Enforcement Bureau, Investigations and Hearings Division, Room 4–C330, 445 12th Street SW., Washington, DC 20554. Joy Ragsdale may be contacted by phone at (202) 418–1697 or by email at *Joy.Ragsdale@fcc.gov.* If Ms. Ragsdale is unavailable, you may contact Ms. Terry Cavanaugh, Acting Chief, Investigations and Hearings Division, by telephone at (202) 418–1420 and by email at *Theresa.Cavanaugh@fcc.gov.*

SUPPLEMENTARY INFORMATION: The Bureau debarred Mr. Barrett C. White from the schools and libraries universal service support mechanism for a period of three years pursuant to 47 CFR 54.8. Attached is the debarment letter, DA 11–1925, which was mailed to Mr. Barrett C. White and released on November 21, 2011. The complete text of the notice of debarment is available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portal II, 445 12th Street SW., Room CY–A257, Washington, DC 20554. In addition, the complete text is available on the FCC's Web site at *http://www.fcc.gov.* The text may also be purchased from the Commission's duplicating inspection and copying during regular business hours at the contractor, Best Copy and Printing, Inc., Portal II, 445 12th Street SW., Room CY–B420, Washington, DC 20554, telephone (202) 488–5300 or (800) 378–3160, facsimile (202) 488–5563, or via email *http://www.bcpiweb.com.*

Federal Communications Commission.

Theresa Z. Cavanaugh,

Acting Chief, Investigations and Hearings Division, Enforcement Bureau.

The debarment letter follows:

November 21, 2011
DA 11–1925

VIA CERTIFIED MAIL RETURN RECEIPT REQUESTED AND E–MAIL

Mr. Barrett C. White
c/o Mr. H. Thomas Murphy III
H. Thomas Murphy, LLC
1029 Milan Street
New Orleans, LA 70115

Re: Notice of Debarment

File No. EB–11–IH–1075

Dear Mr. White:

The Federal Communications Commission (''Commission'') hereby notifies you that, pursuant to Section 54.8 of its rules, you are prohibited from participating in the schools and libraries universal service support mechanism (''E-Rate program'') for three years from either the date of your receipt of this Notice of Debarment, or of its publication in the **Federal Register**, whichever is earlier in time (''the Debarment Date'').[1]

On July 27, 2011, the Commission's Enforcement Bureau (''Bureau'') sent you a Notice of Suspension and Initiation of Debarment Proceedings (''Notice of Suspension'')[2] that was published in the **Federal Register** on August 25, 2011.[3] The Notice of Suspension suspended you from participating in activities associated with or relating to the schools and

[1] 47 CFR 54.8(g) (2010). *See also* 47 CFR 0.111 (delegating authority to the Enforcement Bureau to resolve universal service suspension and debarment proceedings).

[2] Letter from Theresa Z. Cavanaugh, Acting Chief, Investigations and Hearings Division, Enforcement Bureau, Federal Communications Commission to Mr. Barrett C. White, Notice of Suspension and Initiation of Debarment Proceedings, 26 FCC Rcd 10526 (Inv. & Hearings Div., Enf. Bur. 2011) (Attachment 1). An Erratum was published on August 9, 2011 (Attachment 2).

[3] 76 FR 53127–01, August 25, 2011.

libraries universal service support mechanism and described the basis for initiating debarment proceedings against you, the applicable debarment procedures, and the effect of debarment.[4]

As described in the Notice of Suspension, you were suspended from participating in activities associated with or relating to the schools and libraries universal service support mechanism as a result of your conviction for conspiring with others to defraud and obtain money from the E-Rate Program by controlling the application, bidding, and implementation process of the E-Rate program for schools located in four states.[5] As further described in the Notice of Suspension, you conspired with owners of Global Network Technologies, Inc. (''GNT'') to offer and deliver $28,500 in bribes to school officials in exchange for steering E-Rate contract work to GNT.[6] In furtherance of your scheme, you accepted fraudulent billing invoices from a school employee for services never provided by that employee,[7] and concealed material facts concerning the source of your payments to school officials.[8] For your role in the fraudulent scheme, you were sentenced to serve one year and one day in federal prison, followed by two years of supervised release for conspiring to defraud the E-Rate program.[9] The court also ordered you to pay a $4,000 criminal fine.[10] Pursuant to Section 54.8(c) of the Commission's rules, your conviction of criminal conduct in connection with the E-Rate program serves as a basis for your debarment.[11]

In accordance with the Commission's debarment rules, you were required to file with the Commission any opposition to your suspension or its scope, or to your proposed debarment or its scope, no later than thirty (30) calendar days from either the date of your receipt of the Notice of Suspension or of publication of the Notice of Suspension in the **Federal Register**, whichever is earlier in time.[12] The Commission did not receive any such opposition.

For the foregoing reasons, you are debarred for three years from the Debarment Date.[13] During this debarment period, you are excluded from participating in any activities associated with or related to the E-Rate program, including the receipt of funds or discounted services through the schools and libraries support mechanism, or consulting with, assisting, or advising applicants or service providers regarding the schools and libraries support mechanism.[14]

Sincerely,
Theresa Z. Cavanaugh
Acting Chief
Investigations and Hearings Division
Enforcement Bureau

cc: Johnnay Schrieber, Universal Service Administrative Company (via email)
Rashann Duvall, Universal Service Administrative Company (via email)
Juan Rodriguez, Antitrust Division, United States Department of Justice (via email)
Stephanie Toussaint, Antitrust Division, United States Department of Justice (via email)

[FR Doc. 2011–31400 Filed 12–6–11; 8:45 am]

BILLING CODE 6712–01–P

[4] Notice of Suspension, 26 FCC Rcd at 10527.

[5] *United States* v. *Tyrone D. Pipkin,* Criminal Docket No. 11–15 ''A'', Plea Agreement (entered Mar. 29, 2011) (''*Plea Agreement*''). The conspiracy scheme involved schools in Arkansas, Florida, Illinois and Louisiana.

[6] Notice of Suspension, 26 FCC Rcd at 10527.

[7] *Id.*

[8] *Id.*

[9] Notice of Suspension, 26 FCC Rcd at 10527. *See also United States* v. *Barrett C. White,* Criminal Case No. 10–324–L, Factual Basis at 2 (E.D.La. filed Mar. 3, 2011).

[10] *United States* v. *Barrett C. White,* Criminal Docket No. 10–324–L, Judgment at 5 (E.D.La. filed June 9, 2011).

[11] 47 CFR 54.8(c).

[12] 47 CFR 54.8(e)(3), (4). Any opposition had to be filed no later than August 30, 2011.

[13] 47 CFR 54.8(e)(5),(g). *See also* Notice of Suspension, 26 FCC Rcd at 10527.

[14] 47 CFR 54.8(a)(1), (5), (d). *See also* Notice of Suspension, 26 FCC Rcd at 10527.

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

[Docket No. AS11–32]

Appraisal Subcommittee Notice of Meeting

AGENCY: Appraisal Subcommittee of the Federal Financial Institutions Examination Council.

ACTION: Notice of meeting.

Description: In accordance with Section 1104 (b) of Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended, notice is hereby given that the Appraisal Subcommittee (ASC) will meet in closed session:

Location: OCC—250 E Street SW., Room 7C/7CA, Washington, DC 20219.

Date: December 14, 2011.

Time: Immediately following the ASC open session.

Status: Closed.

Matters To Be Considered

November 9, 2011 minutes—Closed Session.

Preliminary discussion of State Compliance Reviews.

Dated: December 2, 2011.

James R. Park,

Executive Director.

[FR Doc. 2011–31373 Filed 12–6–11; 8:45 am]

BILLING CODE P

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

[Docket No. AS11–31]

Appraisal Subcommittee Notice of Meeting

AGENCY: Appraisal Subcommittee of the Federal Financial Institutions Examination Council.

ACTION: Notice of Meeting.

Description: In accordance with Section 1104 (b) of Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended, notice is hereby given that the Appraisal Subcommittee (ASC) will meet in open session for its regular meeting:

Location: OCC—250 E Street SW., Room 7C/7CA, Washington, DC 20219.

Date: December 14, 2011.

Time: 10:30 a.m.

Status: Open.

Matters To Be Considered

Summary Agenda

November 9, 2011 minutes—Open Session.

(No substantive discussion of the above items is anticipated. These matters will be resolved with a single vote unless a member of the ASC requests that an item be moved to the discussion agenda.)

Discussion Agenda

Appraisal Foundation 2012 Grant Proposal.

Appraisal Foundation July 2011 Grant Reimbursement Request.

Appraisal Foundation August 2011 Grant Reimbursement Request.

Iowa Compliance Review.

How To Attend and Observe an ASC Meeting

Email your name, organization and contact information to *meetings@asc.gov.* You may also send a written request via U.S. Mail, fax or commercial carrier to the Executive Director of the ASC, 1401 H Street NW., Ste 760, Washington, DC 20005. The fax number is (202) 289–4101. Your request

must be received no later than 4:30 p.m., ET, on the Monday prior to the meeting. Attendees must have a valid government-issued photo ID and must agree to submit to reasonable security measures. The meeting space is intended to accommodate public attendees. However, if the space will not accommodate all requests, the ASC may refuse attendance on that reasonable basis. The use of any video or audio tape recording device, photographing device, or any other electronic or mechanical device designed for similar purposes is prohibited at ASC meetings.

Dated: December 2, 2011.

James R. Park,

Executive Director.

[FR Doc. 2011–31374 Filed 12–6–11; 8:45 am]

BILLING CODE P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within ten days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (*http://www.fmc.gov*) or by contacting the Office of Agreements at (202) 523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 012148.

Title: CSCL/POS Slot Charter Agreement.

Parties: China Shipping Container Lines Co., Ltd., China Shipping Container Lines (Hong Kong) Co., Ltd., and Hainan P O Shipping Co., Ltd.

Filing Party: Tara L. Leiter, Esquire; Blank Rome LLP; 600 New Hampshire Avenue NW., Washington, DC 20037.

Synopsis: The agreement authorizes China Shipping to charter space to Hainan P O in the trade between the U.S. West Coast and Asia.

Dated: December 1, 2011.

By Order of the Federal Maritime Commission.

Karen V. Gregory,

Secretary.

[FR Doc. 2011–31443 Filed 12–6–11; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License; Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission an application for a license as a Non-Vessel-Operating Common Carrier (NVO) and/or Ocean Freight Forwarder (OFF)—Ocean Transportation Intermediary (OTI) pursuant to section 19 of the Shipping Act of 1984 as amended (46 U.S.C. chapter 409 and 46 CFR 515). Notice is also hereby given of the filing of applications to amend an existing OTI license or the Qualifying Individual (QI) for a license.

Interested persons may contact the Office of Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573, by telephone at (202) 523–5843 or by email at *OTI@fmc.gov.*

Bluesea Logistics Corporation (NVO), 327 Elizabeth Avenue, Apt. #A, Monterey Park, CA 91755–2044, Officers: Li Lin, General Manager/Sec/CFO, (Qualifying Individual), Guanghui Cui, President, Application Type: New NVO License.

Classic Car Transport, LLC dba Classic Car Export (OFF), 1920 W. 143rd Street, #190, Leawood, KS 66224, Officers: Joseph J. Weinrich, Manager, (Qualifying Individual), Steven A. Sharpe, Member, Application Type: New OFF License.

Clover Internacional Inc. dba Clover Marine (OFF), 15700 International Plaza Drive, #100, Houston, TX 77032, Officers: Juan C. Castillo, Special Secretary, (Qualifying Individual), Luis A. Rincon, President/Secretary, Application Type: Name Change.

Didi Logistics Inc (NVO & OFF), 2380 SW 80th Court, Miami, FL 33155, Officers: Diana V. Escobar, President, (Qualifying Individual), Alicia H. Escobar, Vice President, Application Type: New NVO & OFF License.

Equipsa N.V.O.C.C. Inc. (NVO), 2105 NW 102 Avenue, Miami, FL 33172, Officers: Isabel C. Montejo, Vice President Operations, (Qualifying Individual), Arthur Gelfand, President, Application Type: QI Change.

Gwinnett Shipping & Receiving, LLC dba Korea Intermodal USA (NVO), 1418 Beaver Ruin Road, Norcross, GA 30093, Officers: Won A. An, Member, (Qualifying Individual), Joon H. An, Member, Application Type: New NVO. License.

HPK Logistics (USA) Inc dba Trade Wind International (NVO & OFF), 727 Brea Canyon Road, #14, Walnut, CA 91789, Officers: Tigi Cai, Vice President/Treasurer, (Qualifying Individual), Jian Sun, President, Application Type: Add OFF Service.

Infinit Ideas International, Inc. dba Global Intertrans (NVO), 17890 Castleton, #251, City of Industry, CA 91748, Officers: Catherine Tsai, President/Treasurer, Qingfeng aka Daniel Wang, Vice President/Secretary, (Qualifying Individuals), Application Type: Business Structure Change.

Rapid Express 1 Corporation (NVO & OFF), 2258 NW 94 Avenue, Doral, FL 33172, Officers: Rene Parajon, Vice President, (Qualifying Individual), Mirta Parajon, President/Secretary, Application Type: New NVO & OFF License.

Red Arrow Consulting, Inc. dba Red Arrow Logistics (NVO & OFF), 22605 SE 56th Street, #270, Issaquah, WA 98029, Officers: Lorraine E. Lasater, CEO/President/Treasurer, (Qualifying Individual), Lindsey Peter, COO/Vice President, Application Type: QI Change.

Starwin Logistics Inc. (NVO), 160–51 Rockaway Blvd., #200, Jamaica, NY 11434, Officers: Junxian (Jessie) Wang, President/Chairperson/Sec/Treasurer, (Qualifying Individual), Hao Liang, Shareholder, Application Type: New NVO License.

Suddath Global Logistics, LLC dba Suddath Global Logistics, (NVO & OFF), 815 South Main Street, Jacksonville, FL 32207, Officers: Brett J. Macker, Executive Vice President, (Qualifying Individual), Michael Kranisky, President/General Manager, Application Type: Lic. Transfer/QI Chg./Add NVO Service.

Dated: December 2, 2011.

Karen V. Gregory,

Secretary.

[FR Doc. 2011–31437 Filed 12–6–11; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License; Reissuance

Notice is hereby given that the following Ocean Transportation Intermediary licenses have been reissued by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. chapter 409) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR part 515.

License No.	Name/address	Date reissued
003489F	McClellan, Lavone W. dba Acts Customs Brokers, 1386 Salford, Houston, TX 77032	October 28, 2011.
017582F	Trans Global Logistics, Inc., #1 Conan Drive, Midland City, AL 36350	October 7, 2011.

Sandra L. Kusumoto,

Director, Bureau of Certification and Licensing.

[FR Doc. 2011–31438 Filed 12–6–11; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

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 shares of 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 offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than December 22, 2011.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Carl E. Stukenholtz*, Perry, Iowa, individually, and acting in concert with James E. Wendl, Trustee of the James Wendl Revocable Trust; Carol A. Wendl, Trustee of the Carol Wendl Revocable Trust, both of Panora, Iowa; Brian L. Thielges; and Mary R. Thielges, both of Des Moines, Iowa; to acquire control of Exchange Financial, Inc., and thereby indirectly acquire control of Exchange State Bank, both in Adair, Iowa.

B. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Dale Mitchell Ashlock, Gravois Mills, Missouri; Donald Kinahan Ashlock, Olathe, Kansas; and Pershing LLC*, Jersey City, New Jersey; to become part of the group acting in concert to acquire control of First Federal of Olathe Bancorp., Inc., and thereby indirectly acquire control of First Federal Savings and Loan Bank, both in Olathe, Kansas.

Board of Governors of the Federal Reserve System, December 2, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–31368 Filed 12–6–11; 8:45 am]

BILLING CODE 6210–01–P

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.

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 December 30, 2011.

A. Federal Reserve Bank of Atlanta (Chapelle Davis, Assistant Vice President) 1000 Peachtree Street NE., Atlanta, Georgia 30309:

1. *First Advantage Bancorp,* Clarksville, Tennessee; to become a bank holding company by acquiring 100 percent of the voting shares of First Advantage Bank, Clarksville, Tennessee, upon its conversion to a state nonmember bank.

B. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street Chicago, Illinois 60690–1414:

1. *Burling Bancorp, Inc.,* Chicago, Illinois; to become a bank holding company by acquiring 100 percent of the voting shares of Burling Bank, Chicago, Illinois.

C. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *First Federal Olathe Bancorp, Inc.,* Olathe, Kansas; to become a bank holding company by retaining 100 percent of the voting shares of First Federal Savings and Loan Bank, Olathe, Kansas.

D. Federal Reserve Bank of San Francisco (Kenneth Binning, Vice President, Applications and Enforcement) 101 Market Street San Francisco, California 94105–1579:

1. *Grandpoint Capital, Inc.;* Los Angeles, California; to acquire 100 percent of the voting shares of Regents Bancshares, Inc., Vancouver, Washington, and thereby indirectly acquire voting shares of Regents Bank NA, La Jolla, California.

In connection with this application, Applicant also has applied to acquire 100 percent of the equity interest of Peoria Holdings, LLC, Vancouver, Washington, and engage in loan servicing, extending credit and holding, management and disposal of OREO, pursuant to section 225.28(b)(1)of Regulation Y.

Board of Governors of the Federal Reserve System, December 1, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–31277 Filed 12–6–11; 8:45 am]

BILLING CODE 6210–01–P

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.

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 January 3, 2012.

A. Federal Reserve Bank of Minneapolis (Jacqueline G. King, Community Affairs Officer) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Mountain Iron Holdings, LLC,* Buhl, Minnesota; to become a bank holding company by acquiring 100 percent of the voting shares of Timberland Bancorporation, Baxter, Minnesota, and thereby acquire First National Bank of Buhl, Buhl, Minnesota.

Board of Governors of the Federal Reserve System, December 2, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–31369 Filed 12–6–11; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in or To Acquire Companies 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.

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 December 22, 2011.

A. Federal Reserve Bank of Cleveland (Nadine Wallman, Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101–2566:

1. *Park National Corporation,* Newark, Ohio; to acquire 100 percent of the voting shares of SE Property Holdings, LLC, Newark, Ohio, and thereby engage in credit extending activities, pursuant to section 225.28(b)(1) of Regulation Y.

Board of Governors of the Federal Reserve System, December 2, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–31370 Filed 12–6–11; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30-Day–12–11HI]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995. To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Frame development for the residential care facility component of the National Study of Long-Term Care Providers-NEW—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

NCHS seeks approval to collect data needed to develop an up-to-date sampling frame of residential care facilities. The sampling frame will be used to draw a nationally representative sample for a planned new survey, the National Study of Long-Term Care Providers (NSLTCP). The frame-related data will be collected from representatives in state regulatory agencies in the 50 states and the District of Columbia primarily via telephone calls, emails, and in a few cases, via formal written requests. The data to be collected from these state officials include (1) Confirming that we have identified the appropriate licensure categories of residential care facilities within each state that meet the NSLTCP definition and (2) for each relevant licensure category, requesting an electronic file of the licensed residential care facilities for which the agency is responsible if such files with the needed variables are not downloadable from the state's Web site.

The NSLTCP study definition of a residential care facility is one that is licensed, registered, listed, certified, or otherwise regulated by the state; provides room and board with at least two meals a day; provides around-the-clock on-site supervision; helps with activities of daily living (*e.g.,* bathing, eating, or dressing) or health related services, such as medication supervision; serves primarily an adult population; and has at least four licensed, certified, or regulated beds. Facilities licensed to serve the mentally ill or the intellectually disabled/developmentally disabled populations exclusively are excluded. Nursing homes and skilled nursing facilities are also excluded, unless they have a unit or wing meeting the above definition and residents can be separately enumerated.

The electronic files we seek to obtain from the states should include the name, address, phone number, and Web site (if available) of the residential care facility; name, phone number, and email address (if available) of facility director; licensure category; chain affiliation; ownership type; and bed size.

Expected users of the frame data include, but are not limited to CDC's NCHS and its contractors; other Department of Health and Human Services (DHHS) agencies, such as the Office of the Assistant Secretary for Planning and Evaluation and the Agency for Healthcare Research and

Quality; associations, such as Leading Age (formerly the American Association of Homes and Services for the Aging), National Center for Assisted Living, American Seniors Housing Association, and Assisted Living Federation of America; universities; foundations; and other private sector organizations.

Burden is estimated at 2 hours and 35 minutes per state, including time to verify contact information, to respond to a semi-structured telephone protocol, and to develop the facility listing in an electronic format. One year clearance is requested. There is no cost to respondents other than their time to participate. The total estimated annual burden hours are 132.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Form name	Number of respondents	Number of responses/ respondent	Average burden/ response (in hours)
State Government Representatives	Contact info verification	51	1	5/60
State Government Representatives	Telephone protocol	51	1	30/60
State Government Representatives	Electronic file development	51	1	2

Date: November 30, 2011.

Daniel Holcomb,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–31449 Filed 12–6–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day–12–11CE]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call (404) 639–5960 and send comments to Daniel Holcomb, CDC Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

The National Health and Nutrition Examination Survey (NHANES) 1999–2010 Birth Certificate Linkage Study—Pregnant Women—New—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, shall collect statistics on the extent and nature of illness and disability; environmental, social and other health hazards; and determinants of health of the population of the United States.

Division of Health and Nutrition Examination Surveys (DHANES) proposes to re-contact women who were pregnant at the time of their participation in NHANES in 1999–2010 and ask permission to link their data to the child's birth certificate data, for the birth that resulted after the survey. This study is funded in collaboration with CDC's National Center for Chronic Disease Prevention and Health Promotion, Division of Reproductive Health (DRH). Participation is completely voluntary and confidential.

NHANES was conducted periodically between 1970 and 1994, and continuously since 1999 by the NCHS. A supplemental sample of pregnant women was selected in NHANES from 1999–2006. This resulted in a total of 1,350 pregnant women. Although this supplemental sample was discontinued after 2006, there are an estimated 150 pregnant women in the NHANES sample for the years 2007–10. This results in a total estimate of 1,500 women for this project.

The NHANES only collected information about the pregnant women at the time of interview. Having information on their children's birth certificates and birth outcomes could provide insight into issues related to maternal and child health. No other survey has the physical examination and nutritional data that NHANES collects on pregnant women.

Consents for these projects will be sent to the appropriate U.S. states, local areas, or territories, where the birth certificate retrievals will then be conducted. Electronic retrieval per records is estimated at five minutes.

NHANES data users include the U.S. Congress; the World Health Organization; numerous Federal agencies such as the National Institutes of Health, the Environmental Protection Agency, and the United States Department of Agriculture; private groups such as the American Heart Association; schools of public health; private businesses; individual practitioners; and administrators. This submission requests approval for two years. There is no cost to respondents other than their time. The total estimated annual burden is 312 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Women who were pregnant during NHANES 1999–2010.	Health Questionnaire/Consent Form	750	1	20/60	250
State/local vital statistics staff (one per U.S. State or Territory).	Locate and transmit birth certificates	57	13	5/60	62
Total					312

November 30, 2011.

Daniel Holcomb,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–31445 Filed 12–6–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day–12–11JQ]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Data Collection for Evaluation of Education, Communication, and Training Activities—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Global Migration and Quarantine (DGMQ), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) Division of Global Migration and Quarantine (DGMQ) is requesting a three year approval for a generic clearance to conduct evaluation research in order to plan and implement health communication, education, and training activities to improve health and prevent the spread of disease. These activities include communicating with international travelers and other mobile populations, training healthcare providers, and educating public health departments and other federal partners.

The information collection for which approval is sought is in accordance with DGMQ's mission to reduce morbidity and mortality among immigrants, refugees, travelers, expatriates, and other globally mobile populations, and to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States. This mission is supported by delegated legal authorities.

First, section 361 of the Public Health Service (PHS) Act (42 U.S.C. 264) (Attachment A) authorizes the Secretary of Health and Human Services (HHS) to make and enforce regulations necessary to prevent the introduction, transmission or spread of communicable diseases from foreign countries or possessions into the United States and from one state or possession into any other state or possession. These regulations are codified in 42 *Code of Federal Regulations* (CFR) parts 70 and 71.

In addition, the Secretary of Health and Human Services also has the legal authority to establish regulations outlining the requirements for the medical examination of aliens before they may be admitted into the United States. This authority is provided under Section 212(a)(1)(A) of the Immigration and Nationality Act (8 U.S.C. 1182(a)(1)(A)) (Attachment B) and Section 325 of the Public Health Service Act (Attachment C). These regulations are codified in 42 CFR part 34, which establish requirements that determine whether aliens can be admitted into the United States.

Successful implementation of DGMQ's regulatory authority and public health mission as outlined above requires a variety of communication, training and educational activities involving staff, partners, mobile populations and the general public. DGMQ conducts these activities in order to inform, educate and empower key audiences with respect to important public health issues.

This generic OMB clearance will allow DGMQ to quickly collect information about the knowledge, attitudes, and behaviors of key audiences (such as refugees, immigrants, migrants, international travelers, travel industry partners, healthcare providers, non-profit agencies, customs brokers and forwarders, schools, state and local health departments) to help improve and inform these activities during both routine and emergency public health events. This generic OMB clearance will help DGMQ continue to refine these efforts in a timely manner, and will be especially valuable for communication activities that must occur quickly in response to public health emergencies.

DGMQ staff will use a variety of data collection methods for this proposed project: interviews, focus groups, group discussions, surveys, and pre-post tests. Depending on the research questions and audiences involved, data may be gathered in-person, by telephone, online, or using some combination of these formats. Data may be collected in quantitative and/or qualitative forms. Numerous audience variables will be assessed under the auspices of this generic OMB clearance. These include, but are not limited to, knowledge, attitudes, beliefs, behavioral intentions, practices, behaviors, skills, self-efficacy, and information needs and sources. Insights gained from evaluation research will assist in the development, refinement, implementation, and demonstration of outcomes and impact of communication, education, and training activities.

The information being collected will not impose a cost burden on the respondents beyond that associated with their time to provide the required data. The total estimated annual burden is 22,166 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
General Public/Healthcare Professionals Focus groups.	Screening form	3000	1	10/60
	Focus Groups	1500	1	1.5
General Public/Healthcare Professionals Interviews	Screening Form	2000	1	10/60
	Interviews	1000	1	1
General Public/Healthcare Professionals Large Group Discussions.	Screening Forms	2000	1	10/60
	Large Group Discussion	1000	1	1.5
General Public/Healthcare Professionals Surveys	Screening Forms	15000	1	10/60
	Surveys	7500	1	45/60
General Public/Healthcare Professionals Pre/post tests.	Screening Forms	15000	1	10/60
	Pre/Post Tests	7500	1	45/60

Dated: November 30, 2011.

Daniel Holcomb,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–31407 Filed 12–6–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, Office of Public Health Preparedness and Response (BSC, OPHPR)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

Time and Date: 1:30 p.m.–4 p.m., January 3, 2012.

Place: This meeting is accessible by Web Conference. Please contact CDC (see Contact for More Information) to obtain further instructions on how to participate by phone and online.

Status: Open to the public limited only by web conference. Participation by web conference is limited by the number of ports available.

Purpose: This Board is charged with providing advice and guidance to the Secretary, Department of Health and Human Services (HHS), the Assistant Secretary for Health (ASH), the Director, Centers for Disease Control and Prevention (CDC), and the Director, Office of Public Health Preparedness and Response (OPHPR), concerning strategies and goals for the programs and research within OPHPR, monitoring the overall strategic direction and focus of the OPHPR Divisions and Offices, and administration and oversight of peer review of OPHPR scientific programs. For additional information about the Board, please visit: *http://www.cdc.gov/phpr/science/counselors.htm.*

Matters To Be Discussed: The agenda items for this meeting include: a briefing to the Board on the findings from the mid-project review of OPHPR's Preparedness and Emergency Response Research Centers followed by a vote on final recommendations; and an update on OPHPR strategic plan.

Contact for More Information: Sarah Henderson, OPHPR, CDC, 1600 Clifton Road, NE., Mailstop D–44, Atlanta, Georgia 30333; *Telephone:* (770) 488–8341; *Facsimile:* (404) 639–7977; *E-mail: OPHPR.BSC.Questions@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: November 28, 2011.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2011–31109 Filed 12–6–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Request for Nominations of Candidates To Serve on the Board of Scientific Counselors (BSC), Office of Infectious Diseases (OID)

The Centers for Disease Control and Prevention (CDC) is soliciting nominations for possible membership on the BSC, OID. This board consists of 17 experts in fields related to infectious diseases who are selected by the Secretary of the U.S. Department of Health and Human Services (HHS). The board advises the HHS Secretary; the CDC Director; the OID Director; and the Directors of the National Center for Immunization and Respiratory Diseases (NCIRD), the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), and the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) concerning strategies, goals, and priorities for the programs and research within the national centers and monitors the overall strategic direction and focus of OID and the national centers.

Nominations are being sought for individuals who have expertise and qualifications necessary to contribute to the accomplishment of the board's mission. Nominees will be selected by the HHS Secretary or designee from authorities knowledgeable in the fields of infectious diseases and related disciplines, including epidemiology, microbiology, bacteriology, virology, parasitology, mycology, immunology, public health, entomology, clinical medicine, and veterinary medicine, as well as from the general public. Members may be invited to serve for terms of up to four years.

The U.S. Department of Health and Human Services policy stipulates that committee membership shall be balanced in terms of professional training and background, points of view represented, and the committee's function. In addition to a broad range of expertise, consideration is given to a broad representation of geographic areas within the U.S., with diverse representation of both genders, ethnic and racial minorities, and persons with disabilities. Nominees must be U.S. citizens, and cannot be full-time employees of the U.S. Government.

Candidates should submit the following items:

- Current *curriculum vitae,* including complete contact information (name,

affiliation, mailing address, telephone number, email address);

• A letter of recommendation stating the qualifications of the candidate.

Nomination materials must be postmarked by December 30, 2011, and sent to: Kim Distel, Office of Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop D10, Atlanta, Georgia 30333, telephone (404) 639–2100.

Candidates invited to serve will be asked to submit the ''Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at the Centers for Disease Control and Prevention.'' This form allows CDC to determine whether there is a statutory conflict between that person's public responsibilities as a Special Government Employee and private interests and activities, or the appearance of a lack of impartiality, as defined by Federal regulation. The form may be viewed and downloaded at *http://www.usoge.gov/forms/oge450_pdf/oge450_accessible.pdf.* This form should not be submitted as part of a nomination.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention, and the Agency for Toxic Substances and Disease Registry.

Dated: November 29, 2011.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2011–31429 Filed 12–6–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Planning, Research and Evaluation Advisory Committee on Head Start Research and Evaluation

AGENCY: Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of ACF. The meeting will be open to the public.

Name of Committee: Advisory Committee for Head Start Research and Evaluation.

General Function of Committee: The Advisory Committee for Head Start Research and Evaluation will provide feedback on the published final report for the Head Start Impact Study, offering interpretations of the findings, discussing implications for practice and policy, and providing recommendations on follow-up research, including additional analysis of the Head Start Impact Study data. The Committee will also be asked to provide recommendations to the Secretary regarding how to improve Head Start and other early childhood programs by enhancing the use of research-informed practices in early childhood. Finally, the Committee will be asked to provide recommendations on the overall Head Start research agenda, including—but not limited to—how the Head Start Impact Study fits within this agenda. The Committee will provide advice regarding future research efforts to inform HHS about how to guide the development and implementation of best practices in Head Start and other early childhood programs around the country.

DATES: The meeting will be held from 8:30 a.m. to 5 p.m. on January 18–19, 2012.

ADDRESSES: Washington Plaza Hotel, 10 Thomas Circle NW., Washington, DC 20005, *Phone:* (202) 842–1300.

FOR FURTHER INFORMATION CONTACT: Jennifer Brooks, Office of Planning, Research, and Evaluation, email *jennifer.brooks@acfhhs.gov* or call (202) 205–8212.

Agenda: The Committee will review draft recommendations developed by the subcommittees on the topics of quality teaching and learning; parent, family, and community engagement; the impact of Head Start and Early Head Start; health and mental health; and cultural and linguistic responsiveness.

Procedure: Interested persons may present data, information or views, in writing, on issues pending before the Committee. Written submissions may be made to Jennifer Brooks at *jennifer.brooks@acf.hhs.gov* on or before January 2, 2012. All written materials provided to the contact person will be shared with the Committee members.

ACF welcomes the attendance of the public at this advisory committee meeting and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jennifer Brooks at least seven days in advance of the meeting. Information about the Committee and this meeting can be found at the Committee Web site, *http://www.acfhhs.gov/programs/opre/hs/advisory_com/.*

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 22, 2011.

George H. Sheldon,

Acting Assistant Secretary for Children and Families.

[FR Doc. 2011–31196 Filed 12–6–11; 8:45 am]

BILLING CODE M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0608]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; MedWatch: The Food and Drug Administration Medical Products Reporting Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 6, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, *Fax:* (202) 395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0291. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, (301) 796–3794, *Jonnalynn.Capezzuto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

MedWatch: The FDA Medical Products Reporting Program—(OMB Control Number 0910–0291)—Extension

I. Background

To ensure the marketing of safe and effective products, postmarketing adverse outcomes and product problems must be reported for all FDA-regulated human health care products, including drugs, both prescription and over-the-counter (OTC); biologics; medical devices; dietary supplements and other special nutritional products (*e.g.,* infant formula and medical foods); and cosmetics. In addition, FDA has regulatory responsibility for tobacco products and an interest in receiving reports about adverse outcomes and product problems for these products.

Under sections 505, 512, 513, 515, 519 and 903 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355, 360b, 360c, 360e, 360i and 393) and section 351 of the Public Health Service Act (42 U.S.C. 262), FDA has the responsibility to ensure the safety and effectiveness of drugs, biologics, and devices. Under section 502(a) of the FD&C Act (21 U.S.C. 352(a)), a drug or device is misbranded if its labeling is false or misleading. Under section 502(f)(2) of the FD&C Act, it is misbranded if it fails to bear adequate warnings, and under section 502(j), it is misbranded if it is dangerous to health when used as directed in its labeling. Under section 502(t)(2) of the FD&C Act, devices are considered to be misbranded if there has been a failure or refusal to give required notification or to furnish required material or information required under section 519. Requirements regarding mandatory reporting of adverse events or product problems have been codified in parts 310, 314, 600, and 803 (21 CFR 310, 314, 600, and 803), specifically §§ 310.305, 314.80, 314.98, 600.80, 803.30, 803.50, 803.53, 803.56, and specified in sections 760 and 761 of the FD&C Act (21 U.S.C. 379aa and 379aa–1). Mandatory reporting of adverse reactions for human cells, tissues, and cellular and tissue-based products (HCT/Ps) has been codified in 21 CFR 1271.350.

FDA regulates the safety (*i.e.,* adulteration) of dietary supplements under section 402 of the FD&C Act (21 U.S.C. 342). Dietary supplements do not require premarket approval by FDA and the Agency bears the burden to gather and review evidence that a dietary supplement may be adulterated under section 402 of the FD&C Act after that product is marketed. Under section 761(b)(1) of the FD&C Act, a dietary supplement manufacturer, packer, or distributor whose name appears on the label of a dietary supplement marketed in the United States is required to submit to FDA any serious adverse event report it receives regarding use of the dietary supplement in the United States.

Mandatory reporting, since 1993, has been supplemented by voluntary reporting by health care professionals, their patients, and consumers via the MedWatch reporting process. To carry out its responsibilities, the Agency needs to be informed when an adverse event, product problem, error with use of a human medical product or evidence of therapeutic failure (inequivalence) is suspected or identified in clinical use. When FDA receives this information from either health care professionals or patients, the report becomes data that will be used to assess and evaluate the risk associated with the product, and then take whatever action is necessary to reduce, mitigate, or eliminate the public's exposure to the risk through regulatory and public health interventions.

To implement these provisions for reporting on human medical products during their postapproval and marketed lifetimes, two forms are available from the Agency. FDA Form 3500 is used for voluntary (*i.e.,* not mandated by law or regulation) reporting by health care professionals and the public. FDA Form 3500A is used for mandatory reporting (*i.e.,* required by law or regulation).

Respondents to this collection of information are health care professionals; medical care organizations and other user-facilities (*e.g.,* extended care facilities, ambulatory surgical centers); consumers; manufacturers of biological, dietary supplement, and drug products or medical devices; and importers.

II. Use of FDA Form 3500 (Voluntary Version)

The voluntary version of the form is used to submit all reports not mandated by Federal law or regulation. Individual health professionals are not required by law or regulation to submit reports to the Agency or the manufacturer, with the exception of certain adverse reactions following immunization with vaccines as mandated by the National Childhood Vaccine Injury Act of 1986. Those mandatory reports are not submitted to FDA on the 3500 or 3500A form but are submitted to the joint FDA/Centers for Disease Control and Prevention Vaccines Adverse Event Reporting System (VAERS) on the VAERS–1 form (see *http://vaers.hhs.gov/resources/vaers_form.pdf).*

Hospitals are not required by Federal law or regulation to submit reports associated with drug products, biological products, or special nutritional products. However, hospitals and other user facilities are required by Federal law to report medical device-related deaths and serious injuries.

Under Federal law and regulation (section 761(b)(1) of the FD&C Act), a dietary supplement manufacturer, packer, or distributor whose name appears on the label of a dietary supplement marketed in the United States is required to submit to FDA any serious adverse event report it receives regarding use of the dietary supplement in the United States. However, FDA bears the burden to gather and review evidence that a dietary supplement may be adulterated under section 402 of the FD&C Act after that product is marketed. Therefore, the Agency depends on the voluntary reporting by health professionals and especially by consumers of suspected serious adverse events and product quality problems associated with the use of dietary supplements.

III. Use of FDA Form 3500A (Mandatory Version)

A. Drug and Biologic Products

In sections 505(j) and 704 (21 U.S.C. 374) of the FD&C Act, Congress has required that important safety information relating to all human prescription drug products be made available to the FDA so that it can take appropriate action to protect the public health when necessary. Section 702 of the FD&C Act (21 U.S.C. 372) authorizes investigational powers to FDA for enforcement of the FD&C Act. These statutory requirements regarding mandatory reporting have been codified by FDA under 21 parts 310 and 314 (drugs) and 600 (biologics) of the Code of Federal Regulations. Parts 310, 314, and 600 mandate the use of FDA Form 3500A for reporting to FDA on adverse events that occur with drugs and biologics. Mandatory reporting of adverse reactions for HCT/Ps has been codified in 21 CFR 1271.350.

The majority of the mandatory reports for drug products, which at inception of FDA Form 3500A's use were received by the Agency on the paper version of FDA Form 3500A (by mail or FAX), are now submitted and received by the Agency via an electronic submission route. In that case, the FDA Form 3500A is not used.

B. Medical Device Products

Section 519 of the FD&C Act requires manufacturers and importers of devices

intended for human use to establish and maintain records, make reports, and provide information as the Secretary of Health and Human Services may by regulation reasonably require to assure that such devices are not adulterated or misbranded and to otherwise assure its safety and effectiveness. The Safe Medical Device Act of 1990, signed into law on November 28, 1990, amends section 519 of the FD&C Act. The amendment requires that user facilities such as hospitals, nursing homes, ambulatory surgical facilities, and outpatient treatment facilities report deaths related to medical devices to FDA and to the manufacturer, if known. Serious illnesses and injuries are to be reported to the manufacturer or to FDA if the manufacturer is not known. These statutory requirements regarding mandatory reporting have been codified by FDA under 21 CFR part 803, which mandates the use of FDA Form 3500A for reporting to FDA on medical devices. The Medical Device User Fee and Modernization Act of 2002, Public Law 107–250, signed into law October 26, 2002, amended section 519 of the FD&C Act. The amendment (section 303) required FDA to revise the MedWatch forms ''to facilitate the reporting of information * * * relating to reprocessed single-use devices, including the name of the reprocessor and whether the device has been reused.''

C. Nonprescription Drug Products and Dietary Supplements

Section 502(x) in the FD&C Act implements the requirements of the Dietary Supplement and Nonprescription Drug Consumer Protection Act, which became law (Pub. L. 109–462) on December 22, 2006. These requirements apply to manufacturers, packers, and distributors of nonprescription (OTC) human drug products marketed without an approved application. The law requires reports of serious adverse events to be submitted to FDA by manufacturers of dietary supplements and nonprescription drugs.

IV. Proposed Modifications to Existing Forms 3500 and 3500A

A. General Changes

The proposed modifications to FDA Form 3500 and FDA Form 3500A reflect changes that will bring the form into conformation, since the previous authorization in 2008, with current regulations, rules, and guidances.

B. Changes Proposed for FDA Form 3500

No additional fields will be added and no fields deleted. There are no proposed formatting changes to the location or distribution of the fields. Modifications are proposed to several field labels and descriptions to better clarify for reporters the range of reportable products, including tobacco products and food (*e.g.,* food allergens causing allergic or anaphylaxis reactions). Descriptive text in the field labels and instructions were modified to permit a better understanding of data requested. For section E, field E4, the label ''Other'' will be renamed ''Unique Identifier #'' in anticipation of the use of this product information by the Agency for specific characterization and identification of the medical device. The form remains a one-sided, one-page form with instructions for use on the reverse side and a self-addressed, postage-paid return mailer.

C. Changes Proposed for FDA Form 3500A

Certain formatting changes are proposed to allow mandatory reporters to better utilize available space for data entry and facilitate specification of the device product's coding. In section D, field D2, it is proposed that the same field be used to request the procode (D2b) to correspond to the existing common device name (D2a). The D4 field currently named ''Other'' will be renamed ''Unique Identifier #.'' Section H, currently named ''Device Manufacturers Only'' will be renamed ''Manufacturers Only.'' Field H1 will have the ''Other'' checkbox removed and field H6, renamed ''Event Problem and Evaluation Codes,'' will have patient code and device code boxes added, as in the existing form's field F10. In section G, field G5, STN # will be relabeled BLA #. Given the need to contact mandatory reporters in a timely manner, the Agency proposes that a field be added to FDA Form 3500A to request an email address for the mandatory reporter, to supplement the phone number and mailing address currently included on the form. This change is proposed for fields E1 and G1.

V. Proposed Addition of Consumer Version of FDA Form 3500

FDA supports and encourages direct reporting to the Agency by consumers (patients and their caregivers) of suspected serious adverse outcomes and other product problems associated with human medical products (*http://www.fda.gov/Safety/ReportaProblem/default.htm.*) Since the inception of the MedWatch program, launched in July 1993 by then FDA Commissioner David Kessler, the program has been promoting and facilitating voluntary reporting by both the general public and health care professionals (Ref. 1). FDA has further encouraged voluntary reporting by requiring inclusion of the MedWatch toll-free telephone number or the MedWatch Internet address on all outpatient drug prescriptions dispensed, as mandated by section 17 of the Best Pharmaceuticals for Children Act (Pub. L. 107–109).

On March 25, 2008, section 906 of the FDA Amendments Act amended section 502(n) of the FD&C Act and mandated that published direct-to-consumer advertisements for prescription drugs include the following statement printed in conspicuous text (this includes vaccine products): ''You are encouraged to report negative side effects of prescription drugs to the FDA. Visit *http://www.fda.gov/medwatch*, or call 1–(800) FDA–1088.'' Most private vendors of consumer medication information, the drug product-specific instructions dispensed to consumers at outpatient pharmacies, remind patients to report ''side effects'' to FDA and provide contact information to permit reporting via the MedWatch process and FDA Form 3500.

Currently, the non-health care professional public may submit voluntary reports using FDA Form 3500 (*http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053074.htm*). This reporting form was created 20 years ago and modeled after an earlier version of the Agency's reporting form for health care professionals. FDA Form 3500 is provided in paper and electronic formats (HTML version at *http://www.fda.gov/medwatch/report.htm* and fillable pdf version at *http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/ucm082725.pdf*), and is used to report to the Agency about serious adverse events, product problems, product use errors, and therapeutic failure (therapeutic inequivalence). Reporting is supported for all FDA-regulated human medical care products, including drugs, biologicals, medical devices, special nutritional products, dietary supplements, cosmetics, and nonprescription (OTC) human drug products marketed without an approved application.

Qualitative assessment by social scientists, and comments and feedback from the public, have recognized that FDA Form 3500 is written and formatted at a literacy/comprehensibility level that far exceeds

the level recommended for the general public by health literacy experts and does not conform to recommendations in the Plain Writing Act of 2010 (*http://www.gpo.gov/fdsys/pkg/PLAW–111publ274/pdf/PLAW–111publ274.pdf).*

The proposed consumer version of the voluntary FDA Form 3500 will request no new data from the voluntary reporter not already included in the existing FDA Form 3500 that is currently used for reporting from both health care professionals and consumers (patients). Certain existing fields not considered essential data for the consumer report but present on the standard (*i.e.,* health care professional) version of FDA Form 3500 have been eliminated to facilitate and expedite consumer submissions and reduce reporting burden. The formatting and plain language used are compatible with the intent of the Plain Writing Act and is expected to provide non-health care professionals with a second option to the existing FDA Form 3500 that will reduce the burden of reporting by facilitating their understanding of the requested data and further clarify the voluntary reporting process.

The proposed consumer version of FDA Form 3500 evolved from several iterations of draft versions, with input from human factors experts, from other regulatory agencies and with extensive input from consumer advocacy groups and the general public. The Agency recognizes that many consumer reporters have a preference for accessing a copy of the voluntary reporting form on the Internet or submitting to FDA using an electronic version of the form. The Agency currently supports voluntary reporting with the forms submitted by mail, by FAX, by telephone via the toll free 800 number and online at *http://www.fda.gov/medwatch/report.htm.* It is the Agency's expectation that an approved consumer version of the voluntary form will be provided for consumer use by these same channels.

In the **Federal Register** of September 9, 2011 (76 FR 55919), FDA published a 60-day notice requesting public comment on the proposed collection of information. Comments were received from seven individuals and organizations.

VI. Response to Comments

1. 3500 Form

(Comment 1) One comment observed that it may be difficult for FDA to identify the pregnancy status of the person experiencing the reported adverse event and suggested that the Agency add a separate field for documenting pregnancy status.

(Response) FDA agrees that documenting pregnancy status is important; however, FDA does not plan to add an additional checkbox for pregnancy to the forms at this time. In 2005, FDA proposed adding checkboxes for both ''Product Used During Pregnancy'' and ''Product Used During Breast Feeding'' to section B.5 of both forms. FDA received comments expressing concern that these new data fields introduced divergence from International Council on Harmonisation standards and appeared to duplicate information that is usually provided in the narrative section and in coded adverse event terms. The pregnancy status data can also be captured in field B7 as ''Other Relevant History''. FDA agreed with the comments and did not include these checkboxes with the 2005 revisions; FDA believes these reasons are still valid.

(Comment 2) One comment encouraged the FDA to use the voluntary consumer version of the form to allow for electronic filing of reports and to continue to promote the reporting process to the public, whether by the traditional paper-based route or electronically.

(Response) FDA agrees with the comment and expects to support both the promotion of the use of the new consumer version of the voluntary form and to explore methods of facilitating reporting and reducing reporter burden by using online and other electronic means of report submission.

(Comment 3) One comment supported the plan to deploy a consumer version of the voluntary form and suggested that its use also be promoted to health care providers for their use. The comment also encouraged the Agency to expedite a process for converting the paper-based reporting process to allow for electronic submission of voluntary reports using the consumer version of the form.

(Response) FDA agrees that support of electronic submissions of voluntary reports should be supported and facilitated. The new form was designed as a consumer friendly option for use by non-health care professionals. The standard FDA Form 3500 will continue to be the primary form offered to health care professionals. FDA encourages the continued use of FDA Form 3500 by health care professionals; however, if a health care professional chooses to submit a report using the consumer form, it will be accepted by FDA.

(Comment 4) One comment stated that implementing a consumer friendly version of FDA Form 3500 would not ''serve any value'' and suggested that instead a more comprehensible form be created that would be used by health care professionals and consumers.

(Response) The Agency disagrees. The current FDA Form 3500 is widely known, well accepted, and used by the range of health care professionals. Assessment of, and feedback from, consumers has demonstrated the demand and need for a modified form that would serve those non-health care professional reporters, using both literacy-appropriate language and formatting that will serve consumers but not be optimal for health care professional reporting.

(Comment 5) A comment suggested that for the proposed change to field E4 from ''Other'' to ''Unique Identifier'' that the term used be ''UDI#''.

(Response) FDA agrees with this comment.

(Comment 6) One comment supported the development of a consumer friendly version of the voluntary form but observed that with the anticipated increase in the number of consumer-initiated reports that the Agency consider a process for ''broader sharing with industry sponsors of adverse event reports made directly to FDA.''

(Response) FDA agrees that adverse event report data should be more readily available to the public (which includes industry). The current mechanisms that FDA has to share reports with industry are the MedWatch to Manufacturer Program and through requests to Freedom of Information. In addition, as part of Phase II of the FDA Transparency Initiative, FDA is planning to provide the public with online access (in a searchable format) to public information from adverse event reports submitted to FDA.

2. 3500A Form

(Comment 7) One comment asked that no changes be made to the FDA Form 3500A at the present time due to consideration of the costs and expenditure of resources incurred by mandatory reporters who are often using electronic systems to do their required reporting to FDA. In addition, the comment noted that there are several proposed or not yet finalized rules that might further impact the content of the mandatory FDA Form 3500. A comment stated that they would ask for a 12-month implementation time to allow for design, testing, and validation of any software changes necessary.

(Response) The Agency has considered the impact of implementing changes to FDA Form 3500A and the need for mandatory reporters to change their electronic systems to comply with the proposed changes. FDA will allow

for sufficient time for design, testing, and validation of any software changes as a result of any new data requirements that may follow from new requirements based on final rules and regulations.

(Comment 8) One comment stated that for mandatory reporters the estimate of burden has been underestimated and fails to take into consideration the effort by firms to collect facts, prepare investigations, and evaluate the data.

(Response) The Agency disagrees that the estimate for the average time to complete a given report is low. This estimate is intended not to represent the totality of the effort for completing the postmarket drug and device safety surveillance process mandated by law, rule, and regulation for application holders but a fair estimate of data collection, organization, entry, and submission time for a given ''average'' report.

(Comment 9) A comment suggested that for the proposed change to field D4 from ''Other'' to ''Unique Identifier'' that the term used be ''UDI#''.

(Response) FDA agrees with this comment. We recommend changing this to UDI#.

(Comment 10) A comment disagreed with requesting an email address from the reporter in field E1, and a second comment expressed similar reservations but suggested that, if used, the initial reporter understand that this information is optional.

(Response) FDA recognizes that an email address is one of several elements in the contact information that may assist FDA and others in effective postmarket safety surveillance and followup inquiries. The reporter is not compelled to complete the information in this field in order for the report to be considered complete and registered in the appropriate database. A statement that this information is optional will be made clear in the instructions for completing the form.

(Comment 11) A comment disagreed with the proposed change in the Section H heading from ''Device Manufacturers Only'' to ''Manufacturers Only''.

(Response) FDA agrees that this title should not be changed. Section H should be titled ''Device Manufacturers Only'' as it currently appears.

(Comment 12) Two comments recommended the addition of a new checkbox field in Section/field H2 named ''Final report'' that would be used to ''reflect the best efforts of the manufacturer to retrieve and analyze information pertaining to the reported event''.

(Response) FDA disagrees that ''Final report'' should be added to Section H2. This information can be added as part of the text narrative in Section H10.

(Comment 13) Two comments disagreed with the removal of field H1's ''Other'' checkbox and stated that there are rare examples of events that do not meet the regulatory definition of death, serious injury, or malfunction but are considered by the mandatory reporting entity to be necessary and required reports. One comment suggested that if the checkbox is removed, that specific instruction be provided for handling reports that would have been compatible with an ''Other'' designation.

(Response) FDA disagrees. FDA recommends removal of the ''Other'' checkbox. In lieu of the checkbox, FDA proposes that rare events that fit the definition of ''Other significant adverse device experiences'' as specified in FD&C Act section 519(a)(3) can be submitted to the FDA using the mailing address identified in 21 CFR 803.12(a).

(Comment 14) One comment suggested changing the title of field B4 from ''Date of This Report'' to ''Date of First Contact With Initial Reporter''.

(Response) FDA disagrees. On August 21, 2009, FDA published a proposed rule (74 FR 42203) to amend part 803 to require manufacturers, importers, and user facilities to submit medical device reports to the Agency in an electronic format (i.e., the 2009 proposed rule). Section II(4)(D)(2) of the 2009 proposed rule specified that in the final rule, FDA specifically proposed to change §§ 803.32(b)(4), 803.42(b)(4), and 803.52(b)(4) from ''date of report by the initial reporter'' to ''date of this report''. Further it states, ''This change would make part 803 consistent with the way that other FDA Centers interpret FDA Form 3500A, Block B4 and how Block B4 appears on FDA Form 3500A.''

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA Center FDA Form (21 CFR Section)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Center for Biologics Evaluation and Research/Center for Drug Evaluation and Research:					
Form 3500	28,952	1	28,952	0.60 (36 minutes)	17,371
Form 3500A (§§ 310.305, 314.80, 314.98, and 600.80).	599	96	57,504	1.10.	
Center for Devices and Radiological Health:					
Form 3500	4,585	1	4,585	0.60 (36 minutes)	2,751
Form 3500A (§ 803)	1,485	225	334,125	1.10 (66 minutes).	367,538
Center for Food Safety and Applied Nutrition:					
Form 3500	297	1	297	0.6 (36 minutes).	178
Form 3500A	1,039	1	1,039	1.10 (66 minutes).	1,143
Total					452,234

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

VII. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Kessler, D.A., ''Introducing MEDWatch: A New Approach to Reporting Medication and Device Adverse Effects and Product Problems,'' *Journal of the American Medical Association,* 269: 2765–2768, 1993.

Dated: December 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–31341 Filed 12–6–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0858]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study on Comparing Data Obtained From Landline Telephone and Cell Phone Surveys

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on a study entitled ''Experimental Study on Comparing Data Obtained From Landline Telephone and Cell Phone Surveys.''

DATES: Submit either electronic or written comments on the collection of information by February 6, 2012.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* 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: Denver Presley, II, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, (301) 796–3793.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information 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.

Experimental Study on Comparing Data Obtained From Landline Telephone and Cell Phone Surveys—(OMB Control Number 0910–NEW)

I. Background

Since the early 1980s, the Center for Food Safety and Applied Nutrition at FDA has been commissioning several waves of two national consumer surveys, the Food Safety Survey (FSS) and the Health and Diet Survey (HDS), to gather data on consumer knowledge, perceptions, and behaviors regarding food safety and nutrition. The purposes of the surveys are three-fold: (1) To generate nationally representative estimates of knowledge, perception, and practice of interest at a given point in time; (2) to track trends of the estimates over time; and (3) to understand the relationships among knowledge, perceptions, and practices regarding food safety and nutrition and how these relate to demographic characteristics.

Traditionally, all waves of the surveys have been administered via landline telephones and have used the random digit dialing (RDD) technique to recruit national samples of adults (18 years old or above) from households with landline telephone numbers. A noticeable phenomenon that has appeared in our recent surveys is a precipitous decline of younger respondents in completed interviews. For example, the proportion of respondents in the 18 to 29 age group for the FSS has dropped from 17 percent in 2001 to 11 percent in 2006 to only 4 percent in 2010; the corresponding proportion for the HDS has gone from 14 percent in 2002, to 15 percent in 2004, to only 6 percent in 2008.

One possible reason for the decline is the rapid adoption of cell phones in recent years. During the second half of 2010, 28 percent of American adults lived in households with only wireless service (''wireless-only households'' or ''cell-phone only households''), compared to 15 percent in the second half of 2007 and 5 percent in the second half of 2004 (Ref. 1). During the second half of 2010, 17 percent of adults lived in households that received all or almost all calls on cell phones despite having a landline phone (''wireless-mostly households'' or ''cell-phone mostly households''), an increase of 3 percentage points from the first half of 2008 (Ref. 1). Thus, the number of adults reachable by landline phone calls has decreased in recent years. The rate of cell phone adoption, however, has been uneven among adults with different demographic characteristics. In 2010, adults living in wireless-only households were more likely to be 18 to 34 year olds, living in poorer households, without a college or higher educational degree, or Hispanics or Latinos (Ref. 1). Meanwhile, adults who live in landline households differ from those who live in wireless-only households as well those in wireless-mostly households (Ref. 2), and the demographic characteristics of adults living in wireless-mostly households are much less diverse than that of adults living in wireless-only households (Ref. 1).

The under-representation of wireless-only or wireless-mostly adults, especially those in younger age groups, in landline surveys can affect national estimates of the prevalence of certain

consumer perceptions, knowledge or behaviors and understanding of the relationships between certain survey responses and demographic characteristics. For example, previous research found different prevalence rates of drinking and smoking between respondents reached on a landline call versus respondents from wireless-only households (Ref. 1). Wireless-mostly adults were less likely than landline adults to say their health is fair or poor and were less likely to be a current smoker than wireless-only adults (Ref. 2). Voigt et al. (Ref. 3) reported that cell-phone users were less likely to have fathered or given birth to a child than their landline telephone counterparts. The differences observed in these studies are pertinent and potentially problematic for the HDS and FSS because past surveys have shown that age variations were associated with, among other things, consumers' knowledge of dietary fats, and awareness and concern about pesticide and antibiotic residues (Refs. 4 and 5).

Thus, our recent surveys may have become vulnerable to a noncoverage problem due to the fact that many eligible respondents are not included in the survey samples because they do not own landline phones or because they receive calls only or mostly on cell phones. Adults living in wireless-only and wireless-mostly households are less likely to appear in landline telephone samples and often possess characteristics that differ from those of adults in landline households. Thus, a telephone survey that still relies exclusively on landline phone calls to interview respondents may not produce results that are reliable and valid (Refs. 2 and 6), may not yield results that are comparable to results from past landline surveys when this noncoverage problem was absent, or both.

One common approach to addressing potential impacts of cell phone use on landline telephone survey results is to supplement a landline telephone survey with a cell phone survey to achieve a wider coverage of population in the sample of respondents. Existing evidence on the usefulness of this approach varies between national estimates and population subgroup estimates. Many studies conducted around the mid-2000s (for example, Ref. 7), when the use of cell phones was not as common as today, and a 2007 study (Ref. 2) suggested that general population estimates of certain social and political attitudes, voting behavior, and media use and attitudes did not always vary when a landline survey was supplemented or was not supplemented with a cell-phone only survey, especially when the response to a landline survey was weighted to reflect population characteristics. On the other hand, this research also suggested that among young adults and low-income adults, estimates of certain health-related behaviors, such as smoking and binge drinking, differ between those living in households with and without landlines (Ref. 8). In addition, young adults who had a landline phone were less likely to report drinking alcohol or to agree that marijuana smoking is acceptable (Ref. 9). We are, however, not aware of any research that has examined whether food safety or nutrition related perceptions, attitudes, and behaviors differ when landline telephone surveys miss respondents who are not reachable by landline telephone calls.

Therefore, we are concerned that the diminishing survey participation among consumers who are not easily reached by landline telephones may lead to unreliable or biased estimates of critical information and the relationships among knowledge, perceptions, and other food safety and nutrition related variables. These concerns warrant a systematic examination of the impacts of cell phone use on the quality of the FSS and HDS data.

The objective of this data collection is to provide data for an experimental study that compares demographic distributions in and responses to selected FSS and HDS questions by samples of respondents drawn from an overlapping dual frame (Ref. 6), *i.e.,* two overlapping sampling frames: (1) A list-assisted landline telephone frame and (2) a cell phone frame. Using this approach, we will not screen out any households or individuals because of their type(s) of telephone service (landline or cell phone). The study plans to interview 2,000 respondents in English, half of them (1,000) using a 10-minute HDS questionnaire and half of them (1,000) using a 10-minute FSS questionnaire. Each respondent will be randomly assigned to one of the questionnaires. The target distributions within each of the HDS and FSS samples are: 700 respondents who are drawn from the landline frame and complete the questionnaire on a landline telephone; 150 respondents who are drawn from the cell phone frame and complete the questionnaire on a cell phone, regardless of whether they are wireless-only or wireless-mostly; and 150 respondents who are drawn from the cell phone frame, complete the questionnaire on a cell phone, and do not have a landline phone to receive personal calls.

The HDS questionnaire will focus on knowledge of dietary fats, use of food labels, awareness of diet-health relationships, and use and understanding of dietary supplements. The FSS questionnaire will focus on perceptions of general food safety risks, food handling practices, perceived personal vulnerability to food safety risks, consumption of risky foods, and awareness of mercury and fish. All questions have been asked in previous surveys.

The Agency will use the study to assess the impacts of cell phone use on population estimates of nutrition and food safety related perceptions, attitudes, and behaviors. The assessment will help the Agency determine whether and how future administrations of the FSS and HDS should be adjusted to produce reliable, valid, and historically comparable results in response to the growing prevalence of cell phone use.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretest	10	1	10	.167 (10 minutes)	2
Survey	2,000	1	2,000	.167 (10 minutes)	334
Total					336

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

II. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Blumberg, S.J., and J.V. Luke, ''Wireless Substitution: Early Release of Estimates From the National Health Interview Survey, July-December 2010,'' *(http://www.cdc.gov/nchs/nhis.htm),* National Center for Health Statistics, June 2011.
2. Lee, S., J.M. Brick, E.R. Brown, et al., ''Growing Cell-Phone Population and Noncoverage Bias in Traditional Random Digit Dialing Telephone Health Surveys,'' *Health Services Research,* 45: 1121–1139, 2010.
3. Voigt, L.F., S.M. Schwartz, D.R. Doody, et al., ''Feasibility of Including Cellular Telephone Numbers in Random Digit Dialing for Epidemiologic Case-Control Studies,'' *American Journal of Epidemiology,* 173: 118–126, 2011.
4. Yen, S.T., K.L. Jensen, and C.-T.J. Lin, ''Awareness and Perceived Risk of Pesticide and Antibiotic Residues in Food: Socioeconomic Variations Among U.S. Consumers,'' *Food Protection Trends,* 26: 654–661, 2006.
5. Lin, C.-T.J. and S.T. Yen, ''Knowledge of Dietary Facts Among U.S. Consumers,'' *Journal of the American Dietetic Association,* 110: 613–618, 2010.
6. American Association for Public Opinion Research (AAPOR), ''New Considerations for Survey Researchers When Planning and Conducting RDD Telephone Surveys in the United States With Respondents Reached via Cell Phone Numbers,'' *(http://www.aapor.org/Cell_Phone_Task_Force_Report.htm),* 2010.
7. Keeter, S., ''The Impact of Cellular Phone Noncoverage Bias on Polling in the 2004 Presidential Election,'' *Public Opinion Quarterly,* 70: 88–98, 2006.
8. Blumberg, S.J. and J.V. Luke, ''Reevaluating the Need for Concern Regarding Noncoverage Bias in Landline Surveys,'' *American Journal of Public Health,* 99: 1806–1810, 2009.
9. Keeter, S., C. Kennedy, A. Clark, et al., ''What's Missing From National Landline RDD Surveys? The Impact of the Growing Cell-Only Population,'' *Public Opinion Quarterly,* 71: 772–792, 2007.

Dated: December 2, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–31389 Filed 12–6–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0326]

Biologics Price Competition and Innovation Act of 2009; Proposed Recommendations for a User Fee Program for Biosimilar and Interchangeable Biological Product Applications for Fiscal Years 2013 Through 2017; Notice of Public Meeting; Request for Comments

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 the proposed recommendations for a user fee program for biosimilar biological products for fiscal years (FYs) 2013 through 2017.

DATES: The public meeting will be held on Friday, December 16, 2011, from 9 a.m. to 1 p.m. Registration to attend the meeting must be received by December 14, 2011. See section III.B of this document for information on how to register for the meeting. Submit either electronic or written comments by January 6, 2012.

ADDRESSES: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503, Silver Spring, MD, 20993–0002. Please note that visitors to the White Oak Campus must enter through Building 1.

Submit electronic comments to *http://www.regulations.gov*. Submit written comments 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.

Transcripts of the meeting will be available for review at the Division of Dockets Management and on the Internet at *http://www.regulations.gov* approximately 30 days after the public meeting (see section III.C of this document).

FOR FURTHER INFORMATION CONTACT: Rokhsana Safaai-Jazi, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, Rm. 1164, Silver Spring, MD 20993–0002, (301) 796–4463, *Fax:* (301) 847–8443, Email: *BiosimilarsUserFeeProgram@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is announcing a public meeting to discuss proposed recommendations for a user fee program for biosimilar biological products (biosimilars user fee program) for FYs 2013 through 2017. On March 23, 2010, President Obama signed into law the Affordable Care Act (Pub. L. 111–148). The Affordable Care Act contains a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) that amends the Public Health Service Act (PHS Act) and other statutes to create an abbreviated approval pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference biological product. (See sections 7001 through 7003 of the Affordable Care Act.) Section 351(k) of the PHS Act (42 U.S.C. 262(k)), added by the BPCI Act, allows a company to submit an application for licensure of a biosimilar or interchangeable biological product.

The BPCI Act also amends section 735 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g) to include 351(k) applications in the definition of ''human drug application'' for the purposes of the prescription drug user fee provisions. (See section 7002(f)(3)(A) of the Affordable Care Act.) Accordingly, under section 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h), the fee for a biologics license application (BLA) is currently the same regardless of whether the application is submitted under the new 351(k) approval pathway or the preexisting 351(a) approval pathway.

The authority conferred by the Federal Food, Drug, and Cosmetic Act's prescription drug user fee provisions expires in September 2012. The BPCI Act directs FDA to develop recommendations for a biosimilars user fee program for FYs 2013 through 2017. (See section 7002(f)(1) of the Affordable Care Act.) The BPCI Act provides that FDA must consult with a range of groups, including scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups (public stakeholders), and regulated industry (industry stakeholders), in developing the recommendations. As described in section II of this document, FDA consulted with public and industry stakeholders from June 2011 through September 2011.

The BPCI Act requires that FDA must publish the recommendations for a biosimilars user fee program in the **Federal Register** and provide a period of 30 days for the public to provide written comments on the recommendations.

FDA is also required to hold a meeting at which the public may present its views on such recommendations. After consideration of such public views and comments, FDA is to revise the recommendations as necessary and transmit them to Congress by January 15, 2012.

This notice, the 30-day comment period, and the public meeting will satisfy certain of these requirements. After the public meeting, FDA will revise the recommendations as necessary and present them to Congress. (See section 7002(f)(1) of the Affordable Care Act.) Additional information is provided in this document to help potential meeting participants better understand the proposed recommendations.

II. Proposed Biosimilars User Fee Program Recommendations

In developing proposed recommendations for a biosimilars user fee program, FDA has conducted discussions with regulated industry and consulted with public stakeholders, as required by the law. FDA initiated the public consultation process on November 2 and 3, 2010, by holding a public hearing at which stakeholders and other members of the public were given an opportunity to present their views on issues associated with the implementation of the BPCI Act. (See 75 FR 61497, October 5, 2010.) [1] Among other issues relating to the implementation of the BPCI Act, FDA solicited public comment on the following questions related to a biosimilars user fee program:

- If the existing fee structure under the Prescription Drug User Fee Act (PDUFA) were to be considered as a model in establishing a user fee structure for applications and supplements for proposed biosimilar and interchangeable biological products, what factors and changes should FDA take into consideration, and why?
- What factors should FDA take into account when considering whether to recommend that user fees for biosimilar and interchangeable biological products should also be used to monitor safety after approval?

In the **Federal Register** of May 10, 2011 (76 FR 27062),[2] FDA published a notice requesting public input on FDA's proposed principles for development of a biosimilars user fee program, FDA's proposed structure for a biosimilars user fee program that would adhere to these principles, and proposed performance goals for this program.

From June 2011 through September 2011, FDA conducted negotiations with regulated industry, and consultation meetings with public stakeholders, concerning development of recommendations for a biosimilars user fee program. FDA posted minutes of these meetings on its Web site at *http://www.fda.gov/ForIndustry/UserFees/ucm268124.htm.*

The proposed biosimilars user fee program for FYs 2013 through 2017 addresses many of the top priorities identified by public and industry stakeholders, and the most important challenges identified within FDA. The proposed biosimilars user fee program is similar to the PDUFA program in that it includes fees for marketing applications, manufacturing establishments, and products. However, there are some differences because of the nascent state of the biosimilars industry in the United States. For example, there are no currently marketed biosimilar biological products; accordingly, the recommended biosimilars user fee program includes fees for products in the development phase in order to generate fee revenue in the near-term and to enable sponsors to have meetings with FDA early in the development of biosimilar biological product candidates.

As in all of FDA's other medical product user fee programs, under the proposed biosimilars user fee program, user fee funding would supplement dedicated non-user fee funding to ensure sufficient resources for the Agency's biosimilars review program. In each fiscal year, in order to spend biosimilars user fees, FDA would be required to have available and allocate at least $20 million, adjusted for inflation, in non-user fee money for biosimilars review activities.

Under the proposed biosimilars user fee program, FDA would be authorized to spend biosimilars user fees on Agency activities related to the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements. This would include activities related to biosimilar biological product development meetings and investigational new drug applications (INDs). It would also include development of the scientific, regulatory, and policy infrastructure necessary for review of biosimilar biological product applications, such as regulation and policy development related to the review of biosimilar biological product applications, and development of standards for products subject to review and evaluation. It would cover FDA activities at the application stage, such as review of advertising and labeling prior to approval of a biosimilar biological product application or supplement; review of required postmarketing studies and postmarketing studies that have been agreed to by sponsors as a condition of approval; the issuance of action letters that communicate decisions on biosimilar biological product applications; and inspection of biosimilar biological product establishments and other facilities undertaken as part of FDA's review of pending biosimilar biological product applications and supplements (but not inspections unrelated to the review of biosimilar biological product applications and supplements). Finally, it would include some activities at the post-approval stage, such as postmarketing safety activities with respect to biologics approved under biosimilar biological product applications or supplements.

A. Proposed Fees

The four types of fees under the proposed biosimilars user fee program are summarized in this section II.A.

1. Biosimilar Product Development Fees

FDA's proposed biosimilars user fee program includes initial and annual biosimilar product development (BPD) fees for biosimilar biological products in development. The initial BPD fee would be due upon the date of submission of an IND describing an investigation that FDA determines is intended to support a biosimilar biological application for a product, or within 5 days after FDA grants a request for a ''biosimilar biological product development meeting'' (BPD Meeting) for a product. (BPD Meetings are further described in section II.B.7 of this document.)

Additionally, under the proposed BPD program, if FDA determines that an IND is intended to support a biosimilar biological product application for a product, each person that has submitted an IND before the date of enactment of the legislation authorizing the biosimilars user fee program would also be subject to the initial BPD fee. A sponsor would be assessed only one initial BPD fee per product. Regardless of the number of proposed indications for the biosimilar biological product, the sponsor would pay one BPD fee per product. The initial BPD fee for each of the FYs 2013 through 2017 would be equal to 10 percent of the fee established for a human drug

[1] *http://edocket.access.gpo.gov/2010/pdf/2010-24853.pdf.*

[2] *http://www.gpo.gov/fdsys/pkg/FR-2011-05-10/pdf/2011-11348.pdf.*

application under PDUFA for that fiscal year.

Beginning in the next fiscal year after a sponsor has paid the initial BPD fee for a product, the sponsor would pay an annual BPD fee on or before October 1 of each year, until the sponsor submits a marketing application for the product that is accepted for filing, or discontinues participation in the BPD program for the product. A sponsor that has not submitted an IND for the product may discontinue participation in the BPD program by submitting a written declaration to FDA affirming that the sponsor has no present intention of further developing the product as a biosimilar biological product. A sponsor that has submitted an IND for the product would be able to effectuate the discontinuation only after withdrawing the IND as specified in 21 CFR part 312. A sponsor must discontinue participation in the BPD program by August 1 of the year of discontinuation to avoid incurring the fee that otherwise would be due on October 1. A sponsor that maintains an IND for the product after submitting a marketing application for the product that was accepted for filing would not pay the annual BPD fee for that product.

A sponsor that has discontinued participation in the BPD program for a product would be required to pay a reactivation fee in order to resume participation in the BPD program for that product. The reactivation fee would be equal to twice the initial BPD fee for that fiscal year. The reactivation fee would be due within 5 days after FDA grants a request for a BPD Meeting for the product, or upon the date of submission of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application for that product, whichever is earlier. A sponsor that pays a reactivation fee for a product would be required to pay the annual BPD fee for the product beginning in the next fiscal year.

If a sponsor has failed to pay the initial BPD fee, annual BPD fee, or reactivation fee as required, FDA would not provide a BPD Meeting relating to the biosimilar biological product for which the fees are owed. Also, except in extraordinary circumstances, if a sponsor that owes BPD fees submits an IND that FDA determines is intended to support a biosimilar biological product application, FDA would not consider the sponsor's IND to have been received under section 505(i)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(2)). In addition, if a sponsor that owes BPD fees has an existing IND that FDA determines is intended to support a biosimilar biological product application, FDA would prohibit the sponsor from continuing the investigation (this action would be referred to as ''financial hold''). Finally, if a sponsor has failed to pay BPD fees as required, then any biosimilar biological product application or supplement submitted by that sponsor would be considered incomplete and would not be accepted for filing until all fees owed by the sponsor have been paid.

2. Marketing Application Fee

FDA estimates that the cost of reviewing an application for licensure of a biosimilar biological product will be comparable to the cost of reviewing an application for licensure of a biological product under section 351(a) of the PHS Act. FDA therefore proposes to set the marketing application fee for a biosimilar biological product equal to the fee established for a human drug application under PDUFA, minus the cumulative amount of any BPD fees (including any reactivation fees) paid for the product that is the subject of the application. The feedback and consultation that FDA expects to provide to sponsors during the biosimilar biological product development phase is expected to improve the efficiency of the biosimilar biological product development process and the quality of submitted marketing applications. Therefore, FDA considers the BPD phase fees, and the deduction of paid BPD fees from the associated marketing application fee payment, to be a reasonable approach to shift resources forward to the point in development where FDA review is currently being sought by sponsors.

3. Establishment Fees and Product Fees

Because the complexity and level of effort required for FDA oversight of manufacturing and postmarketing safety issues for products licensed under section 351(k) of the PHS Act is expected to be comparable to that required for products licensed under section 351(a), FDA proposes setting biosimilar biological product establishment and product fees equal to the establishment and product fees under PDUFA for any fiscal year. FDA anticipates a modest level of funding from these sources initially because only biosimilar biological products that are approved for marketing would be subject to these fees.

B. Proposed Performance Goals and Procedures

The full description of the proposed performance goals and procedures for the biosimilars user fee program can be found in the draft biosimilars user fee commitment letter (draft commitment letter) posted on FDA's Web site at *http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM281991.pdf.* The proposed performance goals and procedures are described in this section II.B with reference to the section of the draft commitment letter where more detailed information can be found.

1. Review Performance Goals

The proposed biosimilars review program would include review performance goals for biosimilar biological product application submissions and resubmissions, supplements with clinical data, and original manufacturing supplements. Further information concerning these review performance goals can be found in section I of the draft commitment letter. The review performance goals are summarized in tables 1 and 2 of this document.:

TABLE 1—PERFORMANCE GOALS FOR ORIGINAL AND RESUBMITTED APPLICATIONS AND SUPPLEMENTS

Submission cohort	Performance goal				
	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Within 10 Months of the Receipt Date					
Original Biosimilar Biological Product Application Submissions	70%	70%	80%	85%	90%

TABLE 1—PERFORMANCE GOALS FOR ORIGINAL AND RESUBMITTED APPLICATIONS AND SUPPLEMENTS—Continued

Submission cohort	Performance goal				
	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Within 6 Months of the Receipt Date					
Resubmitted Original Biosimilar Biological Product Applications	70%	70%	80%	85%	90%

TABLE 2—PERFORMANCE GOALS FOR ORIGINAL AND RESUBMITTED SUPPLEMENTS

Submission	Performance goal
Original Supplements with Clinical Data	90% Within 10 Months of the Receipt Date.
Resubmitted Supplements with Clinical Data	90% Within 6 Months of the Receipt Date.
Manufacturing Supplements	90% Within 6 Months of the Receipt Date.

2. First Cycle Performance Goals

The proposed biosimilars review program includes first cycle review performance goals for original biosimilar biological product applications and supplements with clinical data. For 90 percent of applications and supplements with clinical data, FDA's goal would be to inform the applicant of any substantive review issues identified during the initial filing review within 74 calendar days of the receipt date. In addition, for 90 percent of applications and supplements with clinical data, FDA's goal would be to inform the applicant of the planned review timeline for the application within 74 calendar days of the receipt date. Section II of the draft commitment letter contains further information concerning these performance goals.

3. Review of Proprietary Names To Reduce Medication Errors

The proposed biosimilars review program includes proprietary name review performance goals. For proprietary names submitted during the biosimilar biological product development phase, FDA's goal would be to review 90 percent within 180 days of receipt. For proprietary names submitted with the biosimilar biological product application, FDA's goal would be to review 90 percent within 90 days of receipt. Section III of the draft commitment letter contains further information concerning these performance goals.

4. Major Dispute Resolution

The proposed biosimilars review program includes a major dispute resolution performance goal. For procedural or scientific matters involving the review of biosimilar biological product applications and supplements that cannot be resolved at the signatory authority level, FDA's goal would be to respond to 90 percent of decision appeals within 30 calendar days of FDA's receipt of the written appeal, provided that certain conditions are met. Section IV of the draft commitment letter contains further information concerning this performance goal.

5. Clinical Holds

The proposed biosimilars review program includes a clinical hold performance goal. FDA's goal would be to respond to 90 percent of sponsors' complete responses to a clinical hold within 30 days of FDA's receipt of the complete response submission. Section V of the draft commitment letter contains further information concerning this performance goal.

6. Special Protocol Assessment

The proposed biosimilars review program includes procedures and performance goals for special protocol assessments. Under the proposed program, provided that certain conditions are met, upon specific request by a sponsor, the Agency would evaluate certain protocols and related issues to assess whether the design is adequate to meet scientific and regulatory requirements identified by the sponsor. FDA's goal would be to provide a written response to the sponsor that includes a succinct assessment of the protocol and answers to the questions posed by the sponsor. For FYs 2013 and 2014, FDA's goal would be to respond to 70 percent of the requests within 45 days of FDA's receipt of the protocol and specific questions. For FY 2015, FDA's goal would be to respond to 80 percent of the requests within the 45-day time frame; for FY 2016, 85 percent, and for FY 2017, 90 percent. Section VI of the draft commitment letter contains further information concerning this performance goal.

7. Meeting Management Goals

FDA proposes performance goals and procedures regarding meetings related to sponsors' biosimilar biological product development programs. Further information concerning these goals can be found in section VII of the draft commitment letter. These goals and procedures would apply to Biosimilar Initial Advisory Meetings and BPD Meetings. Under the proposed program, a Biosimilar Initial Advisory Meeting is an initial assessment limited to a general discussion regarding whether licensure under section 351(k) of the PHS Act may be feasible for a particular product, and, if so, general advice on the expected content of the development program. It does not include any meeting that involves substantive review of summary data or full study reports. A BPD Meeting is any meeting, other than a Biosimilar Initial Advisory Meeting, regarding the content of a development program, including a proposed design for, or data from, a study intended to support a biosimilar biological product application. The four types of BPD Meetings are as follows:

- A BPD Type 1 Meeting is a meeting that is necessary for an otherwise stalled drug development program to proceed (*e.g.,* meeting to discuss clinical holds, dispute resolution meeting), a special protocol assessment meeting, or a meeting to address an important safety issue.
- A BPD Type 2 Meeting is a meeting to discuss a specific issue (*e.g.,* proposed study design or endpoints) or questions where FDA will provide targeted advice regarding an ongoing biosimilar biological product development program. BPD Type 2 Meetings include substantive review of

summary data, but does not include review of full study reports.

• A BPD Type 3 Meeting is an in-depth data review and advice meeting regarding an ongoing biosimilar biological product development program. This type of meeting includes substantive review of full study reports, FDA advice regarding the similarity between the proposed biosimilar biological product and the reference product, and FDA advice regarding additional studies, including design and analysis.

• A BPD Type 4 Meeting is a meeting to discuss the format and content of a biosimilar biological product application or supplement submitted under section 351(k) of the PHS Act.

The proposed review program includes performance goals for responses to meeting requests. Specifically, for 90 percent of BPD Type 1 Meeting requests, FDA's goal would be to notify the requester in writing of the date, time, place, and format for the meeting, as well as expected Center participants, within 14 calendar days of FDA's receipt of the request and meeting package. For 90 percent of BPD Type 2, 3, and 4 Meeting requests and Biosimilar Initial Advisory Meeting requests, FDA's goal would be to notify the requester in writing of the date, time, place, and format for the meeting, as well as expected Center participants, within 21 calendar days of FDA's receipt of the request and meeting package.

The proposed review program also includes performance goals for scheduling meetings within target time frames. The target time frames for each of the five meeting types are as follows:

TABLE 3—TARGET TIME FRAMES FOR MEETING TYPES

Meeting type	Timeframe after receipt of meeting request and meeting package
Biosimilar Initial Advisory Meeting	Meeting should occur within 90 calendar days of FDA receipt.
BPD Type 1 Meeting	Meeting should occur within 30 calendar days of FDA receipt.
BPD Type 2 Meeting	Meeting should occur within 75 calendar days of FDA receipt.
BPD Type 3 Meeting	Meeting should occur within 120 calendar days of FDA receipt.
BPD Type 4 Meeting	Meeting should occur within 60 calendar days of FDA receipt.

The performance goals for each meeting type are as follows:

• For FY 2013, 70 percent of Biosimilar Initial Advisory Meetings and BPD Type 1, 2, 3, and 4 Meetings are held within the target time frame.

• For FY 2014, 70 percent of Biosimilar Initial Advisory Meetings and BPD Type 1, 2, 3, and 4 Meetings are held within the target time frame.

• For FY 2015, 80 percent of Biosimilar Initial Advisory Meetings and BPD Type 1, 2, 3, and 4 Meetings are held within the target time frame.

• For FY 2016, 85 percent of Biosimilar Initial Advisory Meetings and BPD Type 1, 2, 3, and 4 Meetings are held within the target time frame.

• For FY 2017, 90 percent of Biosimilar Initial Advisory Meetings and BPD Type 1, 2, 3, and 4 Meetings are held within the target time frame.

Under the proposed program, in order for a meeting to qualify for these performance goals, certain conditions would need to be met. First, the meeting request and meeting package must include the information outlined in the draft commitment letter. Second, FDA must concur that the meeting will serve a useful purpose (*i.e.,* it is not premature or clearly unnecessary). If FDA determines that a different type of meeting is more appropriate, it may grant a meeting of a different type than requested, which may require the payment of a BPD fee before the meeting will be provided. If a BPD fee is required and the sponsor does not pay the fee within the required time frame, the meeting will be cancelled. If the sponsor pays the BPD fee after the meeting has been cancelled because of non-payment, the target time frame for the meeting will be calculated from the date on which FDA received the payment, not the date on which the sponsor originally submitted the meeting request.

FDA's goal would be to provide meeting minutes within 30 days of the date of the meeting for 90 percent of Biosimilar Initial Advisory Meetings and BPD Type 1, 2, 3, and 4 Meetings. Finally, FDA's goal would be to develop and publish for comment draft guidance on Biosimilar Initial Advisory Meetings and BPD Type 1, 2, 3, and 4 Meetings by the end of the second quarter of FY 2014.

III. What information should you know about the public meeting?

A. When and where will the public meeting occur? What format will FDA use?

We will convene a public meeting to hear the public's views on the proposed recommendations for a biosimilars user fee program. We will conduct the meeting on December 16, 2011, at FDA's White Oak Campus (see **ADDRESSES**). The meeting will include a presentation by FDA and a series of panels representing different stakeholder groups identified in the statute (such as patient advocacy groups, consumer advocacy groups, health professionals, and regulated industry) to provide input on the proposed recommendations. We will also provide an opportunity for other organizations and individuals to make presentations at the meeting or to submit written comments to the docket before the meeting.

B. How do you register for the public meeting or submit comments?

If you wish to attend this meeting, please register by email at: *Biosimilars UserFeeProgram@fda.hhs.gov* by December 14, 2011. Your email should contain complete contact information for each attendee, including: Name title, affiliation, address, email, address, and phone number. Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. On-site registration on the day of the meeting will be based on space availability. We will try to accommodate all persons who wish to make a presentation. If you need special accommodations because of disability, please notify FDA by email to *BiosimilarsUserFeeProgram@fda.hhs.gov* or Rokhsana Safaai-Jazi (see **FOR FURTHER INFORMATION CONTACT**) at least 4 days before the meeting.

In addition, interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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. To ensure consideration, all comments must be received by January 6, 2012.

C. Will meeting transcripts be available?

As soon as a transcript is available, it will be accessible at *http://www.regulations.gov* and *http://www.fda.gov.* It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be made available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

IV. Additional Information on the BPCI Act

The following sources of information on FDA's Web site may serve as useful information:

- The **Federal Register** document that announced the November 2010 public hearing and requested public comments is available at *http://edocket.access.gpo.gov/2010/pdf/2010-24853.pdf.* (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**.)
- Comments submitted in response to the November 2010 public hearing document can be found at *http://www.regulations.gov* using Docket No. FDA–2010–N–0477.
- The **Federal Register** notice document that requested notification of stakeholder intention to participate in consultation meetings in December 2010 is available at *http://edocket.access.gpo.gov/2010/pdf/2010-30713.pdf.*
- The **Federal Register** notice that requested input on the comments relating to the development of a user fee program for biosimilar and interchangeable biological product applications in May 2010 is available at *http://www.gpo.gov/fdsys/pkg/FR-2011-05-10/pdf/2011-11348.pdf.* Additional information regarding implementation of the BPCI Act is available at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/UCM215031.*

Dated: December 5, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–31499 Filed 12–5–11; 4:15 p.m.]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Neurodegeneration, Signaling and Plasticity.

Date: December 13–15, 2011.

Time: 12:15 p.m. to 12:15 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Joanne T Fujii, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4184, MSC 7850, Bethesda, MD 20892, (301) 435–1178, *fujiij@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 30, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–31391 Filed 12–6–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2011–1103]

Merchant Marine Personnel Advisory Committee; Vacancies

AGENCY: Coast Guard, DHS.

ACTION: Request for applications.

SUMMARY: The Coast Guard seeks applications for membership on the Merchant Marine Personnel Advisory Committee (MERPAC). This Committee advises the Secretary of the Department of Homeland Security on matters related to personnel in the U.S. merchant marine, including but not limited to training, qualifications, certification, documentation, and fitness standards.

DATES: Applicants should submit a cover letter and resume in time to reach the Alternate Designated Federal Officer (ADFO) on or before February 6, 2012.

ADDRESSES: Applicants should send their cover letter and resume to the following *address:* Commandant (CG–5221), Attn MERPAC, U.S. Coast Guard, 2100 2nd St. SW., Stop 7126, Washington DC 20593–7126; or by calling (202) 372–1408; or by faxing (202) 372–1926; or by emailing to *rogers.w.henderson@uscg.mil.* This notice is available in our online docket, USCG–2011–1103, at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Rogers W. Henderson, ADFO of MERPAC; telephone (202) 372–1408 or email at *rogers.w.henderson@uscg.mil.*

SUPPLEMENTARY INFORMATION: MERPAC is a Federal advisory committee established under the authority of section 871 of *The Homeland Security Act of 2002,* Title 6, United States Code, section 451. This committee is established in accordance with and operates under the provisions of the *Federal Advisory Committee Act* (FACA) (Title 5, United States Code, Appendix). MERPAC advises the Secretary of the Department of Homeland Security on matters relating to personnel in the U.S. merchant marine, including but not limited to training, qualifications, certification, documentation, and fitness standards. The Committee will advise, consult with, and make recommendations reflecting its independent judgment to the Secretary.

MERPAC is expected to meet approximately twice a year as called for by its charter, once at or near Coast Guard Headquarters, Washington, DC, and once elsewhere in the country. It may also meet for extraordinary purposes. Its subcommittees and working groups may also meet to consider specific tasks as required.

We will consider applications for six positions that expire or become vacant on June 1, 2012. To be eligible, you should have experience in the following areas of expertise: One member for marine educators representing the viewpoint of State Maritime Academies; one member for marine educators

representing the viewpoint of the small vessel industry in maritime training institutions other than state or Federal Maritime Academies; one member for a licensed chief engineering officer authorized to serve on vessels of any horsepower; two members for licensed deck officers; and one member who will represent the general public.

If you are selected as a member who represents the general public, you will be appointed and serve as a Special Government Employee (SGE) as defined in section 202(a) of title 18, United States Code. As a candidate for appointment as a SGE, applicants are required to complete a Confidential Financial Disclosure Report (OGE Form 450). A completed OGE Form 450 is not releasable to the public except under an order issued by a Federal court or as otherwise provided under the Privacy Act (5 U.S.C. 552a). Only the Designated Agency Ethics Official (DAEO) or his or her designee may release a Confidential Financial Disclosure Report.

Registered lobbyists are not eligible to serve on federal advisory committees. Registered lobbyists are lobbyists required to comply with provisions contained in the *Lobbying Disclosure Act of 1995* (Pub. L. 104–65 as amended).

Each MERPAC committee member serves a term of office of up to three years. Members may be considered to serve consecutive terms. All members serve without compensation from the Federal Government; however, upon request, they do receive travel reimbursement and per diem.

In support of the Coast Guard policy on gender and ethnic nondiscrimination, we encourage qualified men and women of all racial and ethnic groups to apply. The Coast Guard values diversity; all the different characteristics and attributes of persons that enhance the mission of the Coast Guard.

If you are interested in applying to become a member of the Committee, send your cover letter and resume to Rogers W. Henderson, ADFO of MERPAC at Commandant (CG–5221), Attn MERPAC, U.S. Coast Guard, 2100 2nd St SW Stop 7126, Washington DC 20593–7126. Send your cover letter and resume in time for it to be received by the ADFO on or before February 6, 2012.

To visit our online docket, go to *http://www.regulations.gov,* enter the docket number for this notice (USCG–2011–1103) in the Search box, and click ''Go''. Please do not post your resume on this site.

Dated: November 30, 2011.

F.J. Sturm,

Acting Director of Commercial Regulations and Standards, U.S. Coast Guard.

[FR Doc. 2011–31333 Filed 12–6–11; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Documents Required Aboard Private Aircraft

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 30-Day notice and request for comments; Extension of an existing information collection: 1651–0058.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Documents Required Aboard Private Aircraft. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours. This document is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (76 FR 60853) on September 30, 2011, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

DATES: Written comments should be received on or before January 6, 2012.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–5806.

SUPPLEMENTARY INFORMATION: U.S. Customs and Border Protection (CBP) encourages the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act (Pub. L. 104–13). Your comments should address one of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies/components estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collections of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological techniques or other forms of information.

Title: Documents Required Aboard Private Aircraft.

OMB Number: 1651–0058.

Form Number: None.

Abstract: In accordance with 19 CFR 122.27, a commander of a private aircraft arriving in the U.S. must present several documents to CBP officers for inspection. These documents include: (1) A pilot certificate/license; (2) a medical certificate; and (3) a certificate of registration, which is also called a ''pink slip'' and is a duplicate copy of the Aircraft Registration Application (FAA Form AC 8050–1). The information on these documents is used by CBP officers as part of the inspection process for private aircraft arriving from a foreign country. This collection of information is authorized by 19 U.S.C. 1433, as amended by Public Law 99–570.

Current Actions: CBP proposes to extend the expiration date of this information collection with a decrease to the burden hours as a result of revised estimates by CBP concerning the number of responses.

Type of Review: Extension (with change).

Affected Public: Individuals.

Estimated Number of Respondents: 120,000.

Estimated Number of Annual Responses: 120,000.

Estimated Time per Response: 1 minute.

Estimated Total Annual Burden Hours: 1,992.

If additional information is required contact: Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 799 9th Street NW., 5th Floor,

Washington DC 20229–1177, at (202) 325–0265.

Dated: December 1, 2011.

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

[FR Doc. 2011–31352 Filed 12–6–11; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5481–N–18]

Notice of Proposed Information Collection: Comment Request; CDBG Urban County Qualification/ Requalification Process, Notice

AGENCY: Office of Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* February 6, 2012.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Departmental Paperwork Reduction Act Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4160, Washington, DC 20410; *telephone:* (202) 708–3400 (this is not a toll-free number) or email Ms. Pollard for a copy of the proposed form and other available information.

FOR FURTHER INFORMATION CONTACT: Gloria Coates, Community Planning and Development Specialist, Entitlement Communities Division, Office of Block Grant Assistance, 451 7th Street SW., Room 7282, Washington, DC 20410; telephone (202) 708–1577 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35, as amended).

This Notice solicits comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the affected agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Community Development Block Grant (CDBG) Urban County Qualification/Requalification Processes.

OMB Control Number, if applicable: 2506–0170.

Description of the need for the information and proposed use: The Housing and Community Development Act of 1974, as amended, at sections 102(a)(6) and 102(e) requires that any county seeking qualification as an urban county notify each unit of general local government within the county that such unit may enter into a cooperation agreement to participate in the CDBG program as part of the county. Section 102(d) of the statute specifies that the period of qualification will be three years. Based on these statutory provisions, counties seeking qualification or requalification as urban counties under the CDBG program must provide information to HUD every three years identifying the units of general local governments (UGLGs) within the county participating as a part of the county for purposes of receiving CDBG funds. The population of UGLGs for each eligible urban county is used in HUD's allocation of CDBG funds for all entitlement and State CDBG grantees.

New York towns undertook a similar process every three years. However, after consultation with program counsel, it has been determined that a requalification process for New York towns is unnecessary because the units of general local government in New York towns do not have the same statutory notice rights (under Section 102(e) of the Housing and Community Development Act of 1974) as units of general local government participating in an urban county. In addition, each New York town has automatic renewing agreements with the incorporated units of general local governments contained within their boundaries. Therefore, it is presumed that all incorporated units of general local government will continue to participate in the New York towns in which they are located unless Headquarters is notified to the contrary.

Agency form numbers, if applicable: N/A.

Members of affected public: Urban counties that are eligible as entitlement grantees of the CDBG program.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: There are currently 183 qualified urban counties participating in the CDBG program that must requalify every three years. On average, three new counties qualify each year. The burden on new counties is greater than for existing counties that requalify. The Department estimates new grantees use, on average, 100 hours to review instructions, contact communities in the county, prepare and review agreements, obtain legal opinions, have agreements executed at the local and county level, and prepare and transmit copies of required documents to HUD. The Department estimates that counties that are requalifying use, on average, 60 hours to complete these actions. The time savings on requalification is primarily a result of a grantee's ability to use agreements with no specified end date. Use of such ''renewable'' agreements enables the grantee to merely notify affected participating UGLGs in writing that their agreement will automatically be renewed unless the UGLG terminates the agreement in writing, rather than executing a new agreement every three years.

Average of 3 new urban counties qualify per year	3 × 100 hrs = 300 hrs.
183 grantees requalify on triennial basis; average annual number of respondents = 61	61 × 60 hrs. = 3,660 hrs.
Total combined burden hours	3,960 hours.

This total number of combined burden hours can be expected to increase annually by 300 hours, given the average of three new urban counties becoming eligible entitlement grantees each year.

Status of the proposed information collection: Existing collection number will expire February 29, 2012.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35, as amended.

Dated: December 2, 2011.

Clifford Taffet,

General Deputy Assistant Secretary for Community Planning and Development.

[FR Doc. 2011–31415 Filed 12–6–11; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5487–N–20]

Notice of Proposed Information for Public Comment for: Capture Energy Efficiency Measures for PIH

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

HUD is creating the Capture Energy Efficiency Measures for PIH (CEEMP) data system to track the amount and types of Energy Conservation Measures (ECMs) being implemented within Public and Indian (PIH) units. The CEEMP data system is necessary in order to support the Department's Agency Performance Goals (APGs), specifically APG #13 which sets precise targets for completing green retrofits and creating energy efficient units. In addition to the direct support of HUD APG #13, the implementation of the CEEMP data system will enable HUD to provide reports to OMB on the progress of ECMs completed with PIH funding. Without the approval of the CEEMP data system, HUD will not be able to track PIH ECMs and will be unable to support the Department's APG #13 or provide OMB with ECM information.

DATES: *Comments Due Date:* February 6, 2012.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number (2577–New) and should be sent to: HUD Desk Officer Office of Management and Budget, New Executive Office Building, Washington, DC 20503: Fax (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Colette Pollard., Departmental Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 Seventh Street SW., Room 4176, Washington, DC 20410; *telephone:* (202) 402–2400, (this is not a toll-free number) or email Ms. Pollard at *Colette.Pollard@hud.gov.*

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35, as amended). This Notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Capture Energy Efficiency Measures for PIH (CEEMP).

OMB Control Number, if Applicable: 2577—New.

Description of the Need for the Information and Proposed Use: HUD is creating the Capture Energy Efficiency Measures for PIH (CEEMP) data system to track the amount and types of Energy Conservation Measures (ECMs) being implemented within Public and Indian (PIH) units. The CEEMP data system is necessary in order to support the Department's Agency Performance Goals (APGs), specifically APG #13 which sets precise targets for completing green retrofits and creating energy efficient units. In addition to the direct support of HUD APG #13, the implementation of the CEEMP data system will enable HUD to provide reports to OMB on the progress of ECMs completed with PIH funding. Without the approval of the CEEMP data system, HUD will not be able to track PIH ECMs and will be unable to support the Department's APG #13 or provide OMB with ECM information.

Agency Form Numbers, if Applicable: N/A, the data will be collected utilizing a web-based application. Recipients will be required to complete the collection online. To the greatest extent possible, all data will be pre-populated to minimize data entry. Once the initial file is created, recipients will be able to update the same file and submit on an ongoing basis.

Members of Affected Public: State, Local or Local Government and Non-profit organization.

Estimation of the Total Number of Hours Needed To Prepare the Information Collection Including Number of Respondents, Frequency of Response, and Hours of Response: The estimated number of respondents is 3,150 with 50,400 annual responses and the total reporting burden is 151,200 hours.

Status of the Proposed Information Collection: New.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35, as amended.

Dated: December 2, 2011.

Merrie Nichols-Dixon,

Deputy Director for Office of Policy, Program and Legislative Initiatives.

[FR Doc. 2011–31421 Filed 12–6–11; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R1–ES–2011–N200;10120–1112–0000–F2]

Endangered and Threatened Wildlife and Plants; Incidental Take Permit Application; Habitat Conservation Plan and Associated Documents; Meteorological Towers, Lanai, HI

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the U.S Fish and Wildlife Service (Service), have received an application from Castle and Cooke Resorts, LLC (applicant) to renew the incidental take permit number TE194350–0, associated with an existing habitat conservation plan (HCP), under the Endangered Species Act of 1973, as amended (ESA). We request public comment on the permit renewal application and HCP, as well as on our preliminary determination that the action is covered under the environmental assessment completed for the initial permit issuance.

DATES: All comments from interested parties must be received on or before January 6, 2012.

ADDRESSES: Please address written comments to Loyal Mehrhoff, Project Leader, Pacific Islands Fish and Wildlife Office, U.S. Fish and Wildlife Service, 300 Ala Moana Boulevard, Room 3–122, Honolulu, HI 96850. You may also send comments by facsimile to (808) 792–9580.

FOR FURTHER INFORMATION CONTACT: Bill Standley, Fish and Wildlife Biologist, U.S. Fish and Wildlife Service (see **ADDRESSES** above), telephone (808) 792–9400.

SUPPLEMENTARY INFORMATION: The applicant is requesting a six-year extension of an incidental take permit for incidental take of the endangered Hawaiian petrel (*Pterodroma sandwichensis*), endangered Hawaiian stilt (*Himantopus mexicanus knudseni*), endangered Hawaiian hoary bat (*Lasiurus cinereus semotus*), and the threatened Newell's (Townsend's) shearwater (*Puffinus auricularis newelli*) on the island of Lanai, Hawaii. The applicant remains in compliance with all of the conditions and authorizations in the original permit and no take has been documented to date. The applicant is also applying to the Hawaii Department of Land and Natural Resources to extend their State incidental take license.

Availability of Documents

You may request copies of the permit application, which includes the application and the original HCP, by contacting the Service's Pacific Islands Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT** above). The original HCP and environmental assessment are also available electronically for review on the U.S. Fish and Wildlife Service Pacific Islands Fish and Wildlife Office Web site at *http://www.fws.gov/pacificislands.*

Comments and materials we receive will become part of the public record and will be available for public inspection by appointment, during regular business hours. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Background

Section 9 of the ESA (16 U.S.C. 1538) and Federal regulations prohibit the ''take'' of fish and wildlife species listed as endangered or threatened. The term ''take'' means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. However, under section 10(a) of the ESA (16 U.S.C. 1539(a)), we may issue permits to authorize incidental take of listed fish and wildlife species. Incidental take is defined by the ESA as take that is incidental to, and not the purpose of, carrying out an otherwise lawful activity. Regulations governing incidental take permits for threatened and endangered species are found at 50 CFR 17.32 and 17.22. If the incidental take permit is renewed, the applicant would receive assurances under the Service's ''No Surprises'' regulations at 50 CFR 17.32(b)(5) and 50 CFR 17.22(b)(5).

On September 26, 2008, we issued an incidental take permit to the applicant for incidental take of the endangered Hawaiian petrel, endangered Hawaiian stilt, endangered Hawaiian hoary bat, and the threatened Newell's (Townsend's) shearwater, pursuant to section 10(a)(1)(B) of the ESA. As required by section 10(a)(2)(A) of the ESA, the applicant has an existing HCP designed to minimize and mitigate any such take of the covered species caused by the construction and operation of up to seven meteorological towers on the island of Lanai. The applicant constructed six of the seven meteorological towers that were covered under the incidental take permit on private land that they own. The meteorological towers are used to collect data on wind patterns. The data are being used to assess the suitability of the project site's wind regime to sustain a wind-turbine facility for electrical energy production. Each meteorological tower is 165-feet (50-meters) tall and each rests on a steel base plate approximately 9 square feet (0.8 square meter) in size. Each tower is supported with aircraft cable guy wires in four directions at each of six guy levels. The guy wire radius is 100 feet to 110 feet (30.5 to 33.5 meters). The guy wires are anchored with standard dead-man type anchors to a depth of 5 to 8 feet (1.5 to 2.4 meters). No listed species are known to inhabit the area in the immediate vicinity of the tower locations; however, incidental take may occur if individual birds or bats flying through the project site air space collide with the towers and guy wires.

Because of the uncertainty regarding the likelihood that listed species would collide with the meteorological towers and guy wires, the HCP established two tiers of mitigation that would be based on the take detected. The mitigation measures to offset the first tier of authorized take have been completed, and to date, no take of any listed species has been documented during the required monitoring program. The HCP included additional mitigation measures that would only be implemented should the first tier of take be exceeded. The completed mitigation included conducting predator control for a period of 2 years within the island's Hawaiian petrel colony, Newell's shearwater nesting habitat, and hoary bat habitat; conducting predator control for 2 years at the island's wastewater treatment plant, where Hawaiian stilts nest; and removing invasive plants, primarily strawberry guava (*Psidium cattleianum*), to facilitate the re-establishment of native vegetation within 3 acres of forest habitat adjacent to the Hawaiian petrel colony and within Newell's shearwater and hoary bat habitat.

During the implementation of the HCP, the applicant demonstrated that it was possible to manage the vegetation at meteorological tower sites such that searchers have a high probability of detecting any wildlife carcasses present and that carcasses were not being removed from the sites by scavengers. Therefore, the Service approved the modification of the monitoring protocol such that surveys were conducted every 30 days rather than 10 days, provided the vegetation was managed and carcass removal rates did not increase.

Prior to the expiration of the incidental take permit in March 2010, the applicant requested that the permit be extended for 6 years (through March 1, 2016). In accordance with regulations at 50 CFR 13.22(c), the applicant may continue the activities authorized by the expired permit until the Service has acted on the application for renewal. While the applicant has since removed five of the six towers originally constructed, the incidental take permit extension would cover the operation of all seven towers so that the applicant could reinstall and operate the meteorological towers without further amending the incidental take permit should additional wind data be needed. The applicant agreed to extend their Memorandum of Understanding with the State of Hawaii, which implemented the mitigation measures on behalf of the applicant, to ensure that the State continues to have access to manage and monitor the mitigation site for the full term of the incidental take permit. The

applicant also extended a Performance Bond secured to fund additional mitigation should it be required.

Preliminary Determination

The Service has made a preliminary determination that the Biological Opinion, Environmental Assessment, Finding of No Significant Impact, and Set of Findings that were previously approved in support of issuance of the original incidental take permit do not require revision because there is no new information relating to the impacts of this action, no additional impacts expected beyond those originally assessed, the required mitigation actions have been implemented pursuant to the existing HCP, and no incidental take has been documented.

Authority

This notice is provided pursuant to section 10(c) of the ESA (16 U.S.C. 1531 *et seq.*) and NEPA regulations (40 CFR 1506.6). The public process for the proposed Federal action will be completed after the public comment period, at which time we will evaluate the permit renewal application and comments submitted thereon to determine whether the application meets the requirements of section 10(a) of the ESA, applicable regulations, and NEPA requirements. If we determine that those requirements are met, we will renew the incidental take permit.

Dated: October 28, 2011.

Richard R. Hannan,

Deputy Regional Director, Pacific Region, Portland, Oregon.

[FR Doc. 2011–31427 Filed 12–6–11; 8:45 am]

BILLING CODE 4310–55–P

INTERNATIONAL TRADE COMMISSION

[DN 2860]

Certain Integrated Circuits, Chipsets, and Products Containing Same Including Televisions, Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *In Re Certain Integrated Circuits, Chipsets, And Products Containing Same including Televisions,* DN 2860; the Commission is soliciting comments on any public interest issues raised by the complaint.

FOR FURTHER INFORMATION CONTACT: James R. Holbein, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov,* and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint filed on behalf of Bracewell & Giuliani on Freescale Semiconductor, Inc. on December 1, 2011. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain integrated circuits, chipsets, and products containing same including televisions. The complaint names Media Tek Inc. of Taiwan; Zoran Corporation of Sunnyvale, CA; Vizio, Inc. of Irvine, CA; Sanyo Electric Co., Ltd. of Japan; Sanyo North America Corporation of San Diego, CA; Sanyo Manufacturing Corporation of Forrest City, Arkansas; TPV Technology Limited of Hong Kong; TPV International (USA) Inc. of Austin TX; Top Victory Electronics (Taiwan) Co., Ltd. of Taiwan; Top Victory Electronics (Fujian) Co., Ltd. of China; AOC International (USA) Ltd. of Fremont, CA; Envision Peripherals, Inc. of Fremont, CA; Amtran Technology Co., Ltd.of Taiwan; and Amtran Logistics, Inc. of Irvine, CA., as respondents.

The complainant, proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five pages in length, on any public interest issues raised by the complaint. Comments should address whether issuance of an exclusion order and/or a cease and desist order in this investigation would negatively affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the orders are used in the United States;

(ii) Identify any public health, safety, or welfare concerns in the United States relating to the potential orders;

(iii) Indicate the extent to which like or directly competitive articles are produced in the United States or are otherwise available in the United States, with respect to the articles potentially subject to the orders; and

(iv) Indicate whether Complainant, Complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to an exclusion order and a cease and desist order within a commercially reasonable time.

Written submissions must be filed no later than by close of business, five business days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

Persons filing written submissions must file the original document and 12 true copies thereof on or before the deadlines stated above with the Office of the Secretary. Submissions should refer to the docket number (''Docket No. 2860'') in a prominent place on the cover page and/or the first page. The Commission's rules authorize filing submissions with the Secretary by facsimile or electronic means only to the extent permitted by section 201.8 of the rules (see Handbook for Electronic Filing Procedures, *http://www.usitc.gov/secretary/fed_reg_notices/rules/documents/handbook_on_electronic_filing.pdf.* Persons with questions regarding electronic filing should contact the Secretary (202) 205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All nonconfidential written submissions will be available for

public inspection at the Office of the Secretary.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of sections 201.10 and 210.50(a)(4) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.50(a)(4)).

By order of the Commission.

Issued: December 1, 2011.

James R. Holbein,

Secretary to the Commission.

[FR Doc. 2011–31348 Filed 12–6–11; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–476 and 731–TA–1179 (Final)]

Multilayered Wood Flooring From China

Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (Commission) determines, pursuant to sections 705(b) and 735(b) of the Tariff Act of 1930 (19 U.S.C. 1671d(b) and 19 U.S.C. 1673d(b)) (the Act), that an industry in the United States is materially injured by reason of those imports from China of multilayered wood flooring, provided for in subheadings 4409.10, 4409.29, 4412.31, 4412.32, 4412.39, 4412.94, 4412.99, 4418.71, 4418.72, 4418.79.00, and 4418.90 of the Harmonized Tariff Schedule of the United States, that the U.S. Department of Commerce has determined are subsidized and/or sold in the United States at less than fair value (''LTFV'').[2]

Background

The Commission instituted these investigations effective October 21, 2010, following receipt of petitions filed with the Commission and Commerce on behalf of the Coalition for American Hardwood Parity (''CAHP''), an *ad hoc* association of U.S. manufacturers of multilayered wood flooring. The following companies are members of the CAHP: Anderson Hardwood Floors, LLC, Fountain Inn, SC; Award Hardwood Floors, Wausau, WI; From the Forest, Weston, WI; Howell Hardwood Flooring, Dothan, AL; Mannington Mills, Inc., Salem, NJ; Nydree Flooring, Forest, VA; and Shaw Industries Group, Inc., Dalton, GA. The final phase of the investigations was scheduled by the Commission following notification of preliminary determinations by Commerce that imports of multilayered wood flooring from China were subsidized within the meaning of section 703(b) of the Act (19 U.S.C. 1671b(b)) and sold at less than fair value within the meaning of 733(b) of the Act (19 U.S.C. 1673b(b)). Notice of the scheduling of the final phase of the Commission's investigations and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on June 9, 2011 (76 FR 33782). The hearing was held in Washington, DC, on October 12, 2011, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission transmitted its determinations in these investigations to the Secretary of Commerce on December 1, 2011. The views of the Commission are contained in USITC Publication 4278 (December 2011), entitled *Multilayered Wood Flooring from China: Investigation Nos. 701–TA–476 and 731–TA–1179 (Final).*

By order of the Commission.

Issued: December 1, 2011.

James R. Holbein,

Secretary to the Commission.

[FR Doc. 2011–31349 Filed 12–6–11; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–818]

Certain Devices With Secure Communication Capabilities, Components Thereof, and Products Containing the Same; Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on November 4, 2011, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of VirnetX, Inc. of Zephyr Cove, Nevada. A supplement was filed on November 22, 2011 which included public versions of the confidential exhibits. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain devices with secure communication capabilities, components thereof, and products containing the same by reason of infringement of certain claims of U.S. Patent No. 8,051,181 (''the '181 patent''). The complaint further alleges that an industry in the United States exists or is in the process of being established as required by subsection (a)(2) of section 337.

The complainant requests that the Commission institute an investigation and, after the investigation, issue an exclusion order and a cease and desist order.

ADDRESSES: The complaint and supplement, except for any confidential information contained therein, are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2011).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on December 1, 2011, *Ordered That*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] Vice Chairman Irving A. Williamson and Commissioners Charlotte R. Lane, Shara L. Aranoff, and Dean A. Pinkert voted in the affirmative. Chairman Deanna Tanner Okun and Commissioner Daniel R. Pearson voted in the negative. As a result of the USITC's affirmative determinations, Commerce will issue antidumping and countervailing duty orders on imports of this product from China.

to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain devices with secure communication capabilities, components thereof, and products containing the same that infringe one or more of claims 1, 2, 4–12, 17, 19, 21, 22, and 24–29 of the '181 patent, and whether an industry in the United States exists or is in the process of being established as required by subsection (a)(2) of section 337;

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is: VirnetX, Inc., 308 Dorla Court, Suite 206, Zephyr Cove, NV 89448.

(b) The respondent is the following entity alleged to be in violation of section 337, and is the party upon which the complaint is to be served: Apple Inc., One Infinite Loop, Cupertino, CA 95014.

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW., Suite 401, Washington, DC 20436; and

(3) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondent in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(d)–(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of the respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

Issued: December 1, 2011.

By order of the Commission.

James R. Holbein,

Secretary to the Commission.

[FR Doc. 2011–31347 Filed 12–6–11; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–817]

Certain Communication Equipment, Components Thereof, and Products Containing the Same, Including Power Over Ethernet Telephones, Switches, Wireless Access Points, Routers and Other Devices Used in LANs, and Cameras; Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on November 1, 2011, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of ChriMar Systems, Inc. d/b/a DMS Technologies of Farmington Hills, Michigan. A supplement was filed on November 10, 2011, and an amended complaint was filed on November 16, 2011. The complaint, as amended and supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain communication equipment, components thereof, and products containing the same, including power over ethernet telephones, switches, wireless access points, routers and other devices used in LANs, and cameras by reason of infringement of certain claims of U.S. Patent No. 7,457,250 (''the '250 patent''). The amended complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainant requests that the Commission institute an investigation and, after the investigation, issue an exclusion order and cease and desist orders.

ADDRESSES: The amended complaint and supplement, except for any confidential information contained therein, are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2011).

Scope of Investigation: Having considered the amended complaint, the U.S. International Trade Commission, on December 1, 2011, *Ordered That*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain communication equipment, components thereof, and products containing the same, including power over ethernet telephones, switches, wireless access points, routers and other devices used in LANs and cameras that infringe one or more of claims 1, 2, 12, 13, 15, 19, 20, 22–26, 29–32, 38, 45, 46, 48, 50, 52, 53, 55, 56, 58–62, 65–68, 74, 81, 82, 84, 86, and 88 of the '250 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to Commission Rule 210.50(b)(1), 19 CFR 210.50(b)(1), the presiding administrative law judge shall take evidence or other information and hear arguments from the parties and other interested persons with respect to the public interest in this investigation, as appropriate, and provide the Commission with findings of fact and a recommended determination on this issue;

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which

this notice of investigation shall be served:

(a) The complainant is:

ChriMar Systems, Inc., d/b/a CMS Technologies, 36528 Grand River Avenue, Suite A–1, Farmington Hills, MI 48335.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the amended complaint is to be served:

Cisco Systems, Inc., 170 West Tasman Drive, San Jose, CA 95134.

Cisco Consumer Products LLC, 120 Theory Drive, Irvine, CA 92617.

Cisco Systems International B.V., Haarlerbergpark, Haarlerbergweg 13–19, 1101 CH, Amsterdam, Netherlands.

Cisco-Linksys LLC, 121 Theory Drive, Irvine, CA 92617.

Hewlett-Packard Co., 3000 Hanover Street, Palo Alto, CA 94304.

3Com Corporation, 350 Campus Drive, Marlborough, MA 01752.

Avaya Inc., 211 Mt. Airy Road, Basking Ridge, NJ 07920.

Extreme Networks, Inc., 3585 Monroe Street, Santa Clara, CA 95051.

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW., Suite 401, Washington, DC 20436; and

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the amended complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(d)–(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the amended complaint and the notice of investigation. Extensions of time for submitting responses to the amended complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the amended complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the amended complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the amended complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: December 1, 2011.

James R. Holbein,

Secretary to the Commission.

[FR Doc. 2011–31346 Filed 12–6–11; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–540 and 541 (Third Review)]

Certain Welded Stainless Steel Pipe From Korea and Taiwan

Determination

On the basis of the record [1] developed in the subject five-year reviews, the United States International Trade Commission (Commission) determines, pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)), that revocation of the antidumping duty orders on certain welded stainless steel pipe from Korea and Taiwan would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission instituted these reviews on July 1, 2011 (76 FR 38688) and determined on October 4, 2011, that it would conduct expedited reviews (76 FR 64106, October 17, 2011).

The Commission transmitted its determination in these reviews to the Secretary of Commerce on December 1, 2011. The views of the Commission are contained in USITC Publication 4280 (December 2011), entitled Certain Welded Stainless Steel Pipe from Korea and Taiwan, Investigation Nos. 731–TA–540 and 541 (Third Review).

By order of the Commission.

Issued: December 1, 2011.

James R. Holbein,

Secretary to the Commission.

[FR Doc. 2011–31345 Filed 12–6–11; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in sec. 207.2(f) of the Commission(s Rules of Practice and Procedure (19 CFR 207.2(f)).

DEPARTMENT OF JUSTICE

Notice of Lodging of a Bankruptcy Settlement Agreement Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act

Notice is hereby given that a proposed Bankruptcy Settlement Agreement between the debtors and the Environmental Protection Agency (hereinafter ''Bankruptcy Settlement Agreement'') in *In re M.D. Moody & Sons, Inc., et al.,* Chap. 11, Jointly Administered under Case No. 3:09-bk-6247, was lodged on or about November 30, 2011 (Docket No. 974), with the United States Bankruptcy Court for the Middle District of Florida, Jacksonville Division. The proposed Bankruptcy Settlement Agreement would resolve the United States' claims under Section 107 of the Comprehensive Environmental Response, Compensation, and Liability Act (''CERCLA'') of 1980, 42 U.S.C. 9607, as amended, against the debtors related to unpaid response costs incurred by the Environmental Protection Agency in connection with the release of hazardous substances at the BCX Superfund Site (''Site'') in Jacksonville, Florida. EPA alleged that the debtors are liable as persons who, by contract, agreement, or otherwise, arranged for the disposal of hazardous substances at the Site. Under the proposed Bankruptcy Settlement Agreement, the debtors will pay the sum of $5,629.05 in full in cash within 30 days of Bankruptcy Court approval of the Bankruptcy Settlement Agreement. Pursuant to the Bankruptcy Settlement Agreement, the Debtors will receive a covenant not to sue from the United States on behalf of EPA for the Site and will receive protection from contribution actions or claims as provided by Section 113(f)(2) of CERCLA, 42 U.S.C. 9613(f)(2) for the matters addressed in the Bankruptcy Settlement Agreement.

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, comments relating to the proposed Bankruptcy Settlement Agreement. Comments should be addressed to the Assistant Attorney General for the Environment and Natural Resources Division, Department of Justice, and either emailed to *pubcommentees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 P.O. Box 7611, Washington, DC 20530, and should refer to *In re M.D. Moody & Sons, Inc., et al.,* Chap. 11, Jointly

Administered under Case No. 3:09-bk-6247 (USBC M.D. Fla.), DOJ Ref. #90–11–3–09152/2.

The Bankruptcy Settlement Agreement may be examined at U.S. EPA Region 4, 61 Forsyth Street, Atlanta, GA 30303 (contact Stacey Haire, Esq. (404) 562–9676). During the public comment period, the Bankruptcy Settlement Agreement may also be examined on the following Department of Justice Web site, *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the Bankruptcy Settlement Agreement may also be obtained by mail from the Consent Decree Library, U.S. Department of Justice, P.O. Box 7611, Washington, DC 20044–7611 or by faxing or emailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax No. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please refer to *In re M.D. Moody & Sons, Inc., et al.,* Chap. 11, Jointly Administered under Case No. 3:09-bk-6247 (USBC M.D. Fla.), DOJ Ref. #90–11–3–09152/2, and enclose a check in the amount of $17.50 (25 cents per page reproduction cost) payable to the U.S. Treasury or, if by email or fax, forward a check in that amount to the Consent Decree Library at the stated address.

Henry Friedman,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2011–31364 Filed 12–6–11; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Foreign Claims Settlement Commission

[F.C.S.C. Meeting and Hearing Notice No. 13–11]

Sunshine Act Meeting

The Foreign Claims Settlement Commission, pursuant to its regulations (45 CFR 503.25) and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of open meetings as follows:

Thursday, December 15, 2011

11 a.m.—Issuance of Proposed Decisions in claims against Libya.

1 p.m.—Oral hearings on objections to Commission's Proposed Decisions in Claim Nos. LIB–II–125; LIB–II–126 and LIB–II–127.

Friday, December 16, 2011

9 a.m.—Oral hearings on objection to Commission's Proposed Decision in Claim Nos. LIB–I–003.

STATUS: Open.

All meetings are held at the Foreign Claims Settlement Commission, 600 E Street, NW., Washington, DC. Requests for information, or advance notices of intention to observe an open meeting, may be directed to: Judith H. Lock, Executive Officer, Foreign Claims Settlement Commission, 600 E Street NW., Suite 6002, Washington, DC 20579. *Telephone:* (202) 616–6975.

Jaleh F. Barrett,

Chief Counsel.

[FR Doc. 2011–31558 Filed 12–5–11; 4:15 pm]

BILLING CODE 4410–BA–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Davis-Bacon Certified Payroll

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Wage and Hour Division (WHD) sponsored information collection request (ICR) titled, ''Davis-Bacon Certified Payroll,'' to the Office of Management and Budget (OMB) for review and approval for continued use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 *et seq.*).

DATES: Submit comments on or before January 6, 2012.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the RegInfo.gov Web site, *http://www.reginfo.gov/public/do/PRAMain,* on the day following publication of this notice or by contacting Michel Smyth by telephone at (202) 693–4129 (this is not a toll-free number) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request to the Office of Information and Regulatory Affairs, *Attn:* OMB Desk Officer for the Department of Labor, Wage and Hour Division (WHD), Office of Management and Budget, Room 10235, Washington, DC 20503, *Telephone:* (202) 395–6929/Fax: (202) 395–6881 (these are not toll-free numbers), *email: OIRA_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at (202) 693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The Copeland Act requires contractors and subcontractors performing work on federally financed or assisted construction contracts to furnish weekly a statement with respect to the wages paid each employee during the preceding week. See 40 U.S.C. 3145; 29 CFR 3.3(b). Regulations 29 CFR 5.5 (a)(3)(ii)(A) requires contractors to submit weekly a copy of all payrolls to the Federal agency contracting for or financing the construction project, if the agency is a party to the contract, accompanied by a signed Statement of Compliance indicating that the payrolls are correct and complete and that each laborer or mechanic has been paid not less than the proper Davis-Bacon prevailing wage rate for the work performed. 29 CFR 5.5(a)(3)(ii)(B).

The DOL has developed optional use Form WH–347, Payroll Form, to aide contractors and subcontractors performing work on federally financed or assisted construction contracts in meeting weekly payroll reporting requirements. 29 CFR 5.5(a)(3)(ii)(A); see also, 29 CFR 3.3(b). Properly filled out, this form will satisfy the requirements of Regulations 29 CFR parts 3 and 5 as to payrolls submitted in connection with contracts subject to the Davis-Bacon and Related Acts.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information if the collection of information does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under OMB Control Number 1235–0008. The current OMB approval is scheduled to expire on December 31, 2011; however, it should be noted that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional information, see the related notice published in the **Federal Register** on August 8, 2011 (76 FR 48181).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within 30 days of publication of this notice in the **Federal Register.** In order to help ensure appropriate consideration, comments should reference OMB Control Number 1235–0008. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: Wage and Hour Division (WHD).

Title of Collection: Davis-Bacon Certified Payroll.

OMB Control Number: 1235–0008.

Affected Public: Private Sector—Businesses or other for-profits.

Total Estimated Number of Respondents: 96,096.

Total Estimated Number of Responses: 2,210,208.

Total Estimated Annual Burden Hours: 2,062,861.

Total Estimated Annual Other Costs Burden: $369,105.

Dated: December 1, 2011.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2011–31372 Filed 12–6–11; 8:45 am]

BILLING CODE 4510–27–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

Proposed Extension of Information Collection Requests Submitted for Public Comment: Disclosures by Insurers to General Account Policyholders; ERISA Technical Release 91–1; Registration for EFAST–2 Credentials; ERISA Procedure 76–1; Prohibited Transaction Exemptions 94–71 and 2003–39; Notice of Blackout Period Under ERISA; Voluntary Fiduciary Correction Program and Class Exemption

AGENCY: Employee Benefits Security Administration, Department of Labor.

ACTION: Notice.

SUMMARY: The Department of Labor (the Department), in accordance with the Paperwork Reduction Act of 1995 (PRA 95) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. The Employee Benefits Security Administration (EBSA) is soliciting comments on the proposed extension of the information collection requests (ICRs) contained in the documents described below. A copy of the ICRs may be obtained by contacting the office listed in the **ADDRESSES** section of this notice. ICRs also are available at reginfo.gov (*http://www.reginfo.gov/public/do/PRAMain*).

DATES: Written comments must be submitted to the office shown in the Addresses section on or before February 6, 2012.

ADDRESSES: G. Christopher Cosby, Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW., Washington, DC 20210, (202) 693–8410, Fax (202) 693–4745 (these are not toll-free numbers).

SUPPLEMENTARY INFORMATION: This notice requests public comment on the Department's request for extension of the Office of Management and Budget's (OMB) approval of ICRs contained in the rules and prohibited transactions described below. The Department is not proposing any changes to the existing ICRs at this time. An agency may not conduct or sponsor, and a person is not required to respond to, an information collection unless it displays a valid OMB control number. A summary of the ICRs and the current burden estimates follows:

Agency: Employee Benefits Security Administration, Department of Labor.

Title: Disclosures by Insurers to General Account Policyholders.

Type of Review: Extension without change of a currently approved collection of information.

OMB Number: 1210–0114.

Affected Public: Business or other for-profit; Not-for-profit institutions.

Respondents: 50,000.

Responses: 96,223.

Estimated Total Burden Hours: 408,948.

Estimated Total Burden Cost (Operating and Maintenance): $32,235.

Description: Section 1460 of the Small Business Job Protection Act of 1996 (Pub. L. 104–188) (SBJPA) amended added a new section 401(c) to the Employee Income Security Act of 1974 (ERISA). This new section, *inter alia,* required the Department to promulgate a regulation providing guidance, applicable only to insurance policies issued on or before December 31, 1998, to or for the benefit of employee benefit plans, to clarify the extent to which assets held in an insurer's general account under such contracts are ''plan assets'' within the meaning of the Employee Retirement Income Security Act (ERISA), because the policies are not ''guaranteed benefit policies'' within the meaning of section 401(b) of ERISA. SBJPA further directed the Department to set standards for how insurers should manage the specified insurance policies (called Transition Policies). Pursuant to the authority and direction given under SBJPA, the Department promulgated a regulation, issued in final form on January 5, 2000 (65 FR 714), and codified at 29 CFR 2550.401c–1. This regulation has not been amended subsequently. The ICR is scheduled to expire on March 31, 2012.

Agency: Employee Benefits Security Administration, Department of Labor.

Title: ERISA Technical Release 91–1.

Type of Review: Extension without change of a currently approved collection of information.

OMB Number: 1210–0084.

Affected Public: Business or other for-profit; Not-for-profit institutions.

Respondents: 15.

Responses: 107,040.

Estimated Total Burden Hours: 1,827.

Estimated Total Burden Cost (Operating and Maintenance): $25,286.

Description: The subject information collection requirements arise from ERISA section 101(e), which establishes

notice requirements that must be satisfied before an employer may transfer excess assets from a defined benefit pension plan to a retiree health benefit account, as permitted under the conditions set forth in section 420 of the Internal Revenue Code of 1986.

The notice requirements of section 101(e) are two-fold. First, subsection (e)(1) requires plan administrators to provide advance written notification of such transfers to participants and beneficiaries. Second, subsection (e)(2)(A) requires employers to provide advance written notification of such transfers to the Secretaries of Labor and the Treasury, the plan administrator, and each employee organization representing participants in the plan. Both notices must be given at least 60 days before the transfer date. The two subsections prescribe the information to be included in each type of notice and further give the Secretary of Labor the authority to prescribe how notice to participants and beneficiaries must be given and any additional reporting requirements deemed necessary.

Although the Department of Labor has not issued regulations under section 101(e), on May 8, 1991, the Department published ERISA Technical Release 91–1, to provide guidance on how to satisfy the notice requirements prescribed by this section.

The Technical Release made two changes in the statutory requirements for the second type of notice. First, it required the notice to include a filing date and the intended asset transfer date. Second, it simplified the statutory filing requirements by providing that filing with the Department of Labor would be deemed sufficient notice to both the Department and the Department of the Treasury as required under the statute. The ICR is scheduled to expire on March 31, 2012.

Agency: Employee Benefits Security Administration, Department of Labor.

Title: Registration for EFAST–2 Credentials.

Type of Review: Revision of a currently approved collection of information.

OMB Number: 1210–0117.

Affected Public: Individuals or households; Business or other for-profit; Not-for-profit institutions.

Respondents: 400,000.

Frequency of Responses: On occasion.

Responses: 400,000.

Estimated Total Burden Hours: 133,333.

Estimated Total Burden Cost (Operating and Maintenance): $0.

Description: ERISA Section 104 requires administrators of pension and welfare benefit plans (collectively, employee benefit plans), and employers sponsoring certain fringe benefit plans and other plans of deferred compensation, to file returns/reports annually with the Secretary of Labor (the Secretary) concerning the financial condition and operation of the plans. Reporting requirements are satisfied by filing the Form 5500 in accordance with its instructions and the related regulations. Beginning with plan year filings for 1999, Form 5500 filings were processed under the ERISA Filing Acceptance System (EFAST), which was designed to simplify and expedite the receipt and processing of the Form 5500 by relying on computer scannable forms and electronic filing technologies. The Office of Management and Budget (OMB) approved this information collection under OMB Control Number 1210–0117.

Beginning with plan year filings for 2009, Form 5500 filings are processed under a new system, the ERISA Filing Acceptance System 2 (EFAST–2), which is designed to simplify and expedite the receipt and processing of the Form 5500 by relying on Internet-based forms and electronic filing technologies. In order to file electronically, employee benefit plan filing authors, schedule authors, filing signers, Form 5500 transmitters, and entities developing software to complete and/or transmit the Form 5500 are required to register for EFAST–2 credentials through the EFAST–2 Web site. Requested information includes: Applicant type (filing author, filing signer, schedule author, transmitter, or software developer); mailing address; fax number (optional); email address; company name, contact person; and daytime telephone number. Registrants must also provide an answer to a challenge question (''What is your date of birth?'' or ''Where is your place of birth?''), which enables users to retrieve forgotten credentials. In addition, registrants must accept a Privacy Agreement; PIN Agreement; and, under penalty of perjury, a Signature Agreement.

On October 23, 2011, OMB approved a revision to OMB Control Number 1210–0117 to reflect the EFAST–2 credential process under the emergency procedures for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35) and 5 CFR 1320.13. OMB's approval of the revision currently is scheduled to expire on April 30, 2012.

Agency: Employee Benefits Security Administration, Department of Labor.

Title: ERISA Procedure 76–1; Advisory Opinion Procedure.

Type of Review: Extension without change of a currently approved collection of information.

OMB Number: 1210–0066.

Affected Public: Business or other for-profit; Not-for-profit institutions.

Respondents: 63.

Responses: 63.

Estimated Total Burden Hours: 652.

Estimated Total Burden Cost (Operating and Maintenance): $1,425,229.

Description: Under ERISA, the Department has responsibility to administer the reporting, disclosure, fiduciary and other standards for pension and welfare benefit plans. In 1976, the Department issued ERISA Procedure 76–1, Procedure for ERISA Advisory Opinions (ERISA Procedure), in order to establish a public process for requesting guidance from EBSA on the application of ERISA to particular circumstances. The ERISA Procedure sets forth specific administrative procedures for requesting either an advisory opinion or an information letter and describes the types of questions that may be submitted. As part of the ERISA Procedure, requesters are instructed to provide information to EBSA concerning the circumstances governing their request. EBSA relies on the information provided by the requester to analyze the issue presented and provide guidance. The ERISA Procedure has been in use since 1976, and the Department has issued hundreds of advisory opinions and information letters under its rules. The ICR is scheduled to expire on June 30, 2012.

Agency: Employee Benefits Security Administration, Department of Labor.

Title: Settlement Agreements Between a Plan and a Party-in-Interest (PTEs 94–71 and 2003–39).

Type of Review: Extension without change of a currently approved collection of information.

OMB Number: 1210–0091.

Affected Public: Business or other for-profit; Not-for-profit institutions.

Respondents: 4.

Responses: 1080.

Estimated Total Burden Hours: 28.

Estimated Total Burden Cost (Operating and Maintenance): $315.

Description: Section 408(a) of ERISA and section 4975(c)(2) of the Internal Revenue Code of 1986 (the Code) give the Secretary of Labor the authority to grant an exemption to a class or order of fiduciaries, disqualified persons, or transactions from all or part of the restrictions imposed by sections 406 and 407(a) of ERISA and from the taxes imposed by sections 4975(a) and (b) of the Code, by reason of section 4975(c)(1)

of the Code. This information collection request (ICR) relates to two prohibited transaction class exemptions (PTEs) that the Department of Labor (the Department) has granted, both of which involve settlement agreements. These two exemptions are described below:

PTE 94–71. Granted on September 30, 1994, PTE 94–71 exempts from certain restrictions of ERISA and certain taxes imposed by the Code, a transaction or activity that is authorized, prior to the execution of the transaction or activity, by a settlement agreement resulting from an investigation of an employee benefit plan conducted by the Department.

PTE 2003–39. Granted on December 31, 2005, PTE 03–39 exempts from certain restrictions of ERISA and certain taxes imposed by the Code, transactions arising out of the settlement of litigation that involve the release of claims against parties in interest in exchange for payment by or on behalf of the party in interest, provided that certain conditions are met.

Because both exemptions involve settlement agreements, the Department has combined their information collection provisions into one ICR and has obtained OMB approval for their paperwork burden. The Department believes that the public and the Federal government are both best served by allowing the public to review and comment on similar exemption provisions in combination. The ICR is scheduled to expire on June 30, 2012.

Agency: Employee Benefits Security Administration, Department of Labor.

Title: Notice of Blackout Period Under ERISA.

Type of Review: Extension without change of a currently approved collection of information.

OMB Number: 1210–0122.

Affected Public: Business or other for-profit; Not-for-profit institutions.

Respondents: 45,200.

Responses: 3,465,447.

Estimated Total Burden Hours: 183,342.

Estimated Total Burden Cost (Operating and Maintenance): $1,628,760.

Description: The Sarbanes-Oxley Act (SOA), enacted on July 30, 2002, added ERISA section 101(i), which requires individual account pension plans to furnish a written notice to participants and beneficiaries in advance of any ''blackout period'' during which their existing rights to direct or diversify their investments under the plan, or obtain a loan or distribution from the plan will be temporarily suspended. Under 306(b)(2) of SOA, the Secretary of Labor was directed to issue interim final rules necessary to implement the SOA amendments. The Department's regulation for this purpose is codified at 29 CFR 2520.101–3. The ICR is scheduled to expire on June 30, 2012.

Agency: Employee Benefits Security Administration, Department of Labor.

Title: Voluntary Fiduciary Correction Program.

Type of Review: Extension without change of a currently approved collection of information.

OMB Number: 1210–0118.

Affected Public: Business or other for-profit; Not-for-profit institutions.

Respondents: 1,525.

Responses: 76,242.

Estimated Total Burden Hours: 6,863.

Estimated Total Burden Cost (Operating and Maintenance): $273,403.

Description: This information collection arises from two related actions: the Voluntary Fiduciary Correction Program (the VFC Program or the Program) and Prohibited Transaction Class Exemption (PTE) 2002–51 (the Exemption). The Department adopted the Program and the Exemption in order to encourage members of the public to voluntarily correct transactions that violate (or are suspected of violating) the fiduciary or prohibited transaction provisions of the ERISA. Both the Program and the Exemption incorporate information collection requirements in order to protect participants and beneficiaries and enable the Department to oversee the appropriate use of the Program and the Exemption. The ICR is scheduled to expire on June 30, 2012.

Focus of Comments

The Department is particularly interested in comments that:

- Evaluate whether the collections of information are necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the collections 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.,* by permitting electronic submissions of responses.

Comments submitted in response to this notice will be summarized and/or included in the ICRs for OMB approval of the extension of the information collection; they will also become a matter of public record.

Dated: November 30, 2011.

Joseph S. Piacentini,

Director, Office of Policy and Research, Employee Benefits Security Administration.

[FR Doc. 2011–31287 Filed 12–6–11; 8:45 am]

BILLING CODE 4510–29–P

NATIONAL SCIENCE FOUNDATION

Emergency Clearance; Public Information Collection Requirements Submitted to the Office of Management and Budget; Notice

AGENCY: National Science Foundation.

ACTION: Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB).

SUMMARY: The National Science Foundation (NSF) is announcing plans to request approval of this collection. In accordance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), we are providing an opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting that OMB approve clearance of this collection for no longer than 3 years.

DATES: Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements by January 6, 2012.

ADDRESSES: Written comments regarding the information collection and requests for copies of the proposed information collection request should be addressed to Suzanne Plimpton, Reports Clearance Officer, National Science Foundation, 4201 Wilson Blvd., Rm. 295, Arlington, VA 22230, or by email to *splimpto@nsf.gov,* and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503. *Attn:* Sharon Mar, NSF Desk Officer.

Comments: Written comments are invited on (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information on respondents, including through the use

of automated collection techniques or other forms of information technology; or (d) ways to 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.

NSF has determined that it cannot reasonably comply with the normal clearance procedures within 5 CFR part 1320 because normal clearance procedures are reasonably likely to prevent or disrupt the collection of information. NSF is requesting emergency review from OMB of this information collection to assure compliance with the America Competes Act, Public Law 100–69, Section 7027, which calls for a study on laboratory equipment donations for schools. If granted, the emergency approval is only valid for 180 days.

During this same period, a regular review of this information collection will be undertaken. During the regular review period, the NSF requests written comments and suggestions from the public and affected agencies concerning this information collection. Comments are encouraged and will be accepted until February 6, 2012 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

FOR FURTHER INFORMATION CONTACT: Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 4201 Wilson Boulevard, Suite 295, Arlington, Virginia 22230; telephone (703) 292–7556; or send email to *splimpto@nsf.gov*. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–(800) 877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays.

SUPPLEMENTARY INFORMATION: Request for Clearance for Study of Laboratory Equipment Donations for Schools.

Title of Collection: Survey of Laboratory Equipment Donations for Schools.

OMB Approval No.: 3145—NEW

Expiration Date of Approval: Not applicable.

Abstract: The National Science Foundation (NSF) requests a three-year clearance for data collection and research related to laboratory equipment donations to schools. The goal of this study is to comply with the America Competes Act, Public Law 100–69, Section 7027, which calls for a study on laboratory equipment donations for schools. The law states: ''Not later than 2 years after the date of enactment of this Act, [August 9, 2007], the Director [of the National Science Foundation] shall transmit a report to Congress examining the extent to which institutions of higher education and entities in the private sector are donating used laboratory equipment to elementary schools and secondary schools. The Director * * * shall survey institutions of higher education and entities in the private sector to determine—

(1) How often, how much, and what type of equipment is donated;

(2) What criteria or guidelines the institutions and entities are using to determine what types of equipment can be donated, what condition the equipment should be in, and which schools receive the equipment;

(3) Whether the institutions and entities provide any support to, or follow-up with the schools; and

(4) How appropriate donations can be encouraged.'' Under a grant from NSF, the American Institutes for Research (AIR) has designed a sample of institutions of higher education (IHEs) drawn from the Integrated Postsecondary Education Data System (IPEDS) using the 2007–2008 school year. IHEs were selected with Carnegie group (2005) based on their total research spending. The assumption is that schools with higher research spending are most likely to donate equipment, so the sample is weighted to capture IHEs with higher levels of spending.

In addition to IHEs, large corporations that have demonstrated a commitment to science, technology, engineering, and mathematics (STEM) education will also be surveyed. This will be a population survey of members of Change the Equation, an independent non-profit organization that is a component of President Obama's ''Educate to Innovate'' initiative. These corporations will represent ''entities in the private sector'' that Congress mandated be surveyed.

Basic analyses will include descriptive statistics on each category of information requested by Congress broken out by Carnegie classification of IHEs, level of IHE research spending, and industry sector and size of private entities. Data will also include summaries of feedback provided by respondents on how appropriate donations can be encouraged. NSF will use the resulting data and analyses primarily to respond to the aforementioned congressional request for information. NSF will also share the information with the educational research community; professional education associations, especially those focused on science, academia; K–12 schools, especially science teachers; and the general public.

Respondents: Individuals, State, Local or Tribal Government, not-for-profit institutions, and for-profit institutions (*i.e.,* corporations). Respondents will be persons representing these entities who have been identified as familiar with their organization's disposal of surplus laboratory equipment.

Estimated Number of Respondents: 400 (300 IHEs and 100 corporations).

Burden on the Public: 400 hours.

Dated: December 2, 2011.

Suzanne Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2011–31366 Filed 12–6–11; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee On Reactor Safeguards Meeting of The ACRS Subcommittee on Materials, Metallurgy & Reactor Fuels

Revision to December 15, 2011, ACRS Meeting Federal Register Notice

The Federal Register Notice for the ACRS Subcommittee Meeting on Materials, Metallurgy & Reactor Fuels scheduled to be held on December 15, 2011, is being revised to notify the following:

The meeting will be open to public attendance with exception of portions that may be closed to protect information that is proprietary, pursuant to 5 U.S.C. 552b(c)(4).

The notice of this meeting was previously published in the **Federal Register** on November 23, 2011 [76 FR 72451–72452]. All other items remain the same as previously published.

Further information regarding this meeting can be obtained by contacting Christopher Brown, Designated Federal Official (*Telephone:* (301) 415–7111, *Email: Christopher.Brown@nrc.gov)* between 7:30 a.m. and 5:15 p.m. (ET).

Dated: December 1, 2011.

Antonio F. Dias,

Technical Advisor, Advisory Committee on Reactor Safeguards.

[FR Doc. 2011–31362 Filed 12–6–11; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket No. A2012–65; Order No. 1007]

Post Office Closing

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: This document informs the public that an appeal of the closing of the Greeley, Iowa post office has been filed. It identifies preliminary steps and provides a procedural schedule. Publication of this document will allow the Postal Service, petitioners, and others to take appropriate action.

DATES: November 29, 2011: Administrative record due (from Postal Service); December 27, 2011, 4:30 p.m., Eastern Time: Deadline for notices to intervene. *See* the Procedural Schedule in the **SUPPLEMENTARY INFORMATION** section for other dates of interest.

ADDRESSES: Submit comments electronically by accessing the ''Filing Online'' link in the banner at the top of the Commission's Web site (*http://www.prc.gov*) or by directly accessing the Commission's Filing Online system at *https://www.prc.gov/prc-pages/filing-online/login.aspx.* Commenters who cannot submit their views electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section as the source for case-related information for advice on alternatives to electronic filing.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at (202) 789–6820 (case-related information) or *DocketAdmins@prc.gov* (electronic filing assistance).

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to 39 U.S.C. 404(d), on November 14, 2011, the Commission received a petition for review of the Postal Service's determination to close the Greeley post office in Greeley, Iowa. The petition for review was filed by Genny Bennett (Petitioner) and is postmarked October 28, 2011. The Commission hereby institutes a proceeding under 39 U.S.C. 404(d)(5) and establishes Docket No. A2012–65 to consider Petitioner's appeal. If Petitioner would like to further explain her position with supplemental information or facts, Petitioner may either file a Participant Statement on PRC Form 61 or file a brief with the Commission no later than December 19, 2011.

Categories of issues apparently raised. Petitioner contends that the Postal Service failed to consider whether or not it will continue to provide a maximum degree of effective and regular postal services to the community (*see* 39 U.S.C. 404(d)(2)(A)(iii)).

After the Postal Service files the administrative record and the Commission reviews it, the Commission may find that there are more legal issues than those set forth above, or that the Postal Service's determination disposes of one or more of those issues. The deadline for the Postal Service to file the applicable administrative record is within 15 days after the date in which the petition for review was filed with the Commission. *See* 39 CFR 3001.113. In addition, the due date for any responsive pleading by the Postal Service is also within 15 days after the date in which the petition for review was filed with the Commission.

Availability; Web site posting. The Commission has posted the appeal and supporting material on its Web site at *http://www.prc.gov.* Additional filings in this case and participant's submissions also will be posted on the Web site, if provided in electronic format or amenable to conversion, and not subject to a valid protective order. Information on how to use the Commission's Web site is available online or by contacting the Commission's webmaster via telephone at (202) 789–6873 or via electronic mail at *prc-webmaster@prc.gov.*

The appeal and all related documents are also available for public inspection in the Commission's docket section. Docket section hours are 8 a.m. to 4:30 p.m., Eastern Time, Monday through Friday, except on Federal government holidays. Docket section personnel may be contacted via electronic mail at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Filing of documents. All filings of documents in this case shall be made using the Internet (Filing Online) pursuant to Commission rules 9(a) and 10(a) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained. *See* 39 CFR 3001.9(a) and 3001.10(a). Instructions for obtaining an account to file documents online may be found on the Commission's Web site, *http://www.prc.gov,* or by contacting the Commission's docket section at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Commission reserves the right to redact personal information which may infringe on an individual's privacy rights from documents filed in this proceeding.

Intervention. Persons, other than the Petitioners and respondents, wishing to be heard in this matter are directed to file a notice of intervention. *See* 39 CFR 3001.111(b). Notices of intervention in this case are to be filed on or before December 27, 2011. A notice of intervention shall be filed using the Internet (Filing Online) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained for hardcopy filing. *See* 39 CFR 3001.9(a) and 3001.10(a).

Further procedures. By statute, the Commission is required to issue its decision within 120 days from the date it receives the appeal. *See* 39 U.S.C. 404(d)(5). A procedural schedule has been developed to accommodate this statutory deadline. In the interest of expedition, in light of the 120-day decision schedule, the Commission may request the Postal Service or other participants to submit information or memoranda of law on any appropriate issue. As required by Commission rules, if any motions are filed, responses are due 7 days after any such motion is filed. *See* 39 CFR 3001.21.

It is ordered:

1. The procedural schedule listed below is hereby adopted.

2. Pursuant to 39 U.S.C. 505, Pamela A. Thompson is designated officer of the Commission (Public Representative) to represent the interests of the general public.

3. The Secretary shall arrange for publication of this notice and order and Procedural Schedule in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

PROCEDURAL SCHEDULE

November 14, 2011	Filing of Appeal.
November 29, 2011	Deadline for the Postal Service to file the applicable administrative record in this appeal.
November 29, 2011	Deadline for the Postal Service to file any responsive pleading.
December 27, 2011	Deadline for notices to intervene (*see* 39 CFR 3001.111(b)).
December 19, 2011	Deadline for Petitioners' Form 61 or initial brief in support of petition (*see* 39 CFR 3001.115(a) and (b)).
January 9, 2012	Deadline for answering brief in support of the Postal Service (*see* 39 CFR 3001.115(c)).

PROCEDURAL SCHEDULE—Continued

January 24, 2012	Deadline for reply briefs in response to answering briefs (*see* 39 CFR 3001.115(d)).
January 31, 2012	Deadline for motions by any party requesting oral argument; the Commission will schedule oral argument only when it is a necessary addition to the written filings (*see* 39 CFR 3001.116).
February 27, 2012	Expiration of the Commission's 120-day decisional schedule (*see* 39 U.S.C. 404(d)(5)).

[FR Doc. 2011–31357 Filed 12–6–11; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. A2012–66; Order No. 1008]

Post Office Closing

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: This document informs the public that an appeal of the closing of the Holland, Iowa post office has been filed. It identifies preliminary steps and provides a procedural schedule. Publication of this document will allow the Postal Service, petitioners, and others to take appropriate action.

DATES: November 29, 2011: Administrative record due (from Postal Service); December 27, 2011, 4:30 p.m., Eastern Time: Deadline for notices to intervene. *See* the Procedural Schedule in the **SUPPLEMENTARY INFORMATION** section for other dates of interest.

ADDRESSES: Submit comments electronically by accessing the ''Filing Online'' link in the banner at the top of the Commission's Web site (*http://www.prc.gov*) or by directly accessing the Commission's Filing Online system at *https://www.prc.gov/prc-pages/filing-online/login.aspx.* Commenters who cannot submit their views electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section as the source for case-related information for advice on alternatives to electronic filing.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at (202) 789–6820 (case-related information) or *DocketAdmins@prc.gov* (electronic filing assistance).

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to 39 U.S.C. 404(d), on November 14, 2011, the Commission received a petition for review of the Postal Service's determination to close the Holland post office in Holland, Iowa. The petition for review was filed by Gary Stoehr, Jr. (Petitioner) and is postmarked November 2, 2011. The Commission hereby institutes a proceeding under 39 U.S.C. 404(d)(5) and establishes Docket No. A2012–66 to consider Petitioner's appeal. If Petitioner would like to further explain his position with supplemental information or facts, Petitioner may either file a Participant Statement on PRC Form 61 or file a brief with the Commission no later than December 19, 2011.

Categories of issues apparently raised. Petitioner contends that (1) the Postal Service failed to adequately consider the economic savings resulting from the closure (*see* 39 U.S.C. 404(d)(2)(A)(iv)); and (2) the Postal Service failed to provide substantial evidence in support of the determination (*see* 39 U.S.C. 404(d)(5)(c)).

After the Postal Service files the administrative record and the Commission reviews it, the Commission may find that there are more legal issues than those set forth above, or that the Postal Service's determination disposes of one or more of those issues. The deadline for the Postal Service to file the applicable administrative record is within 15 days after the date in which the petition for review was filed with the Commission. *See* 39 CFR 3001.113. In addition, the due date for any responsive pleading by the Postal Service is also within 15 days after the date in which the petition for review was filed with the Commission.

Availability; Web site posting. The Commission has posted the appeal and supporting material on its Web site at *http://www.prc.gov.* Additional filings in this case and participant's submissions also will be posted on the Web site, if provided in electronic format or amenable to conversion, and not subject to a valid protective order. Information on how to use the Commission's Web site is available online or by contacting the Commission's webmaster via telephone at (202) 789–6873 or via electronic mail at *prc-webmaster@prc.gov.*

The appeal and all related documents are also available for public inspection in the Commission's docket section. Docket section hours are 8 a.m. to 4:30 p.m., Eastern Time, Monday through Friday, except on Federal government holidays. Docket section personnel may be contacted via electronic mail at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Filing of documents. All filings of documents in this case shall be made using the Internet (Filing Online) pursuant to Commission rules 9(a) and 10(a) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained. *See* 39 CFR 3001.9(a) and 3001.10(a). Instructions for obtaining an account to file documents online may be found on the Commission's Web site, *http://www.prc.gov,* or by contacting the Commission's docket section at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Commission reserves the right to redact personal information which may infringe on an individual's privacy rights from documents filed in this proceeding.

Intervention. Persons, other than the Petitioners and respondents, wishing to be heard in this matter are directed to file a notice of intervention. *See* 39 CFR 3001.111(b). Notices of intervention in this case are to be filed on or before December 27, 2011. A notice of intervention shall be filed using the Internet (Filing Online) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained for hardcopy filing. *See* 39 CFR 3001.9(a) and 3001.10(a).

Further procedures. By statute, the Commission is required to issue its decision within 120 days from the date it receives the appeal. *See* 39 U.S.C. 404(d)(5). A procedural schedule has been developed to accommodate this statutory deadline. In the interest of expedition, in light of the 120-day decision schedule, the Commission may request the Postal Service or other participants to submit information or memoranda of law on any appropriate issue. As required by Commission rules, if any motions are filed, responses are due 7 days after any such motion is filed. *See* 39 CFR 3001.21.

It is ordered:

1. The procedural schedule listed below is hereby adopted.

2. Pursuant to 39 U.S.C. 505, Katrina R. Martinez is designated officer of the Commission (Public Representative) to represent the interests of the general public.

3. The Secretary shall arrange for publication of this notice and order and Procedural Schedule in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

PROCEDURAL SCHEDULE

November 14, 2011	Filing of Appeal.
November 29, 2011	Deadline for the Postal Service to file the applicable administrative record in this appeal.
November 29, 2011	Deadline for the Postal Service to file any responsive pleading.
December 27, 2011	Deadline for notices to intervene (*see* 39 CFR 3001.111(b)).
December 19, 2011	Deadline for Petitioners' Form 61 or initial brief in support of petition (*see* 39 CFR 3001.115(a) and (b)).
January 9, 2012	Deadline for answering brief in support of the Postal Service (*see* 39 CFR 3001.115(c)).
January 24, 2012	Deadline for reply briefs in response to answering briefs (*see* 39 CFR 3001.115(d)).
January 31, 2012	Deadline for motions by any party requesting oral argument; the Commission will schedule oral argument only when it is a necessary addition to the written filings (*see* 39 CFR 3001.116).
March 1, 2012	Expiration of the Commission's 120-day decisional schedule (*see* 39 U.S.C. 404(d)(5)).

[FR Doc. 2011–31358 Filed 12–6–11; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. A2012–70; Order No. 1014]

Post Office Closing

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: This document informs the public that an appeal of the closing of the Mountain City, Nevada post office has been filed. It identifies preliminary steps and provides a procedural schedule. Publication of this document will allow the Postal Service, petitioners, and others to take appropriate action.

DATES: November 30, 2011: Administrative record due (from Postal Service); December 27, 2011, 4:30 p.m., Eastern Time: Deadline for notices to intervene. *See* the Procedural Schedule in the **SUPPLEMENTARY INFORMATION** section for other dates of interest.

ADDRESSES: Submit comments electronically by accessing the ''Filing Online'' link in the banner at the top of the Commission's Web site (*http://www.prc.gov*) or by directly accessing the Commission's Filing Online system at *https://www.prc.gov/prc-pages/filing-online/login.aspx.* Commenters who cannot submit their views electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section as the source for case-related information for advice on alternatives to electronic filing.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at (202) 789–6820 (case-related information) or *DocketAdmins@prc.gov* (electronic filing assistance).

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to 39 U.S.C. 404(d), the Commission received two petitions for review of the Postal Service's determination to close the Mountain City post office in Mountain City, Nevada. The first petition for review received November 15, 2011, was filed by Becky Goff. The second petition for review received November 15, 2011, was filed by the Customers of Mountain City. The earliest postmark date is November 4, 2011. The Commission hereby institutes a proceeding under 39 U.S.C. 404(d)(5) and establishes Docket No. A2012–70 to consider Petitioners' appeal. If Petitioners would like to further explain their position with supplemental information or facts, Petitioners may either file a Participant Statement on PRC Form 61 or file a brief with the Commission no later than December 20, 2011.

Categories of issues apparently raised. Petitioners contend that (1) the Postal Service failed to consider the effect of the closing on the community (*see* 39 U.S.C. 404(d)(2)(A)(i)); (2) the Postal Service failed to consider whether or not it will continue to provide a maximum degree of effective and regular postal services to the community (*see* 39 U.S.C. 404(d)(2)(A)(iii)); (3) the Postal Service failed to adequately consider the economic savings resulting from the closure (*see* 39 U.S.C. 404(d)(2)(A)(iv)); (4) there are factual errors contained in the Final Determination; and (5) the Postal Service failed to provide substantial evidence in support of the determination (*see* 39 U.S.C. 404(d)(5)(c)).

After the Postal Service files the administrative record and the Commission reviews it, the Commission may find that there are more legal issues than those set forth above, or that the Postal Service's determination disposes of one or more of those issues. The deadline for the Postal Service to file the applicable administrative record is within 15 days after the date in which the petition for review was filed with the Commission. *See* 39 CFR 3001.113. In addition, the due date for any responsive pleading by the Postal Service is also within 15 days after the date in which the petition for review was filed with the Commission.

Availability; Web site posting. The Commission has posted the appeal and supporting material on its Web site at *http://www.prc.gov.* Additional filings in this case and participant's submissions also will be posted on the Web site, if provided in electronic format or amenable to conversion, and not subject to a valid protective order. Information on how to use the Commission's Web site is available online or by contacting the Commission's webmaster via telephone at (202) 789–6873 or via electronic mail at *prc-webmaster@prc.gov.*

The appeal and all related documents are also available for public inspection in the Commission's docket section. Docket section hours are 8 a.m. to 4:30 p.m., Eastern Time, Monday through Friday, except on Federal government holidays. Docket section personnel may be contacted via electronic mail at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Filing of documents. All filings of documents in this case shall be made using the Internet (Filing Online) pursuant to Commission rules 9(a) and 10(a) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained. *See* 39 CFR 3001.9(a) and 3001.10(a). Instructions for obtaining an account to file documents online may be found on the Commission's Web site, *http://www.prc.gov,* or by contacting the Commission's docket section at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Commission reserves the right to redact personal information which may infringe on an individual's privacy rights from documents filed in this proceeding.

Intervention. Persons, other than the Petitioners and respondents, wishing to be heard in this matter are directed to file a notice of intervention. *See* 39 CFR 3001.111(b). Notices of intervention in this case are to be filed on or before December 27, 2011. A notice of intervention shall be filed using the Internet (Filing Online) at the Commission's Web site, *http://*

www.prc.gov, unless a waiver is obtained for hardcopy filing. *See* 39 CFR 3001.9(a) and 3001.10(a).

Further procedures. By statute, the Commission is required to issue its decision within 120 days from the date it receives the appeal. *See* 39 U.S.C. 404(d)(5). A procedural schedule has been developed to accommodate this statutory deadline. In the interest of expedition, in light of the 120-day decision schedule, the Commission may request the Postal Service or other participants to submit information or memoranda of law on any appropriate issue. As required by Commission rules, if any motions are filed, responses are due 7 days after any such motion is filed. *See* 39 CFR 3001.21.

It is ordered:

1. The procedural schedule listed below is hereby adopted.

2. Pursuant to 39 U.S.C. 505, Cassandra L. Hicks is designated officer of the Commission (Public Representative) to represent the interests of the general public.

3. The Secretary shall arrange for publication of this notice and order and Procedural Schedule in the **Federal Register**.

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

PROCEDURAL SCHEDULE

November 15, 2011	Filing of Appeal.
November 30, 2011	Deadline for the Postal Service to file the applicable administrative record in this appeal.
November 30, 2011	Deadline for the Postal Service to file any responsive pleading.
December 27, 2011	Deadline for notices to intervene (*see* 39 CFR 3001.111(b)).
December 20, 2011	Deadline for Petitioners' Form 61 or initial brief in support of petition (*see* 39 CFR 3001.115(a) and (b)).
January 9, 2012	Deadline for answering brief in support of the Postal Service (*see* 39 CFR 3001.115(c)).
January 24, 2012	Deadline for reply briefs in response to answering briefs (*see* 39 CFR 3001.115(d)).
January 31, 2012	Deadline for motions by any party requesting oral argument; the Commission will schedule oral argument only when it is a necessary addition to the written filings (*see* 39 CFR 3001.116).
March 5, 2012	Expiration of the Commission's 120-day decisional schedule (*see* 39 U.S.C. 404(d)(5)).

[FR Doc. 2011–31376 Filed 12–6–11; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. A2012–72; Order No. 1016]

Post Office Closing

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: This document informs the public that an appeal of the closing of the Home, Kansas post office has been filed. It identifies preliminary steps and provides a procedural schedule. Publication of this document will allow the Postal Service, petitioners, and others to take appropriate action.

DATES: December 1, 2011: Administrative record due (from Postal Service); December 27, 2011, 4:30 p.m., Eastern Time: Deadline for notices to intervene. *See* the Procedural Schedule in the **SUPPLEMENTARY INFORMATION** section for other dates of interest.

ADDRESSES: Submit comments electronically by accessing the ''Filing Online'' link in the banner at the top of the Commission's Web site (*http://www.prc.gov*) or by directly accessing the Commission's Filing Online system at *https://www.prc.gov/prc-pages/filing-online/login.aspx.* Commenters who cannot submit their views electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section as the source for case-related information for advice on alternatives to electronic filing.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at (202) 789–6820 (case-related information) or *DocketAdmins@prc.gov* (electronic filing assistance).

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to 39 U.S.C. 404(d), the Commission received two petitions for review of the Postal Service's determination to close the Home post office in Home, Kansas. The first petition for review received November 16, 2011, was filed by Pat and Jim Schramm. The second petition for review received November 29, 2011, was filed by Kenneth and Carol Koch. The earliest postmark date is November 9, 2011. The Commission hereby institutes a proceeding under 39 U.S.C. 404(d)(5) and establishes Docket No. A2012–72 to consider Petitioners' appeal. If Petitioners would like to further explain their position with supplemental information or facts, Petitioners may either file a Participant Statement on PRC Form 61 or file a brief with the Commission no later than December 21, 2011.

Categories of issues apparently raised. Petitioners contend that (1) The Postal Service failed to consider the effect of the closing on the community (*see* 39 U.S.C. 404(d)(2)(A)(i)); (2) the Postal Service failed to adequately consider the economic savings resulting from the closure (*see* 39 U.S.C. 404(d)(2)(A)(iv)); (3) the Postal Service failed to follow procedures required by law regarding closures (*see* 39 U.S.C. 404(d)(5)(B)); and (4) there are factual errors contained in the Final Determination.

After the Postal Service files the administrative record and the Commission reviews it, the Commission may find that there are more legal issues than those set forth above, or that the Postal Service's determination disposes of one or more of those issues. The deadline for the Postal Service to file the applicable administrative record is within 15 days after the date in which the petition for review was filed with the Commission. *See* 39 CFR 3001.113. In addition, the due date for any responsive pleading by the Postal Service is also within 15 days after the date in which the petition for review was filed with the Commission.

Availability; Web site posting. The Commission has posted the appeal and supporting material on its Web site at *http://www.prc.gov.* Additional filings in this case and participant's submissions also will be posted on the Web site, if provided in electronic format or amenable to conversion, and not subject to a valid protective order. Information on how to use the Commission's Web site is available online or by contacting the Commission's webmaster via telephone at (202) 789–6873 or via electronic mail at *prc-webmaster@prc.gov.*

The appeal and all related documents are also available for public inspection in the Commission's docket section. Docket section hours are 8 a.m. to 4:30 p.m., Eastern Time, Monday through Friday, except on Federal government holidays. Docket section personnel may be contacted via

electronic mail at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Filing of documents. All filings of documents in this case shall be made using the Internet (Filing Online) pursuant to Commission rules 9(a) and 10(a) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained. *See* 39 CFR 3001.9(a) and 3001.10(a). Instructions for obtaining an account to file documents online may be found on the Commission's Web site, *http://www.prc.gov,* or by contacting the Commission's docket section at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Commission reserves the right to redact personal information which may infringe on an individual's privacy rights from documents filed in this proceeding.

Intervention. Persons, other than the Petitioners and respondents, wishing to be heard in this matter are directed to file a notice of intervention. *See* 39 CFR 3001.111(b). Notices of intervention in this case are to be filed on or before December 27, 2011. A notice of intervention shall be filed using the Internet (Filing Online) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained for hardcopy filing. *See* 39 CFR 3001.9(a) and 3001.10(a).

Further procedures. By statute, the Commission is required to issue its decision within 120 days from the date it receives the appeal. *See* 39 U.S.C. 404(d)(5). A procedural schedule has been developed to accommodate this statutory deadline. In the interest of expedition, in light of the 120-day decision schedule, the Commission may request the Postal Service or other participants to submit information or memoranda of law on any appropriate issue. As required by Commission rules, if any motions are filed, responses are due 7 days after any such motion is filed. *See* 39 CFR 3001.21.

It is ordered:

1. The procedural schedule listed below is hereby adopted.

2. Pursuant to 39 U.S.C. 505, Malin Moench is designated officer of the Commission (Public Representative) to represent the interests of the general public.

3. The Secretary shall arrange for publication of this notice and order and Procedural Schedule in the **Federal Register.**

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

PROCEDURAL SCHEDULE

November 16, 2011	Filing of Appeal.
December 1, 2011	Deadline for the Postal Service to file the applicable administrative record in this appeal.
December 1, 2011	Deadline for the Postal Service to file any responsive pleading.
December 27, 2011	Deadline for notices to intervene (*see* 39 CFR 3001.111(b)).
December 21, 2011	Deadline for Petitioners' Form 61 or initial brief in support of petition (*see* 39 CFR 3001.115(a) and (b)).
January 10, 2012	Deadline for answering brief in support of the Postal Service (*see* 39 CFR 3001.115(c)).
January 25, 2012	Deadline for reply briefs in response to answering briefs (*see* 39 CFR 3001.115(d)).
February 1, 2012	Deadline for motions by any party requesting oral argument; the Commission will schedule oral argument only when it is a necessary addition to the written filings (*see* 39 CFR 3001.116).
March 8, 2012	Expiration of the Commission's 120-day decisional schedule (*see* 39 U.S.C. 404(d)(5)).

[FR Doc. 2011–31378 Filed 12–6–11; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. A2012–73; Order No. 1017]

Post Office Closing

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: This document informs the public that an appeal of the closing of the Miller, Nebraska post office has been filed. It identifies preliminary steps and provides a procedural schedule. Publication of this document will allow the Postal Service, petitioners, and others to take appropriate action.

DATES: December 1, 2011: Administrative record due (from Postal Service); December 27, 2011, 4:30 p.m., Eastern Time: Deadline for notices to intervene. *See* the Procedural Schedule in the **SUPPLEMENTARY INFORMATION** section for other dates of interest.

ADDRESSES: Submit comments electronically by accessing the ''Filing Online'' link in the banner at the top of the Commission's Web site (*http://www.prc.gov*) or by directly accessing the Commission's Filing Online system at *https://www.prc.gov/prc-pages/filing-online/login.aspx.* Commenters who cannot submit their views electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section as the source for case-related information for advice on alternatives to electronic filing.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at (202) 789–6820 (case-related information) or *DocketAdmins@prc.gov* (electronic filing assistance).

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to 39 U.S.C. 404(d), on November 16, 2011, the Commission received a petition for review of the Postal Service's determination to close the Miller post office in Miller, Nebraska. The petition for review was filed by Teresa Saathoff, (Petitioner) and is postmarked November 8, 2011. The Commission hereby institutes a proceeding under 39 U.S.C. 404(d)(5) and establishes Docket No. A2012–73 to consider Petitioner's appeal. If Petitioner would like to further explain her position with supplemental information or facts, Petitioner may either file a Participant Statement on PRC Form 61 or file a brief with the Commission no later than December 21, 2011.

Categories of issues apparently raised. Petitioner contends that (1) The Postal Service failed to consider whether or not it will continue to provide a maximum degree of effective and regular postal services to the community (*see* 39 U.S.C. 404(d)(2)(A)(iii)).

After the Postal Service files the administrative record and the Commission reviews it, the Commission may find that there are more legal issues than those set forth above, or that the Postal Service's determination disposes of one or more of those issues. The deadline for the Postal Service to file the applicable administrative record is within 15 days after the date in which the petition for review was filed with the Commission. *See* 39 CFR 3001.113. In addition, the due date for any responsive pleading by the Postal Service is also within 15 days after the date in which the petition for review was filed with the Commission.

Availability; Web site posting. The Commission has posted the appeal and

supporting material on its Web site at *http://www.prc.gov.* Additional filings in this case and participant's submissions also will be posted on the Web site, if provided in electronic format or amenable to conversion, and not subject to a valid protective order. Information on how to use the Commission's Web site is available online or by contacting the Commission's webmaster via telephone at (202) 789–6873 or via electronic mail at *prc-webmaster@prc.gov.*

The appeal and all related documents are also available for public inspection in the Commission's docket section. Docket section hours are 8 a.m. to 4:30 p.m., Eastern Time, Monday through Friday, except on Federal government holidays. Docket section personnel may be contacted via electronic mail at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Filing of documents. All filings of documents in this case shall be made using the Internet (Filing Online) pursuant to Commission rules 9(a) and 10(a) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained. *See* 39 CFR 3001.9(a) and 3001.10(a). Instructions for obtaining an account to file documents online may be found on the Commission's Web site, *http://www.prc.gov,* or by contacting the Commission's docket section at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Commission reserves the right to redact personal information which may infringe on an individual's privacy rights from documents filed in this proceeding.

Intervention. Persons, other than the Petitioners and respondents, wishing to be heard in this matter are directed to file a notice of intervention. *See* 39 CFR 3001.111(b). Notices of intervention in this case are to be filed on or before December 27, 2011. A notice of intervention shall be filed using the Internet (Filing Online) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained for hardcopy filing. *See* 39 CFR 3001.9(a) and 3001.10(a).

Further procedures. By statute, the Commission is required to issue its decision within 120 days from the date it receives the appeal. *See* 39 U.S.C. 404(d)(5). A procedural schedule has been developed to accommodate this statutory deadline. In the interest of expedition, in light of the 120-day decision schedule, the Commission may request the Postal Service or other participants to submit information or memoranda of law on any appropriate issue. As required by Commission rules, if any motions are filed, responses are due 7 days after any such motion is filed. *See* 39 CFR 3001.21.

It is ordered:

1. The procedural schedule listed below is hereby adopted.

2. Pursuant to 39 U.S.C. 505, Emmett Rand Costich is designated officer of the Commission (Public Representative) to represent the interests of the general public.

3. The Secretary shall arrange for publication of this notice and order and Procedural Schedule in the **Federal Register**.

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

PROCEDURAL SCHEDULE

November 16, 2011	Filing of Appeal.
December 1, 2011	Deadline for the Postal Service to file the applicable administrative record in this appeal.
December 1, 2011	Deadline for the Postal Service to file any responsive pleading.
December 27, 2011	Deadline for notices to intervene (*see* 39 CFR 3001.111(b)).
December 21, 2011	Deadline for Petitioners' Form 61 or initial brief in support of petition (*see* 39 CFR 3001.115(a) and (b)).
January 10, 2012	Deadline for answering brief in support of the Postal Service (*see* 39 CFR 3001.115(c)).
January 25, 2012	Deadline for reply briefs in response to answering briefs (*see* 39 CFR 3001.115(d)).
February 1, 2012	Deadline for motions by any party requesting oral argument; the Commission will schedule oral argument only when it is a necessary addition to the written filings (*see* 39 CFR 3001.116).
March 7, 2012	Expiration of the Commission's 120-day decisional schedule (*see* 39 U.S.C. 404(d)(5)).

[FR Doc. 2011–31379 Filed 12–6–11; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. A2012–71; Order No. 1015]

Post Office Closing

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: This document informs the public that an appeal of the closing of the Viola, Idaho post office has been filed. It identifies preliminary steps and provides a procedural schedule. Publication of this document will allow the Postal Service, petitioners, and others to take appropriate action.

DATES: November 30, 2011: Administrative record due (from Postal Service); December 27, 2011, 4:30 p.m., Eastern Time: Deadline for notices to intervene. *See* the Procedural Schedule in the **SUPPLEMENTARY INFORMATION** section for other dates of interest.

ADDRESSES: Submit comments electronically by accessing the ''Filing Online'' link in the banner at the top of the Commission's Web site (*http://www.prc.gov*) or by directly accessing the Commission's Filing Online system at *https://www.prc.gov/prc-pages/filing-online/login.aspx.* Commenters who cannot submit their views electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section as the source for case-related information for advice on alternatives to electronic filing.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at (202) 789–6820 (case-related information) or *DocketAdmins@prc.gov* (electronic filing assistance).

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to 39 U.S.C. 404(d), the Commission received two petitions for review of the Postal Service's determination to close the Viola post office in Viola, Idaho. The first petition for review received November 15, 2011, was filed by Dan Hardesty. The second petition for review received November 15, 2011, was filed by the Patrons of Viola. The earliest postmark date is November 7, 2011. The Commission hereby institutes a proceeding under 39 U.S.C. 404(d)(5) and establishes Docket No. A2012–71 to consider Petitioners' appeal. If Petitioners would like to further explain their position with supplemental information or facts, Petitioners may either file a Participant Statement on PRC Form 61 or file a brief with the Commission no later than December 20, 2011.

Categories of issues apparently raised. Petitioners contend that (1) the Postal Service failed to consider the effect of

the closing on the community (*see* 39 U.S.C. 404(d)(2)(A)(i)); (2) the Postal Service failed to consider whether or not it will continue to provide a maximum degree of effective and regular postal services to the community (*see* 39 U.S.C. 404(d)(2)(A)(iii)); (3) the Postal Service failed to adequately consider the economic savings resulting from the closure (*see* 39 U.S.C. 404(d)(2)(A)(iv)); and (4) the Postal Service failed to follow procedures required by law regarding closures (*see* 39 U.S.C. 404(d)(5)(B)).

After the Postal Service files the administrative record and the Commission reviews it, the Commission may find that there are more legal issues than those set forth above, or that the Postal Service's determination disposes of one or more of those issues. The deadline for the Postal Service to file the applicable administrative record is within 15 days after the date in which the petition for review was filed with the Commission. *See* 39 CFR 3001.113. In addition, the due date for any responsive pleading by the Postal Service is also within 15 days after the date in which the petition for review was filed with the Commission.

Availability; Web site posting. The Commission has posted the appeal and supporting material on its Web site at *http://www.prc.gov.* Additional filings in this case and participant's submissions also will be posted on the Web site, if provided in electronic format or amenable to conversion, and not subject to a valid protective order. Information on how to use the Commission's Web site is available online or by contacting the Commission's webmaster via telephone at (202) 789–6873 or via electronic mail at *prc-webmaster@prc.gov.*

The appeal and all related documents are also available for public inspection in the Commission's docket section. Docket section hours are 8 a.m. to 4:30 p.m., Eastern Time, Monday through Friday, except on Federal government holidays. Docket section personnel may be contacted via electronic mail at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Filing of documents. All filings of documents in this case shall be made using the Internet (Filing Online) pursuant to Commission rules 9(a) and 10(a) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained. *See* 39 CFR 3001.9(a) and 3001.10(a). Instructions for obtaining an account to file documents online may be found on the Commission's Web site, *http://www.prc.gov,* or by contacting the Commission's docket section at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Commission reserves the right to redact personal information which may infringe on an individual's privacy rights from documents filed in this proceeding.

Intervention. Persons, other than the Petitioners and respondents, wishing to be heard in this matter are directed to file a notice of intervention. *See* 39 CFR 3001.111(b). Notices of intervention in this case are to be filed on or before December 27, 2011. A notice of intervention shall be filed using the Internet (Filing Online) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained for hardcopy filing. *See* 39 CFR 3001.9(a) and 3001.10(a).

Further procedures. By statute, the Commission is required to issue its decision within 120 days from the date it receives the appeal. *See* 39 U.S.C. 404(d)(5). A procedural schedule has been developed to accommodate this statutory deadline. In the interest of expedition, in light of the 120-day decision schedule, the Commission may request the Postal Service or other participants to submit information or memoranda of law on any appropriate issue. As required by Commission rules, if any motions are filed, responses are due 7 days after any such motion is filed. *See* 39 CFR 3001.21.

It is ordered:

1. The procedural schedule listed below is hereby adopted.

2. Pursuant to 39 U.S.C. 505, Patricia A. Gallagher is designated officer of the Commission (Public Representative) to represent the interests of the general public.

3. The Secretary shall arrange for publication of this notice and order and Procedural Schedule in the **Federal Register**.

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

PROCEDURAL SCHEDULE

November 15, 2011	Filing of Appeal.
November 30, 2011	Deadline for the Postal Service to file the applicable administrative record in this appeal.
November 30, 2011	Deadline for the Postal Service to file any responsive pleading.
December 27, 2011	Deadline for notices to intervene (*see* 39 CFR 3001.111(b)).
December 20, 2011	Deadline for Petitioners' Form 61 or initial brief in support of petition (*see* 39 CFR 3001.115(a) and (b)).
January 9, 2012	Deadline for answering brief in support of the Postal Service (*see* 39 CFR 3001.115(c)).
January 24, 2012	Deadline for reply briefs in response to answering briefs (*see* 39 CFR 3001.115(d)).
January 31, 2012	Deadline for motions by any party requesting oral argument; the Commission will schedule oral argument only when it is a necessary addition to the written filings (*see* 39 CFR 3001.116).
March 6, 2012	Expiration of the Commission's 120-day decisional schedule (*see* 39 U.S.C. 404(d)(5)).

[FR Doc. 2011–31377 Filed 12–6–11; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. A2012–68; Order No. 1010]

Post Office Closing

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: This document informs the public that an appeal of the closing of the Spring Dale, West Virginia post office has been filed. It identifies preliminary steps and provides a procedural schedule. Publication of this document will allow the Postal Service, petitioners, and others to take appropriate action.

DATES: November 29, 2011: Administrative record due (from Postal Service); December 27, 2011, 4:30 p.m., Eastern Time: Deadline for notices to intervene. *See* the Procedural Schedule in the **SUPPLEMENTARY INFORMATION** section for other dates of interest.

ADDRESSES: Submit comments electronically by accessing the ''Filing Online'' link in the banner at the top of the Commission's Web site (*http://www.prc.gov*) or by directly accessing the Commission's Filing Online system at *https://www.prc.gov/prc-pages/filing-online/login.aspx.* Commenters who cannot submit their views electronically should contact the person identified in

the **FOR FURTHER INFORMATION CONTACT** section as the source for case-related information for advice on alternatives to electronic filing.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at (202) 789–6820 (case-related information) or *DocketAdmins@prc.gov* (electronic filing assistance).

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to 39 U.S.C. 404(d), the Commission received four petitions for review of the Postal Service's determination to close the Spring Dale post office in Spring Dale, West Virginia. The first petition for review, received November 14, 2011, was filed by Paul E. McClung. The second petition for review, received November 16, 2011, was filed by Angie Brown. The third petition for review, received November 18, 2011, was filed by Gary Walker. The fourth petition for review, received November 22, 2011, was filed by Betty Puckett. The fifth petition for review, received November 29, 2011, was filed by Melissa Porter. The earliest postmark date is November 1, 2011. The Commission hereby institutes a proceeding under 39 U.S.C. 404(d)(5) and establishes Docket No. A2012–68 to consider Petitioners' appeal. If Petitioners would like to further explain their position with supplemental information or facts, Petitioners may either file a Participant Statement on PRC Form 61 or file a brief with the Commission no later than December 19, 2011.

Categories of issues apparently raised. Petitioners contend that (1) The Postal Service failed to consider the effect of the closing on the community (*see* 39 U.S.C. 404(d)(2)(A)(i)); (2) the Postal Service failed to consider whether or not it will continue to provide a maximum degree of effective and regular postal services to the community (*see* 39 U.S.C. 404(d)(2)(A)(iii)); (3) the Postal Service failed to adequately consider the economic savings resulting from the closure (*see* 39 U.S.C. 404(d)(2)(A)(iv)); (4) the Postal Service failed to follow procedures required by law regarding closures (*see* 39 U.S.C. 404(d)(5)(B)); (5) there are factual errors contained in the Final Determination; and (6) the Postal Service failed to provide substantial evidence in support of the determination (*see* 39 U.S.C. 404(d)(5)(c).

After the Postal Service files the administrative record and the Commission reviews it, the Commission may find that there are more legal issues than those set forth above, or that the Postal Service's determination disposes of one or more of those issues. The deadline for the Postal Service to file the applicable administrative record is within 15 days after the date in which the petition for review was filed with the Commission. *See* 39 CFR 3001.113. In addition, the due date for any responsive pleading by the Postal Service is also within 15 days after the date in which the petition for review was filed with the Commission.

Availability; Web site posting. The Commission has posted the appeal and supporting material on its Web site at *http://www.prc.gov.* Additional filings in this case and participant's submissions also will be posted on the Web site, if provided in electronic format or amenable to conversion, and not subject to a valid protective order. Information on how to use the Commission's Web site is available online or by contacting the Commission's webmaster via telephone at (202) 789–6873 or via electronic mail at *prc-webmaster@prc.gov.*

The appeal and all related documents are also available for public inspection in the Commission's docket section. Docket section hours are 8 a.m. to 4:30 p.m., Eastern Time, Monday through Friday, except on Federal government holidays. Docket section personnel may be contacted via electronic mail at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Filing of documents. All filings of documents in this case shall be made using the Internet (Filing Online) pursuant to Commission rules 9(a) and 10(a) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained. *See* 39 CFR 3001.9(a) and 3001.10(a). Instructions for obtaining an account to file documents online may be found on the Commission's Web site, *http://www.prc.gov,* or by contacting the Commission's docket section at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Commission reserves the right to redact personal information which may infringe on an individual's privacy rights from documents filed in this proceeding.

Intervention. Persons, other than the Petitioners and respondents, wishing to be heard in this matter are directed to file a notice of intervention. *See* 39 CFR 3001.111(b). Notices of intervention in this case are to be filed on or before December 27, 2011. A notice of intervention shall be filed using the Internet (Filing Online) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained for hardcopy filing. *See* 39 CFR 3001.9(a) and 3001.10(a).

Further procedures. By statute, the Commission is required to issue its decision within 120 days from the date it receives the appeal. *See* 39 U.S.C. 404(d)(5). A procedural schedule has been developed to accommodate this statutory deadline. In the interest of expedition, in light of the 120-day decision schedule, the Commission may request the Postal Service or other participants to submit information or memoranda of law on any appropriate issue. As required by Commission rules, if any motions are filed, responses are due 7 days after any such motion is filed. *See* 39 CFR 3001.21.

It is ordered:

1. The procedural schedule listed below is hereby adopted.

2. Pursuant to 39 U.S.C. 505, Manon Boudreault is designated officer of the Commission (Public Representative) to represent the interests of the general public.

3. The Secretary shall arrange for publication of this notice and order and Procedural Schedule in the **Federal Register.**

By the Commission.

Shoshana M. Grove,

Secretary.

PROCEDURAL SCHEDULE

November 14, 2011	Filing of Appeal.
November 29, 2011	Deadline for the Postal Service to file the applicable administrative record in this appeal.
November 29, 2011	Deadline for the Postal Service to file any responsive pleading.
December 27, 2011	Deadline for notices to intervene (*see* 39 CFR 3001.111(b)).
December 19, 2011	Deadline for Petitioners' Form 61 or initial brief in support of petition (*see* 39 CFR 3001.115(a) and (b)).
January 9, 2012	Deadline for answering brief in support of the Postal Service (*see* 39 CFR 3001.115(c)).
January 24, 2012	Deadline for reply briefs in response to answering briefs (*see* 39 CFR 3001.115(d)).
January 31, 2012	Deadline for motions by any party requesting oral argument; the Commission will schedule oral argument only when it is a necessary addition to the written filings (*see* 39 CFR 3001.116).

PROCEDURAL SCHEDULE—Continued

February 29, 2012	Expiration of the Commission's 120-day decisional schedule (*see* 39 U.S.C. 404(d)(5)).

[FR Doc. 2011–31361 Filed 12–6–11; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. A2012–67; Order No. 1009]

Post Office Closing

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: This document informs the public that an appeal of the closing of the Nixon, Nevada post office has been filed. It identifies preliminary steps and provides a procedural schedule. Publication of this document will allow the Postal Service, petitioners, and others to take appropriate action.

DATES: November 29, 2011: Administrative record due (from Postal Service); December 27, 2011, 4:30 p.m., Eastern Time: Deadline for notices to intervene. *See* the Procedural Schedule in the **SUPPLEMENTARY INFORMATION** section for other dates of interest.

ADDRESSES: Submit comments electronically by accessing the ''Filing Online'' link in the banner at the top of the Commission's Web site (*http://www.prc.gov*) or by directly accessing the Commission's Filing Online system at *https://www.prc.gov/prc-pages/filing-online/login.aspx.* Commenters who cannot submit their views electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section as the source for case-related information for advice on alternatives to electronic filing.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at (202) 789–6820 (case-related information) or *DocketAdmins@prc.gov* (electronic filing assistance).

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to 39 U.S.C. 404(d), on November 14, 2011, the Commission received a petition for review of the Postal Service's determination to close the Nixon post office in Nixon, Nevada. The petition for review was filed by Wayne Burke, on behalf of the Pyramid Lake Paiute Tribe, (Petitioner) and is postmarked October 31, 2011. The Commission hereby institutes a proceeding under 39 U.S.C. 404(d)(5) and establishes Docket No. A2012–67 to consider Petitioner's appeal. If Petitioner would like to provide further information or facts, Petitioner may either file a Participant Statement on PRC Form 61 or file a brief with the Commission no later than December 19, 2011.

Categories of issues apparently raised. Petitioner contends that (1) The Postal Service failed to consider the effect of the closing on the community (*see* 39 U.S.C. 404(d)(2)(A)(i)); and (2) the Postal Service failed to consider whether or not it will continue to provide a maximum degree of effective and regular postal services to the community (*see* 39 U.S.C. 404(d)(2)(A)(iii)).

After the Postal Service files the administrative record and the Commission reviews it, the Commission may find that there are more legal issues than those set forth above, or that the Postal Service's determination disposes of one or more of those issues. The deadline for the Postal Service to file the applicable administrative record is within 15 days after the date in which the petition for review was filed with the Commission. *See* 39 CFR 3001.113. In addition, the due date for any responsive pleading by the Postal Service is also within 15 days after the date in which the petition for review was filed with the Commission.

Availability; Web site posting. The Commission has posted the appeal and supporting material on its Web site at *http://www.prc.gov.* Additional filings in this case and participant's submissions also will be posted on the Web site, if provided in electronic format or amenable to conversion, and not subject to a valid protective order. Information on how to use the Commission's Web site is available online or by contacting the Commission's webmaster via telephone at (202) 789–6873 or via electronic mail at *prc-webmaster@prc.gov.*

The appeal and all related documents are also available for public inspection in the Commission's docket section. Docket section hours are 8 a.m. to 4:30 p.m., Eastern Time, Monday through Friday, except on Federal government holidays. Docket section personnel may be contacted via electronic mail at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Filing of documents. All filings of documents in this case shall be made using the Internet (Filing Online) pursuant to Commission rules 9(a) and 10(a) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained. *See* 39 CFR 3001.9(a) and 3001.10(a). Instructions for obtaining an account to file documents online may be found on the Commission's Web site, *http://www.prc.gov,* or by contacting the Commission's docket section at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Commission reserves the right to redact personal information which may infringe on an individual's privacy rights from documents filed in this proceeding.

Intervention. Persons, other than the Petitioners and respondents, wishing to be heard in this matter are directed to file a notice of intervention. *See* 39 CFR 3001.111(b). Notices of intervention in this case are to be filed on or before December 27, 2011. A notice of intervention shall be filed using the Internet (Filing Online) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained for hardcopy filing. *See* 39 CFR 3001.9(a) and 3001.10(a).

Further procedures. By statute, the Commission is required to issue its decision within 120 days from the date it receives the appeal. *See* 39 U.S.C. 404(d)(5). A procedural schedule has been developed to accommodate this statutory deadline. In the interest of expedition, in light of the 120-day decision schedule, the Commission may request the Postal Service or other participants to submit information or memoranda of law on any appropriate issue. As required by Commission rules, if any motions are filed, responses are due 7 days after any such motion is filed. *See* 39 CFR 3001.21.

It is ordered:

1. The procedural schedule listed below is hereby adopted.

2. Pursuant to 39 U.S.C. 505, Tracy Ferguson is designated officer of the Commission (Public Representative) to represent the interests of the general public.

3. The Secretary shall arrange for publication of this notice and order and Procedural Schedule in the **Federal Register.**

By the Commission.

Shoshana M. Grove,

Secretary.

PROCEDURAL SCHEDULE

November 14, 2011	Filing of Appeal.
November 29, 2011	Deadline for the Postal Service to file the applicable administrative record in this appeal.
November 29, 2011	Deadline for the Postal Service to file any responsive pleading.
December 27, 2011	Deadline for notices to intervene (*see* 39 CFR 3001.111(b)).
December 19, 2011	Deadline for Petitioners' Form 61 or initial brief in support of petition (*see* 39 CFR 3001.115(a) and (b)).
January 9, 2012	Deadline for answering brief in support of the Postal Service (*see* 39 CFR 3001.115(c)).
January 24, 2012	Deadline for reply briefs in response to answering briefs (*see* 39 CFR 3001.115(d)).
January 31, 2012	Deadline for motions by any party requesting oral argument; the Commission will schedule oral argument only when it is a necessary addition to the written filings (*see* 39 CFR 3001.116).
February 28, 2012	Expiration of the Commission's 120-day decisional schedule (*see* 39 U.S.C. 404(d)(5)).

[FR Doc. 2011–31360 Filed 12–6–11; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. A2012–69; Order No. 1013]

Post Office Closing

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: This document informs the public that an appeal of the closing of the Porterville, Mississippi post office has been filed. It identifies preliminary steps and provides a procedural schedule. Publication of this document will allow the Postal Service, petitioners, and others to take appropriate action.

DATES: November 30, 2011: Administrative record due (from Postal Service); December 27, 2011, 4:30 p.m., Eastern Time: Deadline for notices to intervene. *See* the Procedural Schedule in the **SUPPLEMENTARY INFORMATION** section for other dates of interest.

ADDRESSES: Submit comments electronically by accessing the ''Filing Online'' link in the banner at the top of the Commission's Web site (*http://www.prc.gov*) or by directly accessing the Commission's Filing Online system at *https://www.prc.gov/prc-pages/filing-online/login.aspx.* Commenters who cannot submit their views electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section as the source for case-related information for advice on alternatives to electronic filing.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at (202) 789–6820 (case-related information) or *DocketAdmins@prc.gov* (electronic filing assistance).

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to 39 U.S.C. 404(d), on November 15, 2011, the Commission received a petition for review of the Postal Service's determination to close the Porterville post office in Porterville, Mississippi. The petition for review was filed by Johnie B. Stuart, (Petitioner) and is postmarked October 31, 2011. The Commission hereby institutes a proceeding under 39 U.S.C. 404(d)(5) and establishes Docket No. A2012–69 to consider Petitioner's appeal. If Petitioner would like to further explain his position with supplemental information or facts, Petitioner may either file a Participant Statement on PRC Form 61 or file a brief with the Commission no later than December 20, 2011.

Categories of issues apparently raised. Petitioner contends that (1) The Postal Service failed to consider the effect of the closing on the community (*see* 39 U.S.C. 404(d)(2)(A)(i)); (2) the Postal Service failed to consider whether or not it will continue to provide a maximum degree of effective and regular postal services to the community (*see* 39 U.S.C. 404(d)(2)(A)(iii)); (3) the Postal Service failed to adequately consider the economic savings resulting from the closure (*see* 39 U.S.C. 404(d)(2)(A)(iv)); and (4) there are factual errors contained in the Final Determination.

After the Postal Service files the administrative record and the Commission reviews it, the Commission may find that there are more legal issues than those set forth above, or that the Postal Service's determination disposes of one or more of those issues. The deadline for the Postal Service to file the applicable administrative record is within 15 days after the date in which the petition for review was filed with the Commission. *See* 39 CFR 3001.113. In addition, the due date for any responsive pleading by the Postal Service is also within 15 days after the date in which the petition for review was filed with the Commission.

Availability; Web site posting. The Commission has posted the appeal and supporting material on its Web site at *http://www.prc.gov.* Additional filings in this case and participant's submissions also will be posted on the Web site, if provided in electronic format or amenable to conversion, and not subject to a valid protective order. Information on how to use the Commission's Web site is available online or by contacting the Commission's webmaster via telephone at (202) 789–6873 or via electronic mail at *prc-webmaster@prc.gov.*

The appeal and all related documents are also available for public inspection in the Commission's docket section. Docket section hours are 8 a.m. to 4:30 p.m., Eastern Time, Monday through Friday, except on Federal government holidays. Docket section personnel may be contacted via electronic mail at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Filing of documents. All filings of documents in this case shall be made using the Internet (Filing Online) pursuant to Commission rules 9(a) and 10(a) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained. *See* 39 CFR 3001.9(a) and 3001.10(a). Instructions for obtaining an account to file documents online may be found on the Commission's Web site, *http://www.prc.gov,* or by contacting the Commission's docket section at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Commission reserves the right to redact personal information which may infringe on an individual's privacy rights from documents filed in this proceeding.

Intervention. Persons, other than the Petitioners and respondents, wishing to be heard in this matter are directed to file a notice of intervention. *See* 39 CFR 3001.111(b). Notices of intervention in this case are to be filed on or before December 27, 2011. A notice of intervention shall be filed using the Internet (Filing Online) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained for hardcopy filing. *See* 39 CFR 3001.9(a) and 3001.10(a).

Further procedures. By statute, the Commission is required to issue its decision within 120 days from the date it receives the appeal. *See* 39 U.S.C.

404(d)(5). A procedural schedule has been developed to accommodate this statutory deadline. In the interest of expedition, in light of the 120-day decision schedule, the Commission may request the Postal Service or other participants to submit information or memoranda of law on any appropriate issue. As required by Commission rules, if any motions are filed, responses are due 7 days after any such motion is filed. *See* 39 CFR 3001.21.

It is ordered:

1. The procedural schedule listed below is hereby adopted.

2. Pursuant to 39 U.S.C. 505, Robert N. Sidman is designated officer of the Commission (Public Representative) to represent the interests of the general public.

3. The Secretary shall arrange for publication of this notice and order and Procedural Schedule in the **Federal Register.**

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

PROCEDURAL SCHEDULE

November 15, 2011	Filing of Appeal.
November 30, 2011	Deadline for the Postal Service to file the applicable administrative record in this appeal.
November 30, 2011	Deadline for the Postal Service to file any responsive pleading.
December 27, 2011	Deadline for notices to intervene (*see* 39 CFR 3001.111(b)).
December 20, 2011	Deadline for Petitioners' Form 61 or initial brief in support of petition (*see* 39 CFR 3001.115(a) and (b)).
January 9, 2012	Deadline for answering brief in support of the Postal Service (*see* 39 CFR 3001.115(c)).
January 24, 2012	Deadline for reply briefs in response to answering briefs (*see* 39 CFR 3001.115(d)).
January 31, 2012	Deadline for motions by any party requesting oral argument; the Commission will schedule oral argument only when it is a necessary addition to the written filings (*see* 39 CFR 3001.116).
February 28, 2012	Expiration of the Commission's 120-day decisional schedule (*see* 39 U.S.C. 404(d)(5)).

[FR Doc. 2011–31359 Filed 12–6–11; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC–29878]

Notice of Applications for Deregistration Under Section 8(f) of the Investment Company Act of 1940

November 30, 2011.

The following is a notice of applications for deregistration under section 8(f) of the Investment Company Act of 1940 for the month of November 2011. A copy of each application may be obtained via the Commission's Web site by searching for the file number, or an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090. An order granting each application will be issued unless the SEC orders a hearing. Interested persons may request a hearing on any application by writing to the SEC's Secretary at the address below and serving the relevant applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on December 29, 2011, and should be accompanied by proof of service on the applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

FOR FURTHER INFORMATION CONTACT: Diane L. Titus at (202) 551–6810, SEC, Division of Investment Management, Office of Investment Company Regulation, 100 F Street NE., Washington, DC 20549–8010.

Veracity Funds [File No. 811–21483]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On May 13, 2011, applicant transferred its assets to Munder Veracity Small-Cap Value Fund, a series of Munder Series Trust, based on net asset value. Expenses of $150,293 incurred in connection with the reorganization were paid by Integrity Asset Management, LLC, applicant's investment adviser.

Filing Date: The application was filed on October 12, 2011, and amended on November 17, 2011.

Applicant's Address: Integrity Asset Management, LLC, 18500 Lake Rd., Suite 300, Rocky River, OH 44116.

Old Mutual Emerging Managers Fund, L.L.C. [File No. 811–21898]

Old Mutual Emerging Managers Institutional Fund, L.L.C. [File No. 811–21997]

Summary: Applicants, closed-end investment companies, seek an order declaring that they have each ceased to be an investment company. On March 31, 2011, applicants transferred their assets to Larch Lane Multi-Strategy Fund, L.L.C. (f/k/a Old Mutual Absolute Return Fund, L.L.C.) and Larch Lane Multi-Strategy Institutional Fund, L.L.C. (f/k/a/Old Mutual Absolute Return Institutional Fund, L.L.C.), respectively, based on net asset value. Expenses of $119,600 and $10,400, respectively, incurred in connection with the reorganizations were allocated to applicants; however, Larch Lane Advisors LLC, investment adviser to both applicants, will bear these expenses in accordance with an expense limitation agreement.

Filing Dates: The applications were filed on August 12, 2011 and amended on November 10, 2011.

Applicants' Address: 800 Westchester Ave., S–528, Rye Brook, NY 10573.

Old Mutual Emerging Managers Master Fund, L.L.C. [File No. 811–21912]

Summary: Applicant, a closed-end investment company and a master fund in a master/feeder structure, seeks an order declaring that it has ceased to be an investment company. On March 31, 2011, applicant transferred its assets to Larch Lane Multi-Strategy Master Fund, L.L.C. (f/k/a Old Mutual Absolute Return Master Fund, L.L.C.), based on net asset value. Applicant incurred no expenses in connection with the reorganization.

Filing Dates: The application was filed on August 12, 2011 and amended on November 10, 2011.

Applicant's Address: 800 Westchester Ave., S–528, Rye Brook, NY 10573.

Larch Lane Multi-Strategy Fund, L.L.C. [File No. 811–21896]

Larch Lane Multi-Strategy Institutional Fund, L.L.C. [File No. 811–21998]

Summary: Applicants, closed-end investment companies and feeder funds in a master/feeder structure, seek an order declaring that they have each ceased to be an investment company.

On August 1, 2011, the master fund in which each applicant invested transferred its remaining assets and specified liabilities to a Delaware statutory trust (''liquidating trust''), based on net asset value. Each applicant's investors received a pro rata interest in the liquidating trust based on the number of each applicant's units owned by the investor. The liquidating trust periodically will make cash distributions, based on each investor's pro rata ownership interest, as assets are liquidated. Expenses of $73,125 and $8,125, respectively, incurred in connection with the liquidations were paid by applicants.

Filing Dates: The applications were filed on August 12, 2011, and August 15, 2011, respectively, and amended on November 14, 2011.

Applicants' Address: 800 Westchester Ave., S–618, Rye Brook, NY 10573.

Larch Lane Multi-Strategy Master Fund, L.L.C. [File No. 811–21911]

Summary: Applicant, a closed-end investment company and a master fund in a master/feeder structure, seeks an order declaring that it has ceased to be an investment company. On August 1, 2011, applicant transferred its remaining assets and specified liabilities to a Delaware statutory trust (''liquidating trust''), based on net asset value. Each investor in applicant's feeder funds received a pro rata interest in the liquidating trust and will receive periodic cash distributions from the liquidating trust as its assets are liquidated. Applicant incurred no expenses in connection with the liquidation.

Filing Dates: The application was filed on August 12, 2011 and amended on November 14, 2011.

Applicant's Address: 800 Westchester Ave., S–618, Rye Brook, NY 10573.

Hatteras Ramius Advantage Fund [File No. 811–22285]

Summary: Applicant, a closed-end investment company and a feeder fund in a master/feeder structure, seeks an order declaring that it has ceased to be an investment company. By August 18, 2011, applicant had repurchased all of its shares at net asset value. Expenses of $1,970 incurred in connection with applicant's liquidation were paid by Hatteras Capital Investment Management, LLC, investment adviser to the master fund in which applicant invested, or an affiliate.

Filing Dates: The application was filed on August 26, 2011, and amended on November 14, 2011.

Applicant's Address: 8540 Colonnade Center Dr., Suite 401, Raleigh, NC 27615.

Hatteras Ramius Advantage Institutional Fund [File No. 811–22284]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. By August 18, 2011, applicant had repurchased all of its shares at net asset value, other than those held by its investment adviser, Hatteras Capital Investment Management, LLC (''Hatteras Capital''). Applicant continues to hold approximately $569,925 in underlying funds that impose restrictions on investors redeeming their interests. Hatteras Capital will remain applicant's sole shareholder during the completion of applicant's liquidation. Expenses of $1,970 incurred in connection with the liquidation will be paid by Hatteras Capital or an affiliate.

Filing Dates: The application was filed on August 26, 2011, and amended on November 14, 2011.

Applicant's Address: 8540 Colonnade Center Dr., Suite 401, Raleigh, NC 27615.

Ibero-America Fund, Inc. [File No. 811–5189]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On September 30, 2011, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses of $281,780 incurred in connection with the liquidation were paid by applicant.

Filing Date: The application was filed on October 31, 2011.

Applicant's Address: 1345 Avenue of the Americas, New York, NY 10105.

EquiTrust Series Fund, Inc. [File No. 811–2125]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On July 15, 2011, applicant transferred its assets to corresponding series of Money Market Obligations Trust, Federated Total Return Series, Inc., Federated Investment Series Funds, Inc., Federated Asset Allocation Fund, and Federated Equity Funds, based on net asset value. Expenses of $743,975 incurred in connection with the reorganization were paid by applicant's investment adviser, EquiTrust Investment Management Services, Inc., or its affiliates.

Filing Date: The application was filed on October 27, 2011.

Applicant's Address: 5400 University Ave., West Des Moines, IA 50266.

Legg Mason Light Street Trust, Inc. [File No. 811–8943]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On December 15, 2009, applicant transferred its assets to Legg Mason Partners Equity Trust, based on net asset value. Expenses of $151,600 incurred in connection with the reorganization were paid by applicant, the acquiring fund and Legg Mason, Inc.

Filing Date: The application was filed on November 10, 2011.

Applicant's Address: 100 International Dr., 7th Floor, Baltimore, MD 21202.

Metzler/Payden Investment Group [File No. 811–21085]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On January 21, 2011, applicant transferred its assets to Metzler/Payden European Emerging Markets Fund, a series of Payden & Rygel Investment Group, based on net asset value. Expenses of $95,352 incurred in connection with the reorganization were paid by applicant and the acquiring fund.

Filing Date: The application was filed on October 27, 2011.

Applicant's Address: 333 South Grand Ave., 32nd Floor, Los Angeles, CA 90071.

EquiTrust Variable Insurance Series Fund [File No. 811–5069]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On July 15, 2011, applicant transferred its assets to corresponding series of Federated Prime Money Fund II, Federated Quality Bond Fund II, Federated Capital Income Fund II and Federated Capital Appreciation Fund II, all series of the Federated Insurance Series, based on net asset value. Expenses of approximately $568,118 incurred in connection with the reorganization were paid by EquiTrust Investment Management Services Inc. or its affiliates.

Filing Dates: The application was filed on October 27, 2011.

Applicant's Address: 5400 University Avenue, West des Moines, IA 50266.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–31298 Filed 12–6–11; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65866; File No. S7–24–89]

Joint Industry Plan; Notice of Filing and Immediate Effectiveness of Amendment No. 26 to the Joint Self-Regulatory Organization Plan Governing the Collection, Consolidation and Dissemination of Quotation and Transaction Information for Nasdaq-Listed Securities Traded on Exchanges on an Unlisted Trading Privileges Basis Submitted by the BATS Exchange, Inc., BATS Y–Exchange, Inc., Chicago Board Options Exchange, Incorporated, Chicago Stock Exchange, Inc., EDGA Exchange, Inc., EDGX Exchange, Inc., Financial Industry Regulatory Authority, Inc., International Securities Exchange LLC, NASDAQ OMX BX, Inc., NASDAQ OMX PHLX LLC, Nasdaq Stock Market LLC, National Stock Exchange, Inc., New York Stock Exchange LLC, NYSE Amex, Inc., and NYSE Arca, Inc.

December 2, 2011.

Pursuant to Rule 608 of the Securities Exchange Act of 1934 (the ''Act'') [1] notice is hereby given that on November 11, 2011, the operating committee (''Operating Committee'' or ''Committee'') [2] of the Joint Self-Regulatory Organization Plan Governing the Collection, Consolidation, and Dissemination of Quotation and Transaction Information for Nasdaq-Listed Securities Traded on Exchanges on an Unlisted Trading Privilege Basis (''Nasdaq/UTP Plan'' or ''Plan'') filed with the Securities and Exchange Commission (''Commission'') an amendment to the Plan.[3] This amendment represents Amendment No. 26 (''Amendment'') to the Plan and proposes to harmonize the price structures among the U.S. national market system plans by replacing the annual administrative fees that the Participants impose in respect of real-time data with monthly access fees. Pursuant to Rule 608(b)(3)(i) under the Act, the Participants designated the Amendment as establishing or changing a fee or other charge collected on behalf of all of the participants in connection with access to, or use of, the facilities contemplated by the Amendment. As a result, the Amendment has been put into effect upon filing with the Commission. At any time within 60 days of the filing of the Amendment, the Commission may summarily abrogate the Amendment and require that the Amendment be refiled in accordance with paragraph (a)(1) of Rule 608 and reviewed in accordance with paragraph (b)(2) of Rule 608, if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or the maintenance of fair and orderly markets, to remove impediments to, and perfect the mechanisms of, a national market system or otherwise in furtherance of the purposes of the Act. The Commission is publishing this notice to solicit comments from interested persons.

I. Rule 608(a)

A. Purpose of the Amendments

The Participants propose to harmonize the price structures among the U.S. national market system plans by replacing the annual administrative fees that the Participants impose in respect of real-time data with monthly access fees. The proposed Nasdaq/UTP Plan access fees are similar to those that the Network A and Network B Participants impose under the CTA and CQ Plans and that the OPRA Participants impose under the OPRA Plan.

The Participants propose to establish the monthly fee for access to UTP Level 1 real-time data feeds at $1,500 for direct access and at $500 for indirect access.

The Participants propose to impose the direct access fee on parties that receive access to any one or more UTP Level 1 real-time data feeds by means of a linkage or interface directly with the Plan's Securities Information Processor (Nasdaq) via an extranet or other connection that Nasdaq has approved. The Participants propose to impose the indirect access fee on parties that receive ''indirect access'' to any one or more UTP Level 1 real-time data feeds by means of a data feed service that a third-party data feed provider makes available. Distributors receiving access both directly and indirectly shall be liable only for direct access fees.

The references to ''data feeds'' would include the receipt of data in an uncontrolled format. The data recipient is responsible for the telecommunications facilities necessary to access data.

Currently, the Participants impose the following annual administrative fee on distributors for access to UTP Level 1 Service:

Delayed distributor	$250
0–999 real-time terminals	500
1,000–4,999 real-time terminals	1,250
5,000–9,999 real-time terminals	2,250
10,000+ real-time terminals	3,750

The Participants propose to replace each of the real-time administrative fees with the access fees. As a result, the Participants propose to delete the real-time annual administrative fees from the fee schedule. The $250 annual administrative fee that the Participants impose on delayed distributors would remain in effect.

The Participants project that replacing the annual administrative fees with monthly access fees would increase annual revenues received under the Nasdaq/UTP Plan approximately five percent for 2012.

From an administrative perspective, the administrator under the Nasdaq/UTP Plan would require parties with direct or indirect access to UTP Level 1 real-time data feeds to enter into the same market data agreements that they are required to enter into today.

B. Governing or Constituent Documents

Not applicable.

C. Implementation of Amendment

The Participants have manifested their approval of the proposed Amendment by means of their execution of the Amendment. The Participants propose to make the rate changes effective for calendar year 2012.

D. Development and Implementation Phases

Not applicable.

E. Analysis of Impact on Competition

The proposed Amendment does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The access fees amount to a competitive response to the access fees that the

[1] 17 CFR 242.608.

[2] The Plan Participants (collectively, ''Participants'') are the: BATS Exchange, Inc. (''BATS''); BATS Y–Exchange, Inc.(''BATS Y''); Chicago Board Options Exchange, Incorporated (''CBOE''); Chicago Stock Exchange, Inc. (''CHX''); EDGA Exchange, Inc. (''EDGA''); EDGX Exchange, Inc.(''EDGX''); Financial Industry Regulatory Authority, Inc. (''FINRA''); International Securities Exchange LLC (''ISE''); NASDAQ OMX BX, Inc. (''BX''); NASDAQ OMX PHLX LLC (''PHLX''); Nasdaq Stock Market LLC (''Nasdaq''); National Stock Exchange, Inc. (''NSX''); New York Stock Exchange LLC (''NYSE''); NYSE Amex, Inc. (''NYSEAmex''); and NYSE Arca, Inc. (''NYSEArca'').

[3] The Plan governs the collection, processing, and dissemination on a consolidated basis of quotation information and transaction reports in Eligible Securities for each of its Participants. This consolidated information informs investors of the current quotation and recent trade prices of Nasdaq securities. It enables investors to ascertain from one data source the current prices in all the markets trading Nasdaq securities. The Plan serves as the required transaction reporting plan for its Participants, which is a prerequisite for their trading Eligible Securities. *See* Securities Exchange Act Release No. 55647 (April 19, 2007) 72 FR 20891 (April 26, 2007).

Participants in the CTA, CQ and OPRA Plans impose. The proposed monthly access fees and the monthly access fees that currently apply under those other national market system plans compare as follows:

	Network A	Network B	OPRA	Proposed under NASDAQ/UTP Plan
Direct Access:				
Last Sale	$1,000	$350		
Bid/Ask	1,100	400		
Total	2,100	750	[4] 2,500	1,500
Indirect Access:				
Last Sale	500	200		
Bid/Ask	700	250		
Total	1,200	450	600	500

The Participants in the CTA and CQ Plans have imposed access fees since the Commission declared the plans effective in the 1970s. Those fees went unchanged from the rates initially adopted in the 1970s until 2009, when the Participants in those Plans raised them to the levels indicated above. The CTA and CQ Plan Participants coupled raising those fees with eliminating program classification charges, stating that the net result would be approximately revenue neutral. In its approval order,[5] the Commission found that the replacement of the program classification charges with the hike in the access fees is consistent with Rule 608(b)(2) of the Act. It stated that:

> The Commission believes that eliminating program classification charges and replacing them with separate fees for the receipt of Network A and Network B market data are fair and reasonable and provide for an equitable allocation of dues, fees, and other charges among vendors, data recipients and other persons using CTA Network A and Network B facilities.[6]

The Participants believe that the same holds true for the Nasdaq/UTP Plan's proposal. The proposed access fees compare favorably to those currently imposed under the CTA, CQ and OPRA Plans, including those approved by the Commission less than two years ago. The Nasdaq/UTP Plan Participants do not impose the program classification charges that the CTA and CQ Plan Participants eliminated. In addition to the favorable comparability of the Nasdaq/UTP Plan Participants' proposed access fees, the Plan's other charges also compare favorably to their CTA, CQ and OPRA Plan counterparts. These include device charges, charges for nonprofessional subscriber services, per-query fees, and television ticker fees.

In addition to the CTA, CQ and OPRA Plans, many individual exchanges around the world impose access fees for the receipt of market data feeds. On the other hand, few exchanges impose annual administrative fees.

As a result, this Amendment promotes consistency in price structures among the national market system plans, as well as consistency with the preponderance of other market data providers. It would make access fees easier to administer and enable data recipients to compare their charges under the respective national market system plans more easily. It would make for a more straightforward and streamlined administrative process for both the network administrator and the vendors.

Access fees allow those who gain access to the Plan's data feeds to contribute an appropriate amount for their receipt of market data under the Plan. They provide for an equitable allocation of dues, fees, and other charges among data feed customers, end users and others receiving and using market data made available under the Plan.

The Participants propose to impose the access fees uniformly on all vendors that receive UTP Level 1 real-time data in a data feed/uncontrolled format (including members of the Participant markets and non-members). The Participants do not believe that the proposed plan Amendment introduces terms that are unreasonably discriminatory for the purposes of Section 11A(c)(1)(D) of the Act.

F. Written Understanding or Agreements relating to Interpretation of, or Participation in, Plan

The Participants have no written understandings or agreements relating to interpretation of the Plan as a result of the Amendment.

G. Approval by Sponsors in Accordance with Plan

Each of the Plan's Participants has executed a written Amendment to the Plan.

H. Description of Operation of Facility Contemplated by the Proposed Amendment

Not applicable.

I. Terms and Conditions of Access

See Item A(1) above.

J. Method of Determination and Imposition, and Amount of, Fees and Charges

The Participants believe that the level of the access fee allows vendors to contribute an appropriate amount for their receipt and use of market data under the Plan. The access fees amount to a competitive response to the access fees that the Participants in the CTA, CQ and OPRA Plans impose.

The Participants believe that the proposed access fees are fair and reasonable and provide for an equitable allocation of dues, fees, and other charges among vendors, data recipients and other persons using the Participants' facilities.

K. Method and Frequency of Processor Evaluation

Not applicable.

L. Dispute Resolution

Not applicable.

[4] The total OPRA Plan direct access fee of $2,500 consists of a $1,000 monthly direct access fee and a $1,500 monthly redistribution fee that OPRA imposes on vendors that distribute OPRA data to any person, whether on a real-time or delayed basis.

[5] *See* Securities Exchange Act Release No. 61226 (December 22, 2009); 74 FR 68893 (December 29, 2009) (SR–CTA/CQ–2009–02).

[6] *Id.*

II. Rule 601(a)

A. Reporting Requirements

Not applicable.

B. Manner of Collecting, Processing, Sequencing, Making Available and Disseminating Last Sale Information

Not applicable.

C. Manner of Consolidation

Not applicable.

D. Standards and Methods Ensuring Promptness, Accuracy and Completeness of Transaction Reports

Not applicable.

E. Rules and Procedures Addressed to Fraudulent or Manipulative Dissemination

Not applicable.

F. Terms of Access to Transaction Reports

Not applicable.

G. Identification of Marketplace of Execution

Not Applicable.

III. Solicitation of Comments

The Commission seeks general comments on Amendment No. 26. Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov.* Please include File Number S7–24–89 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number S7–24–89. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all written statements with respect to the proposed Plan amendment that are filed with the Commission, and all written communications relating to the proposed Plan amendment 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 Web site viewing and printing in the Commission's Public Reference Room on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for Web site viewing and printing at the Office of the Secretary of the Committee, currently located at the CBOE, 400 S. LaSalle Street, Chicago, IL 60605. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number S7–24–89 and should be submitted on or December 28, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–31414 Filed 12–6–11; 8:45 am]

BILLING CODE 8011–01–P

[7] 17 CFR 200.30–3(a)(27).

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Federal Register Citation of Previous Announcement: [76 FR 74835, December 1, 2011].

STATUS: Open Meeting.

PLACE: 100 F Street, NE., Washington, DC.

DATE AND TIME OF PREVIOUSLY ANNOUNCED MEETING: Tuesday, December 6, 2011.

CHANGE IN THE MEETING: Cancellation of Meeting.

The Open Meeting scheduled for Tuesday, December 6, 2011 at 10 a.m. has been cancelled.

For further information please contact the Office of the Secretary at (202) 551–5400.

Dated: December 2, 2011.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–31484 Filed 12–5–11; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65862; File No. SR–NYSEArca–2011–86]

Self-Regulatory Organizations; NYSE Arca Inc.; Notice of Filing of Proposed Rule Change To List and Trade the Accuvest Global Opportunities ETF Under NYSE Arca Equities Rule 8.600

December 1, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that, on November 16, 2011, NYSE Arca, Inc. (''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. 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 Exchange proposes to list and trade the following under NYSE Arca Equities Rule 8.600 (''Managed Fund Shares''): The Accuvest Global Opportunities ETF. The text of the proposed rule change is available at the Exchange, the Commission's Public Reference Room, and *www.nyse.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to list and trade the following Managed Fund

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Shares[3] (''Shares'') under NYSE Arca Equities Rule 8.600: The Accuvest Global Opportunities ETF (''Fund'').[4] The Shares will be offered by AdvisorShares Trust (''Trust''), a statutory trust organized under the laws of the State of Delaware and registered with the Commission as an open-end management investment company.[5] The investment adviser to the Fund is AdvisorShares Investments, LLC (''Adviser''). Accuvest Global Advisers is the Fund's sub-adviser (''Sub-Adviser'') and provides day-to-day portfolio management of the Fund. Foreside Fund Services, LLC (''Distributor'') is the principal underwriter and distributor of the Fund's Shares.

Commentary .06 to Rule 8.600 provides that, if the investment adviser to the investment company issuing Managed Fund Shares is affiliated with a broker-dealer, such investment adviser shall erect a ''fire wall'' between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such investment company portfolio.[6] In addition, Commentary .06 further requires that personnel who make decisions on the open-end fund's portfolio composition must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the open-end fund's portfolio. Commentary .06 to Rule 8.600 is similar to Commentary .03(a)(i) and (iii) to NYSE Arca Equities Rule 5.2(j)(3); however, Commentary .06 in connection with the establishment of a ''fire wall'' between the investment adviser and the broker-dealer reflects the applicable open-end fund's portfolio, not an underlying benchmark index, as is the case with index-based funds. Neither the Adviser nor the Sub-Adviser is affiliated with a broker-dealer. In the event (a) The Adviser or the Sub-Adviser becomes newly affiliated with a broker-dealer, or (b) any new adviser or sub-adviser becomes affiliated with a broker-dealer, it will implement a fire wall with respect to such broker-dealer regarding access to information concerning the composition and/or changes to the portfolio, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio.

Description of the Fund

According to the Registration Statement, the Fund will seek long-term capital appreciation in excess of global equity benchmarks such as the MSCI All Country World Index. The Fund will be a ''fund-of-funds'' that seeks to achieve its investment objective by investing primarily in other U.S.-listed exchange-traded products (''Underlying ETPs'').[7] The Sub-Adviser will seek to achieve the Fund's investment objective by investing in Underlying ETPs that provide diversified exposure to select economies around the world. The Sub-Adviser will rank countries on a monthly basis using its proprietary country ranking model in order to determine their relative attractiveness. The Sub-Adviser then will endeavor to invest in Underlying ETPs that individually or in combination correspond generally to the price and yield performance of the specific countries (or regions) identified as most attractive by the model. The Fund's portfolio will be invested only in countries with the highest ranking as identified by the Sub-Adviser's proprietary country ranking process.

The Fund intends to invest primarily in the securities of Underlying ETPs consistent with the requirements of Section 12(d)(1) of the 1940 Act, or any rule, regulation or order of the Commission or interpretation thereof. The Fund will only make such investments in conformity with the requirements of Section 817 of the Internal Revenue Code of 1986, as amended (''Code'').[8]

The Fund, through its investment in Underlying ETPs, may invest in equity securities, which represent ownership interests in a company or partnership and consist of common stocks, preferred stocks, warrants to acquire common stock, securities convertible into common stock, investments in master limited partnerships and American Depositary Receipts (''ADRs''), as well as Global Depositary Receipts (''GDRs'', together with ADRs, ''Depositary Receipts'').[9] The Fund, through its

[3] A Managed Fund Share is a security that represents an interest in an investment company registered under the Investment Company Act of 1940 (15 U.S.C. 80a) (''1940 Act'') organized as an open-end investment company or similar entity that invests in a portfolio of securities selected by its investment adviser consistent with its investment objectives and policies. In contrast, an open-end investment company that issues Investment Company Units, listed and traded on the Exchange under NYSE Arca Equities Rule 5.2(j)(3), seeks to provide investment results that correspond generally to the price and yield performance of a specific foreign or domestic stock index, fixed income securities index or combination thereof.

[4] The Commission approved NYSE Arca Equities Rule 8.600 and the listing and trading of certain funds of the PowerShares Actively Managed Exchange-Traded Funds Trust on the Exchange pursuant to Rule 8.600 in Securities Exchange Act Release No. 57619 (April 4, 2008) 73 FR 19544 (April 10, 2008) (SR–NYSEArca–2008–25). The Commission also has approved listing and trading on the Exchange of a number of actively managed funds under Rule 8.600. *See, e.g.,* Securities Exchange Act Release Nos. 57801 (May 8, 2008), 73 FR 27878 (May 14, 2008) (SR–NYSEArca–2008–31) (order approving Exchange listing and trading of twelve actively-managed funds of the WisdomTree Trust); 60460 (August 7, 2009), 74 FR 41468 (August 17, 2009) (SR–NYSEArca–2009–55) (order approving listing of Dent Tactical ETF); 63076 (October 12, 2010), 75 FR 63874 (October 18, 2010) (SR–NYSEArca–2010–79) (order approving Exchange listing and trading of Cambria Global Tactical ETF); 63802 (January 31, 2011), 76 FR 6503 (February 4, 2011) (SR–NYSEArca–2010–118) (order approving Exchange listing and trading of the SiM Dynamic Allocation Diversified Income ETF and SiM Dynamic Allocation Growth Income ETF).

[5] The Trust is registered under the 1940 Act. On May 9, 2011, the Trust filed with the Commission Post-Effective Amendment No. 25 to Form N–1A under the Securities Act of 1933 (15 U.S.C. 77a), and under the 1940 Act relating to the Fund (File Nos. 333–157876 and 811–22110) (''Registration Statement''). The description of the operation of the Trust and the Fund herein is based, in part, on the Registration Statement. In addition, the Commission has issued an order granting certain exemptive relief to the Trust under the1940 Act. *See* Investment Company Act Release No. 29291 (May 28, 2010) (File No. 812–13677) (''Exemptive Order'').

[6] An investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (''Advisers Act''). As a result, the Adviser and Sub-Adviser and their related personnel are subject to the provisions of Rule 204A–1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A–1 under the Advisers Act. In addition, Rule 206(4)–7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) Adopted and implemented written policies and procedures reasonably designed to prevent violation, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) Above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

[7] Underlying ETPs include Investment Company Units (as described in NYSE Arca Equities Rule 5.2(j)(3)); Portfolio Depositary Receipts (as described in NYSE Arca Equities Rule 8.100); Trust Issued Receipts (as described in NYSE Arca Equities Rule 8.200); Commodity-Based Trust Shares (as described in NYSE Arca Equities Rule 8.201); Currency Trust Shares (as described in NYSE Arca Equities Rule 8.202); Commodity Index Trust Shares (as described in NYSE Arca Equities Rule 8.203); Trust Units (as described in NYSE Arca Equities Rule 8.500); Managed Fund Shares (as described in NYSE Arca Equities Rule 8.600), and closed-end funds. The Underlying ETPs all will be listed and traded in the U.S. on registered exchanges. The Underlying ETPs in which the Fund may invest will primarily be index-based exchange-traded funds that hold substantially all of their assets in securities representing a specific index.

[8] 26 CFR 1.817–5.

[9] ADRs and GDRs are certificates evidencing ownership of shares of a foreign issuer. Depositary Receipts may be sponsored or unsponsored. These

investment in Underlying ETPs, may invest in closed-end funds, pooled investment vehicles that are registered under the 1940 Act and whose shares are listed and traded on U.S. national securities exchanges. The Fund, through its investment in Underlying ETPs, may invest in shares of real estate investment trusts (''REITs''), which are pooled investment vehicles that invest primarily in real estate or real estate related loans.

The Sub-Adviser has developed its country ranking model around the premise that in the long run, country-specific effects are the most important drivers of global equity returns.

Investment Process and Portfolio Construction

According to the Registration Statement, through its proprietary country ranking model, the Sub-Adviser ranks countries on a monthly basis in order to determine their relative merit.

The Sub-Adviser will use a four step process to create its portfolio allocations:

1. Qualify Countries: In order to determine which countries are to be included in the country ranking model, the Sub-Adviser will apply two consistent criteria. All qualified countries (a) must be part of the MSCI All Country World Index and (b) have a liquid Underlying ETP that tracks the performance of its equity market.

2. Analyze Factor Data: The Sub-Adviser will collect and analyze monthly factor data on every qualified country in the model. Currently, the Sub-Adviser uses nearly 40 factors that are classified within fundamental (*e.g.,* short-term earnings growth), momentum (*e.g.,* 3 month local price momentum), risk (*e.g.,* change in 30-day standard deviation), and valuation (*e.g.,* earnings growth) factor groups.

3. Rank Countries: Each month the Sub-Adviser will use the weighted individual factor scores for each country in the model to assign each country a relative attractiveness score. This monthly score will be used to rank countries from most attractive to least attractive.

4. Create Portfolio: The Sub-Adviser will create the portfolio based on the underlying attractiveness score of each country in the model. The most attractive 5–6 countries will receive allocations in the portfolio, and the Sub-Adviser will purchase single country Underlying ETPs that represent investments in those countries' equity markets. No single country Underlying ETP may receive more than a 25% allocation at purchase price.

The Underlying ETPs in which the Fund will invest will primarily hold substantially all of their assets in securities representing a country (or region) specific index.

The Underlying ETPs may invest in complex securities such as equity options, index options, repurchase agreements, foreign currency contracts, swaps, and futures contracts.

Other Investments

To respond to adverse market, economic, political or other conditions,[10] the Fund may invest 100% of its total assets, without limitation, in high-quality short-term debt securities and money market instruments. The Fund may be invested in these instruments for extended periods, depending on the Sub-Adviser's assessment of market conditions. These short-term debt securities and money market instruments include shares of other mutual funds, commercial paper, certificates of deposit, bankers' acceptances, U.S. Government securities,[11] repurchase agreements [12] and bonds that are BBB or higher. The Fund may also invest a substantial portion of its assets in such instruments at any time to maintain liquidity or pending selection of investments in accordance with its policies.

Under normal market conditions, while the Fund will primarily invest in Underlying ETPs, the Fund may, to a limited extent, invest directly in other investments, as described below.

The Fund, or the Underlying ETPs in which it invests, may invest in U.S. government securities.

The Fund may invest in exchange-traded notes (''ETNs''). ETNs are debt obligations of investment banks which are traded on exchanges and the returns of which are linked to the performance of market indexes.

The Fund, or the Underlying ETPs in which it invests, may invest in U.S. Treasury zero-coupon bonds. These securities are U.S. Treasury bonds which have been stripped of their unmatured interest coupons, the coupons themselves, and receipts or certificates representing interests in such stripped debt obligations and coupons. Interest is not paid in cash during the term of these securities, but is accrued and paid at maturity.

Diversification. The Fund may not (i) With respect to 75% of its total assets, purchase securities of any issuer (except securities issued or guaranteed by the U.S. Government, its agencies or instrumentalities or shares of investment companies) if, as a result, more than 5% of its total assets would be invested in the securities of such issuer; or (ii) acquire more than 10% of the outstanding voting securities of any one issuer. For purposes of this policy, the issuer of the underlying security will be deemed to be the issuer of any respective Depositary Receipt.[13]

Concentration. The Fund may not invest 25% or more of its total assets in the securities of one or more issuers conducting their principal business activities in the same industry or group of industries. This limitation does not apply to investments in securities issued or guaranteed by the U.S. Government, its agencies or instrumentalities, or shares of investment companies. The Fund will not invest 25% or more of its total assets in any investment company that so concentrates. For purposes of this policy, the issuer of the underlying

certificates are issued by depositary banks and generally trade on an established market in the United States or elsewhere. The underlying shares are held in trust by a custodian bank or similar financial institution in the issuer's home country. The depositary bank may not have physical custody of the underlying securities at all times and may charge fees for various services, including forwarding dividends and interest and corporate actions.

[10] Adverse market conditions would include large downturns in the broad market value of two or more times current average volatility, where the Sub-Adviser views such downturns as likely to continue for an extended period of time. Adverse economic conditions would include significant negative results in factors deemed critical at the time by the Sub-Adviser, including significant negative results regarding unemployment, Gross Domestic Product, consumer spending or housing numbers. Adverse political conditions would include events such as government overthrows or instability, where the Sub-Adviser expects that such events may potentially create a negative market or economic condition for an extended period of time.

[11] Securities issued or guaranteed by the U.S. government or its agencies or instrumentalities include U.S. Treasury securities, which are backed by the full faith and credit of the U.S. Treasury and which differ only in their interest rates, maturities, and times of issuance.

[12] The Fund may enter into repurchase agreements with financial institutions, which may be deemed to be loans. The Fund follows certain procedures designed to minimize the risks inherent in such agreements. These procedures include effecting repurchase transactions only with large, well-capitalized and well-established financial institutions whose condition will be continually monitored by the Sub-Adviser. In addition, the value of the collateral underlying the repurchase agreement will always be at least equal to the repurchase price, including any accrued interest earned on the repurchase agreement. In the event of a default or bankruptcy by a selling financial institution, the Fund will seek to liquidate such collateral. In addition, the Fund may enter into reverse repurchase agreements without limit as part of the Fund's investment strategy. Reverse repurchase agreements involve sales by the Fund of portfolio assets concurrently with an agreement by the Fund to repurchase the same assets at a later date at a fixed price.

[13] The diversification standard is set forth in Section 5(b)(1) of the 1940 Act.

security will be deemed to be the issuer of any respective Depositary Receipt.[14]

The Fund will seek to qualify for treatment as a regulated investment company (''RIC'') under Subchapter M of the Code.[15]

The Fund will not purchase illiquid securities, including Rule 144A securities, and loan participation interests.[16] Further, in accordance with the Exemptive Order, the Fund will not invest in options, futures or swaps. The Fund's investments will be consistent with the Fund's investment objective and will not be used to enhance leverage.

Except for Underlying ETPs that may hold non-U.S. issues, the Fund will not otherwise invest in non-U.S. issues.

Net Asset Value (''NAV'')

The Fund will calculate NAV by: (i) Taking the current market value of its total assets; (ii) subtracting any liabilities; and (iii) dividing that amount by the total number of Shares owned by shareholders. The Fund will calculate NAV once each business day as of the regularly scheduled close of trading on the New York Stock Exchange (''NYSE'') (normally, 4 p.m., Eastern Time).

In calculating NAV, the Fund generally will value investment portfolios at market price. If market prices are unavailable or the Adviser believes that they are unreliable, or when the value of a security has been materially affected by events occurring after the relevant market closes, the Fund will price those securities at fair value as determined in good faith using methods approved by the Fund's Board of Trustees.

Creations and Redemptions

Creations and redemptions of Shares will occur in large specified blocks of Shares, referred to as ''Creation Units.'' According to the Registration Statement, the Shares of the Fund will be ''created'' at their NAV by authorized participants only in block-size Creation Units of 25,000 Shares or more. An authorized participant enters into an agreement (''Participant Agreement'') with the Fund's Distributor or a Depository Trust Company participant that has executed a Participant Agreement with the Distributor, and deposits into the Fund a portfolio of securities closely approximating the holdings of the Fund and a specified amount of cash, together totaling the NAV of the Creation Unit(s), in exchange for 25,000 Shares of the Fund (or multiples thereof). Similarly, Shares can only be redeemed in Creation Units, generally 25,000 Shares or more, principally in-kind for a portfolio of securities held by the Fund and a specified amount of cash together totaling the NAV of the Creation Unit(s). Shares will not be redeemable from the Fund except when aggregated in Creation Units. The prices at which creations and redemptions occur will be based on the next calculation of NAV after an order is received in a form prescribed in the Participant Agreement.

The Shares will conform to the initial and continued listing criteria under NYSE Arca Equities Rule 8.600. The Exchange represents that, for initial and/or continued listing, the Fund will be in compliance with Rule 10A–3 under the Exchange Act,[17] as provided by NYSE Arca Equities Rule 5.3. A minimum of 100,000 Shares will be outstanding at the commencement of trading on the Exchange. The Exchange will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time.

Availability of Information

The Fund's Web site (*www.advisorshares.com*), which will be publicly available prior to the public offering of Shares, will include a form of the prospectus for the Fund that may be downloaded. The Fund's Web site will include additional quantitative information updated on a daily basis, including, for the Fund, (1) Daily trading volume, the prior business day's reported closing price, NAV and mid-point of the bid/ask spread at the time of calculation of such NAV (''Bid/Ask Price''),[18] and a calculation of the premium and discount of the Bid/Ask Price against the NAV, and (2) data in chart format displaying the frequency distribution of discounts and premiums of the daily Bid/Ask Price against the NAV, within appropriate ranges, for each of the four previous calendar quarters. On each business day, before commencement of trading in Shares in the Core Trading Session on the Exchange, the Fund will disclose on its Web site the Disclosed Portfolio as defined in NYSE Arca Equities Rule 8.600(c)(2) that will form the basis for the Fund's calculation of NAV at the end of the business day.[19]

On a daily basis, the Adviser will disclose on the Fund's Web site for each portfolio security or other financial instrument of the Fund the following information: Ticker symbol (if applicable), name of security or financial instrument, number of shares or dollar value of financial instruments held in the portfolio, and percentage weighting of the security or financial instrument in the portfolio. The Web site information will be publicly available at no charge.

In addition, a basket composition file, which includes the security names and share quantities required to be delivered in exchange for Fund Shares, together with estimates and actual cash components, will be publicly disseminated daily prior to the opening of the NYSE via the National Securities Clearing Corporation. The basket represents one Creation Unit of the Fund.

Investors can also obtain the Trust's Statement of Additional Information

[14] *See* Form N–1A, Item 9. The Commission has taken the position that a fund is concentrated if it invests more than 25% of the value of its total assets in any one industry. *See, e.g.,* Investment Company Act Release No. 9011 (October 30, 1975), 40 FR 54241 (November 21, 1975).

[15] 26 U.S.C. 851. One of several requirements for RIC qualification is that the Fund must receive at least 90% of the Fund's gross income each year from dividends, interest, payments with respect to securities loans, gains from the sale or other disposition of stock, securities or foreign currencies, or other income derived with respect to the Fund's investments in stock, securities, foreign currencies and net income from an interest in a qualified publicly traded partnership (''90% Test''). A second requirement for qualification as a RIC is that the Fund must diversify its holdings so that, at the end of each fiscal quarter of the Fund's taxable year: (a) At least 50% of the market value of the Fund's total assets is represented by cash and cash items, U.S. Government securities, securities of other RICs, and other securities, with these other securities limited, in respect to any one issuer, to an amount not greater than 5% of the value of the Fund's total assets or 10% of the outstanding voting securities of such issuer; and (b) not more than 25% of the value of its total assets are invested in the securities (other than U.S. Government securities or securities of other RICs) of any one issuer or two or more issuers which the Fund controls and which are engaged in the same, similar, or related trades or businesses, or the securities of one or more qualified publicly traded partnership (''Asset Test'').

[16] A fund's portfolio security is illiquid if it cannot be disposed of in the ordinary course of business within seven days at approximately the value ascribed to it by the fund. *See* Investment Company Act Release No. 14983 (March 12, 1986), 51 FR 9773 (March 21, 1986) (adopting amendments to Rule 2a–7 under the 1940 Act); Investment Company Act Release No. 17452 (April 23, 1990), 55 FR 17933 (April 30, 1990) (adopting Rule 144A under the Securities Act of 1933).

[17] 17 CFR 240.10A–3.

[18] The Bid/Ask Price of the Fund will be determined using the midpoint of the highest bid and the lowest offer on the Exchange as of the time of calculation of the Fund's NAV. The records relating to Bid/Ask Prices will be retained by the Fund and its service providers.

[19] Under accounting procedures followed by the Fund, trades made on the prior business day (''T'') will be booked and reflected in NAV on the current business day (''T+1''). Accordingly, the Fund will be able to disclose at the beginning of the business day the portfolio that will form the basis for the NAV calculation at the end of the business day.

(''SAI''), the Fund's Shareholder Reports, and its Form N–CSR and Form N–SAR, filed twice a year. The Trust's SAI and Shareholder Reports are available free upon request from the Trust, and those documents and the Form N–CSR and Form N–SAR may be viewed on-screen or downloaded from the Commission's Web site at *www.sec.gov.* Information regarding market price and trading volume of the Shares is and will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. Information regarding the previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers. Quotation and last sale information for the Shares will be available via the Consolidated Tape Association (''CTA'') high-speed line, and, for the Underlying ETPs, will be available from the national securities exchanges on which they are listed. In addition, the Portfolio Indicative Value, as defined in NYSE Arca Equities Rule 8.600 (c)(3), will be widely disseminated by one or more major market data vendors at least every 15 seconds during the Core Trading Session.[20] The dissemination of the Portfolio Indicative Value, together with the Disclosed Portfolio, will allow investors to determine the value of the underlying portfolio of the Fund on a daily basis and will provide a close estimate of that value throughout the trading day.

Additional information regarding the Trust and the Shares, including investment strategies, risks, creation and redemption procedures, fees, portfolio holdings disclosure policies, distributions and taxes is included in the Registration Statement. All terms relating to the Fund that are referred to, but not defined in, this proposed rule change are defined in the Registration Statement.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Fund.[21] Trading in Shares of the Fund will be halted if the circuit breaker parameters in NYSE Arca Equities Rule 7.12 have been reached. Trading also may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) The extent to which trading is not occurring in the securities and/or the financial instruments comprising the Disclosed Portfolio of the Fund; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Trading in the Shares will be subject to NYSE Arca Equities Rule 8.600(d)(2)(D), which sets forth circumstances under which Shares of the Fund may be halted.

Trading Rules

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. Shares will trade on the NYSE Arca Marketplace from 4 a.m. to 8 p.m. Eastern Time in accordance with NYSE Arca Equities Rule 7.34 (Opening, Core, and Late Trading Sessions). The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in NYSE Arca Equities Rule 7.6, Commentary .03, the minimum price variation (''MPV'') for quoting and entry of orders in equity securities traded on the NYSE Arca Marketplace is $0.01, with the exception of securities that are priced less than $1.00 for which the MPV for order entry is $0.0001.

Surveillance

The Exchange intends to utilize its existing surveillance procedures applicable to derivative products (which include Managed Fund Shares) to monitor trading in the Shares. The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws.

The Exchange's current trading surveillance focuses on detecting securities trading outside their normal patterns. When such situations are detected, surveillance analysis follows and investigations are opened, where appropriate, to review the behavior of all relevant parties for all relevant trading violations.

The Exchange may obtain information via the Intermarket Surveillance Group (''ISG'') from other exchanges that are members of ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement.[22] All Underlying ETPs are listed on national securities exchanges, all of which are members of ISG.

In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

Information Bulletin

Prior to the commencement of trading, the Exchange will inform its Equity Trading Permit (''ETP'') Holders in an Information Bulletin (''Bulletin'') of the special characteristics and risks associated with trading the Shares. Specifically, the Bulletin will discuss the following: (1) The procedures for purchases and redemptions of Shares in Creation Unit aggregations (and that Shares are not individually redeemable); (2) NYSE Arca Equities Rule 9.2(a), which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Shares; (3) the risks involved in trading the Shares during the Opening and Late Trading Sessions when an updated Portfolio Indicative Value will not be calculated or publicly disseminated; (4) how information regarding the Portfolio Indicative Value is disseminated; (5) the requirement that ETP Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (6) trading information.

In addition, the Bulletin will reference that the Fund is subject to various fees and expenses described in the Registration Statement. The Bulletin will discuss any exemptive, no-action, and interpretive relief granted by the Commission from any rules under the Exchange Act. The Bulletin will also disclose that the NAV for the Shares will be calculated after 4 p.m. Eastern Time each trading day.

2. Statutory Basis

The basis under the Exchange Act for this proposed rule change is the requirement under Section 6(b)(5)[23] that an exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will

[20] Currently, it is the Exchange's understanding that several major market data vendors display and/or make widely available Portfolio Indicative Values published on CTA or other data feeds.

[21] *See* NYSE Arca Equities Rule 7.12, Commentary .04.

[22] For a list of the current members of ISG, *see www.isgportal.org.* The Exchange notes that not all components of the Disclosed Portfolio for the Fund may trade on markets that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

[23] 15 U.S.C. 78f(b)(5).

be listed and traded on the Exchange pursuant to the initial and continued listing criteria in NYSE Arca Equities Rule 8.600. The Exchange has in place surveillance procedures that are adequate to properly monitor trading in the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws. The Exchange may obtain information via ISG from other exchanges that are members of ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement. All Underlying ETPs will be listed on national securities exchanges, all of which are members of ISG, and the listing and trading of such securities is subject to rules of the exchanges on which they are listed and traded, as approved by the Commission. The Fund will not purchase illiquid securities, including Rule 144A securities, and loan participation interests. Further, the Fund will not invest in options, futures or swaps. The Fund's investments will be consistent with the Fund's investment objective and will not be used to enhance leverage. Except for Underlying ETPs that may hold non-U.S. issues, the Fund will not otherwise invest in non-U.S. issues.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that the Exchange will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time. In addition, a large amount of information is publicly available regarding the Fund and the Shares, thereby promoting market transparency. Quotation and last sale information for the Shares will be available via the CTA high-speed line and, for the Underlying ETPs, will be available from the national securities exchange on which they are listed. In addition, the Portfolio Indicative Value will be widely disseminated at least every 15 seconds during the Core Trading Session by one or more major market data vendors. On each business day, before commencement of trading in Shares in the Core Trading Session on the Exchange, the Fund will disclose on its Web site the Disclosed Portfolio that will form the basis for the Fund's calculation of NAV at the end of the business day. On a daily basis, the Adviser will disclose for each portfolio security or other financial instrument of the Fund the following information: Ticker symbol (if applicable), name of security or financial instrument, number of Shares or dollar value of financial instruments held in the portfolio, and percentage weighting of the security or financial instrument in the portfolio. The Web site for the Fund will include a form of the prospectus for the Fund and additional data relating to NAV and other applicable quantitative information. Moreover, prior to the commencement of trading, the Exchange will inform its ETP Holders in an Information Bulletin of the special characteristics and risks associated with trading the Shares. Trading in Shares of the Fund will be halted if the circuit breaker parameters in NYSE Arca Equities Rule 7.12 have been reached or because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. Trading in the Shares will be subject to NYSE Arca Equities Rule 8.600(d)(2)(D), which sets forth circumstances under which Shares of the Fund may be halted. In addition, as noted above, investors will have ready access to information regarding the Fund's holdings, the Portfolio Indicative Value, the Disclosed Portfolio, and quotation and last sale information for the Shares.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of additional types of actively-managed exchange-traded products that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures relating to trading in the Shares and may obtain information via ISG from other exchanges that are members of ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement. In addition, as noted above, investors will have ready access to information regarding the Fund's holdings, the Portfolio Indicative Value, the Disclosed Portfolio, and quotation and last sale information for the Shares.

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

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) As the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2011–86 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2011–86. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the

Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Section, 100 F Street NE., Washington, DC 20549–1090, on official business days between 10 a.m. and 3 p.m. Copies of the filing will also be available for inspection and copying at the NYSE's principal office and on its Internet Web site at *www.nyse.com.* All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2011–86 and should be submitted on or before December 28, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[24]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–31337 Filed 12–6–11; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65861; File No. SR–ISE–2011–77]

Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Network and Gateway Fees

December 1, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that, on November 17, 2011, the International Securities Exchange, LLC (the ''Exchange'' or the ''ISE'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. 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 ISE is proposing to amend its network and gateway fees. The text of the proposed rule change is available on the Exchange's Web site (*http://www.ise.com*), at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this proposed rule change is to amend the Exchange's network and gateway fees.

Network Fees

The Exchange recently transitioned to new data centers. The Exchange's primary data center is at Equinix, while Telx serves as the back-up data center. At its old data center, ISE offered a number of connectivity options, including two Dedicated Line Connections and an Ethernet/Managed Service Provider connection with multiple Megabit connection options. At the new data centers, however, the Exchange only offers two Ethernet connection options, a one Gigabit (GB) connection at a cost of $500 per month and a ten GB connection at a cost of $4,000 per month. As a result, the Exchange proposes to remove from its Schedule of Fees the other existing Ethernet/Managed Service Provider Megabit connection options[3] as well as the two Dedicated Line Connection options[4] as these are no longer available at the new data centers. With the unavailability of Dedicated Line Connections, the Exchange also no longer provides the Order Routing Service[5] and proposes to remove this fee from its Schedule of Fees. Additionally, at the new data centers, members are no longer able to connect to the Exchange via third-party managed service providers. The Exchange, therefore, proposes to remove reference to Managed Service Provider from its Schedule of fees also.

Finally, in addition to ISE, the new data centers house a number of firms, some of whom are ISE members and others that are not. Non-ISE members at Equinix and Telx include software vendors who have developed a front end application that provides its customers a connection to ISE. These customers are members of ISE and instead of connecting to ISE directly choose to connect to the Exchange through these software vendors. To allow these and other prospective non-ISE members to cross-connect their servers to ISE servers, we propose to offer the same connectivity options that we currently offer to ISE members.

Gateway Fees

Up until the transition to the new data centers, members were able to lease ''gateway'' equipment, *i.e.,* Routers, Switches and Servers, through ISE in order to establish a connection to the Exchange. As noted on the Exchange's Schedule of Fees, the cost of leasing this equipment was 4.75% of ISE's equipment costs. The Exchange also charged a one-time fee of $500 to members who wanted the Exchange to install, move, add, change or remove any such equipment. The Exchange no longer leases any such equipment and proposes to remove these fees from its Schedule of Fees.

The Exchange has designated this proposal to be operative on December 1, 2011.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[6] in general, and with Section 6(b)(4) of the Act,[7] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among Exchange members and other

[24] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Ethernet/Managed Service Provider connection costs are identified on the Exchange's Schedule of Fees as follows: $100 per month for 1—10 Megabits (MB); $250 per month for 11—100 MBs; $500 per month for 101 MBs—1 Gigabit (GB); and $4,000 per month for 10GBs.

[4] The Dedicated Line Connection costs are identified on the Exchange's Schedule of Fees as follows: for a T–1 and smaller connections, $300 per line per month; for T–3 connections, $1,500 per line per month.

[5] The Order Routing Service is identified on the Exchange's Schedule of Fees as follows: $100 per line per month.

[6] 15 U.S.C. 78f.

[7] 15 U.S.C. 78f(b)(4).

persons using its facilities. In particular, the proposed rule change will provide greater transparency into the connectivity options available to market participants. The proposed rule change treats similarly situated market participants in the same manner by assessing the same fees to all market participants, whether or not they are a member of the Exchange, based on their connectivity needs. The Exchange notes that the one GB and the ten GB connectivity options are similar to those currently in place at other exchanges. For example, NASDAQ OMX PHLX, Inc. (''PHLX'') currently offers a one GB and a ten GB network connection option to market participants that connect to that exchange.[8]

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not 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 not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[9] At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend 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. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

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 Exchange Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ISE–2011–77 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISE–2011–77. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISE–2011–77 and should be submitted on or before December 28, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Kevin M. O'Neill,

Deputy Secretary.

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[8] *See* PHLX Fee Schedule at *http://www.nasdaqtrader.com/content/marketregulation/membership/phlx/feesched.pdf.*

[9] 15 U.S.C. 78s(b)(3)(A)(ii).

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65860; File No. SR–NYSEArca-2011–85]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change Relating to the Listing and Trading of SPDR SSgA Real Assets ETF; SPDR SSgA Income Allocation ETF; SPDR SSgA Conservative Global Allocation ETF; SPDR SSgA Global Allocation ETF; and SPDR SSgA Aggressive Global Allocation ETF Under NYSE Arca Equities Rule 8.600

December 1, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 16, 2011, NYSE Arca, Inc. (''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. 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 Exchange proposes to list and trade the following under NYSE Arca Equities Rule 8.600 (''Managed Fund Shares''): SPDR SSgA Real Assets ETF; SPDR SSgA Income Allocation ETF; SPDR SSgA Conservative Global Allocation ETF; SPDR SSgA Global Allocation ETF; and SPDR SSgA Aggressive Global Allocation ETF. The text of the proposed rule change is available at the Exchange, the Commission's Public Reference Room, and *http://www.nyse.com.*

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 those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to list and trade the following Managed Fund Shares [3] (''Shares'') under NYSE Arca Equities Rule 8.600: SPDR SSgA Real Assets ETF; SPDR SSgA Income Allocation ETF; SPDR SSgA Conservative Global Allocation ETF; SPDR SSgA Global Allocation ETF; and SPDR SSgA Aggressive Global Allocation ETF (each, a ''Fund'' and, collectively, ''Funds'').[4] The Shares will be offered by SSgA Active ETF Trust (''Trust''), which is organized as a Massachusetts business trust and is registered with the Commission as an open-end management investment company.[5] SSgA FM serves as the investment adviser to the Funds (''Adviser''). State Street Global Markets, LLC (''Distributor'') is the principal underwriter and distributor of the Funds' Shares. State Street Bank and Trust Company (''Administrator,'' ''Custodian'' or ''Transfer Agent'') serves as administrator, custodian and transfer agent for the Funds.

Commentary .06 to Rule 8.600 provides that, if the investment adviser to the investment company issuing Managed Fund Shares is affiliated with a broker-dealer, such investment adviser shall erect a ''fire wall'' between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such investment company portfolio. In addition, Commentary .06 further requires that personnel who make decisions on the open-end fund's portfolio composition must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the open-end fund's portfolio.[6] Commentary .06 to Rule 8.600 is similar to Commentary .03(a)(i) and (iii) to NYSE Arca Equities Rule 5.2(j)(3); however, Commentary .06 in connection with the establishment of a ''fire wall'' between the investment adviser and the broker-dealer reflects the applicable open-end fund's portfolio, not an underlying benchmark index, as is the case with index-based funds. The Adviser is affiliated with a broker-dealer and has implemented a ''fire wall'' with respect to such broker-dealer regarding access to information concerning the composition and/or changes to the Funds' portfolios. In the event (a) The Adviser or any sub-adviser becomes newly affiliated with a broker-dealer, or (b) any new adviser or sub-adviser becomes affiliated with a broker-dealer, it will implement a fire wall with respect to such broker-dealer regarding access to information concerning the composition and/or changes to a portfolio, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio.

SPDR SSgA Real Assets ETF

The SPDR SSgA Real Assets ETF will seek to achieve a real return consisting of capital appreciation and current income. The Fund will invest substantially all of its assets in the SSgA Real Assets Portfolio (''Real Assets Portfolio''), a separate series of the SSgA Master Trust with an identical investment objective as the Fund. As a result, the Fund will invest indirectly through the Real Assets Portfolio. The Adviser will invest, under normal circumstances,[7] at least 80% of the Real Assets Portfolio's net assets among exchange traded products (''ETPs'') that provide exposure to ''real assets.'' The Adviser considers ''real assets'' to include the following four primary asset classes: (i) Inflation protected securities issued by the United States government, its agencies and/or instrumentalities, as well as inflation protected securities issued by foreign governments, agencies, and/or instrumentalities; (ii) domestic and international real estate securities; (iii) commodities; and (iv) publicly-traded companies in natural resources and/or commodities businesses. The Real Assets Portfolio will concentrate at least 25% of its assets in companies primarily involved in the energy sector and real estate industry through ETPs. The Real Assets Portfolio's allocation among those asset classes will be in proportions consistent with the Adviser's evaluation of the expected returns and risks of each asset class as well as the allocation that, in the Adviser's view, will best meet the Real Assets Portfolio's investment objective. The allocations to each asset class will change over time as the Adviser's expectations of each asset class shift. The Real Assets Portfolio's indirect holdings by virtue of investing in ETPs representing those asset classes will consist of a diversified mix of domestic and international equity securities, government and corporate bonds, inflation protected securities, commodities and real estate investment trusts (''REITs''). ETPs may include

[3] A Managed Fund Share is a security that represents an interest in an investment company registered under the Investment Company Act of 1940 (15 U.S.C. 80a) (''1940 Act'') organized as an open-end investment company or similar entity that invests in a portfolio of securities selected by its investment adviser consistent with its investment objectives and policies. In contrast, an open-end investment company that issues Investment Company Units, listed and traded on the Exchange under NYSE Arca Equities Rule 5.2(j)(3), seeks to provide investment results that correspond generally to the price and yield performance of a specific foreign or domestic stock index, fixed income securities index or combination thereof.

[4] The Commission has previously approved listing and trading on the Exchange of a number of actively managed funds under Rule 8.600. *See, e.g.,* Securities Exchange Act Release Nos. 57801 (May 8, 2008), 73 FR 27878 (May 14, 2008) (SR–NYSEArca–2008–31) (order approving Exchange listing and trading of twelve actively-managed funds of the WisdomTree Trust); 60460 (August 7, 2009), 74 FR 41468 (August 17, 2009) (SR–NYSEArcav2009–55) (order approving listing of Dent Tactical ETF); 61365 (January 15, 2010), 75 FR 4124 (January 26, 2010) (SR–NYSEArca–2009–114) (order approving listing and trading of Grail McDonnell Fixed Income ETFs); 60981 (November 10, 2009), 74 FR 59594 (November 18, 2009) (SR–NYSEArca–2009–79) (order approving listing of five fixed income funds of the PIMCO ETF Trust); 63076 (October 12, 2010), 75 FR 63874 (October 18, 2010) (SR–NYSEArca–2010–79) (order approving listing of Cambria Global Tactical ETF).

[5] The Trust is registered under the 1940 Act. On September 12, 2011, the Trust filed with the Commission Form N–1A under the Securities Act of 1933 (15 U.S.C. 77a), and under the 1940 Act relating to the Funds (File Nos. 333–173276 and 811–22542) (''Registration Statement''). The description of the operation of the Trust and the Funds herein is based, in part, on the Registration Statement. In addition, the Commission has issued an order granting certain exemptive relief to the Trust under the1940 Act. *See* Investment Company Act Release No. 29524 (December 13, 2010) (File No. 812–13487) (''Exemptive Order'').

[6] An investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (''Advisers Act''). As a result, the Adviser and its related personnel are subject to the provisions of Rule 204A–1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A–1 under the Advisers Act. In addition, Rule 206(4)–7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) Adopted and implemented written policies and procedures reasonably designed to prevent violation, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

[7] The term ''under normal circumstances'' includes, but is not limited to, the absence of extreme volatility or trading halts in the equity markets or the financial markets generally; operational issues causing dissemination of inaccurate market information; or force majeure type events such as systems failure, natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption or any similar intervening circumstance.

exchange traded funds that seek to track the performance of a market index (''Underlying ETFs'') (including Underlying ETFs managed by the Adviser); exchange traded commodity trusts; and exchange traded notes (''ETNs'').[8]

SPDR SSgA Income Allocation ETF

The SPDR SSgA Income Allocation ETF will seek to provide a total return by focusing on investments in income and yield-generating assets. The Fund will invest substantially all of its assets in the SSgA Income Portfolio (''Income Portfolio''), a separate series of the SSgA Master Trust with an identical investment objective as the Fund. As a result, the Fund will invest indirectly through the Income Portfolio. The Adviser will invest the assets of the Income Portfolio among ETPs that provide exposure to four primary asset classes: (i) Equity, domestic and international securities; (ii) investment grade and high yield debt securities; (iii) hybrid equity/debt (such as preferred stock and convertible securities); and (iv) REITs. The Income Portfolio's allocation among those asset classes will be in proportions consistent with the Adviser's evaluation of the expected returns and risks of each asset class as well as the allocation that, in the Adviser's view, will best meet the Income Portfolio's investment objective. The allocations to each asset class will change over time as the Adviser's expectations of each asset class shift. The Income Portfolio's indirect holdings by virtue of investing in ETPs representing these asset classes will consist of a diversified mix of domestic and international equity securities, investment grade and high yield government and corporate bonds, hybrid securities such as preferred stock and convertible securities, Build America Bonds, commodities, and REITs.

SPDR SSgA Conservative Global Allocation ETF

The SPDR SSgA Conservative Global Allocation ETF will seek to provide current income, capital preservation and the avoidance of excessive portfolio volatility. The Fund will invest substantially all of its assets in the SSgA Conservative Global Allocation Portfolio (''Conservative Allocation Portfolio''), a separate series of the SSgA Master Trust with an identical investment objective as the Fund. As a result, the Fund will invest indirectly through the Conservative Allocation Portfolio. The Adviser will invest the assets of the Conservative Allocation Portfolio among ETPs that provide exposure to domestic and international debt and equity securities with a larger allocation to debt securities than to other asset classes. The Conservative Allocation Portfolio[9] has a higher allocation to fixed income securities than to equity securities. These fixed income securities tend to be less volatile than traditional equity securities. The Conservative Allocation Portfolio typically will allocate approximately 60% of its assets to debt related securities, though this percentage can vary based on the Adviser's tactical decisions. The allocations to each asset class will change over time as the Adviser's expectations of each asset class shift. The Conservative Allocation Portfolio's indirect holdings by virtue of investing in ETPs representing these asset classes will consist of a diversified mix of domestic and international, including emerging markets, equity securities across all market capitalizations, investment grade and high yield government and corporate bonds, inflation protected securities, mortgage pass through securities, commercial mortgage backed securities, asset backed securities, commodities and REITs.

SPDR SSgA Global Allocation ETF

The SPDR SSgA Global Allocation ETF will seek to provide current income and capital preservation, with a secondary emphasis on capital appreciation. The Fund will invest substantially all of its assets in the SSgA Global Allocation Portfolio (''Global Allocation Portfolio''), a separate series of the SSgA Master Trust with an identical investment objective as the Fund. As a result, the Fund will invest indirectly through the Global Allocation Portfolio. The Adviser will invest the assets of the Global Allocation Portfolio among ETPs that provide balanced exposure to domestic and international debt and equity securities. The Global Allocation Portfolio typically will allocate approximately 60% of its assets to equity securities, though this percentage can vary based on the Adviser's tactical decisions. The allocations to each asset class will change over time as the Adviser's expectations of each asset class shift. The Global Allocation Portfolio's indirect holdings by virtue of investing in ETPs representing these asset classes will consist of a diversified mix of domestic and international, including emerging market, equity securities across all market capitalizations, investment grade and high yield government and corporate bonds, inflation protected securities, mortgage pass through securities, commercial mortgage backed securities, asset backed securities, commodities and REITs.

SPDR SSgA Aggressive Global Allocation ETF

The SPDR SSgA Aggressive Global Allocation ETF will seek to provide capital appreciation, with a secondary emphasis on current income. The Fund will invest substantially all of its assets in the SSgA Aggressive Global Allocation Portfolio (''Aggressive Allocation Portfolio'' and, together with the Real Assets Portfolio, Income Portfolio, Conservative Allocation Portfolio, and Global Allocation Portfolio, collectively, ''Portfolios''), a separate series of the SSgA Master Trust with an identical investment objective as the Fund. As a result, the Fund will invest indirectly through the Aggressive Allocation Portfolio. The Adviser will invest the assets of the Aggressive Allocation Portfolio among ETPs that provide exposure to domestic and international debt and equity securities with a larger allocation to equity securities than the other asset classes. The Aggressive Allocation Portfolio will have a higher allocation to equity securities than to fixed income securities. These equity securities will tend to be more volatile than traditional equity securities. The Aggressive Allocation Portfolio typically will allocate approximately 80% or more of its assets to equity securities, though this percentage can vary based on the Adviser's tactical decisions. The Aggressive Allocation Portfolio's indirect holdings by virtue of investing in ETPs representing these asset classes will consist of a diversified mix of domestic and international, including emerging market, equity securities across all market capitalizations, investment grade and high yield

[8] For each of the Funds, ETPs include Investment Company Units (as described in NYSE Arca Equities Rule 5.2(j)(3)); Index-Linked Securities (as described in NYSE Arca Equities Rule 5.2(j)(6)); Portfolio Depositary Receipts (as described in NYSE Arca Equities Rule 8.100); Trust Issued Receipts (as described in NYSE Arca Equities Rule 8.200); Commodity-Based Trust Shares (as described in NYSE Arca Equities Rule 8.201); Currency Trust Shares (as described in NYSE Arca Equities Rule 8.202); Commodity Index Trust Shares (as described in NYSE Arca Equities Rule 8.203); Trust Units (as described in NYSE Arca Equities Rule 8.500); Managed Fund Shares (as described in NYSE Arca Equities Rule 8.600), and closed-end funds. The ETPs all will be listed and traded in the U.S. on registered exchanges.

[9] Email from Timothy J. Malinowski, Senior Director, NYSE Euronext, to Edward Y. Cho, Special Counsel, Division of Trading and Markets, Commission, dated November 18, 2011.

government and corporate bonds, inflation protected securities, mortgage pass through securities, commercial mortgage backed securities, asset backed securities, government and corporate bonds, commodities and REITs.

Master Feeder Structure of the Funds

The Funds are intended to be managed in a ''master-feeder'' structure, under which each Fund will invest substantially all of its assets in a corresponding ''master fund,'' which is a separate mutual fund that has an identical investment objective. As a result, each Fund (*i.e.,* a ''feeder fund'') will have an indirect interest in all of the securities owned by each corresponding master fund.[10] Because of this indirect interest, each Fund's investment returns should be the same as those of the corresponding master fund, adjusted for the expenses of the feeder fund. In extraordinary instances, each Fund reserves the right to make direct investments in securities.

The Adviser will manage the investments of each respective Portfolio. Under the master-feeder arrangement, investment advisory fees charged at the master-fund level are deducted from the advisory fees charged at the feeder-fund level. This arrangement avoids a ''layering'' of fees, *e.g.,* a Fund's total annual operating expenses would be no higher as a result of investing in a master-feeder arrangement than they would be if the Fund pursued its investment objectives directly. In addition, each Fund may discontinue investing through the master-feeder arrangement and pursue its investment objectives directly if the Fund's Board of Trustees determines that doing so would be in the best interests of shareholders.

Each Fund is classified as a ''diversified'' investment company under the 1940 Act.[11]

The Funds, other than the SPDR SSgA Real Assets ETF, will not concentrate their investments in any particular industry or sector. The SPDR SSgA Real Assets ETF will concentrate its investments (*i.e.,* invest more than 25% of its assets) in companies primarily involved in the energy and real estate industries.[12]

The Funds intend to qualify for and to elect treatment as a separate regulated investment company (''RIC'') under Subchapter M of the Internal Revenue Code.[13] As such, each Fund should not be subject to Federal income tax on its net investment income and capital gains, if any, to the extent that it timely distributes such income and capital gains to its shareholders. In order to be taxable as a RIC, a Fund must distribute annually to its shareholders at least 90% of its net investment income (generally net investment income plus the excess of net short-term capital gains over net long-term capital losses) and at least 90% of its net tax exempt interest income, for each tax year, if any, to its shareholders (''Distribution Requirement'') and also must meet several additional requirements. Among these requirements are the following: (i) At least 90% of the Fund's gross income each taxable year must be derived from dividends, interest, payments with respect to securities loans, gains from the sale or other disposition of stock, securities or foreign currencies, or other income derived with respect to its business of investing in such stock, securities or currencies, and net income derived from an interest in qualified publicly traded partnerships; (ii) at the end of each fiscal quarter of the Fund's taxable year, at least 50% of the market value of its total assets must be represented by cash and cash items, U.S. government securities, securities of other RICs and other securities, with such other securities limited, in respect to any one issuer, to an amount not greater than 5% of the value of the Fund's total assets or more than 10% of the outstanding voting securities of such issuer, and (iii) at the end of each fiscal quarter of the Fund's taxable year, not more than 25% of the value of its total assets is invested in the securities (other than U.S. government securities or securities of other RICs) of any one issuer or the securities of two or more issuers engaged in the same, similar, or related trades or businesses if the Fund owns at least 20% of the voting power of such issuers, or the securities of one or more qualified publicly traded partnerships.

Other Investments

While each Fund will invest substantially all of its assets in its respective Portfolio, each Fund may directly invest in certain other investments, as described below.

Each Fund may (either directly or through its investments in its corresponding Portfolio) invest in the following types of investments: money market instruments, such as repurchase agreements, money market funds (including money market funds managed by the Adviser); variable rate demand notes, U.S. government and U.S. government agency securities; loan focused closed-end funds; and collateralized loan obligation debt securities.

Each Fund may invest in preferred securities and in convertible securities. Convertible securities are bonds, debentures, notes, preferred stocks or other securities that may be converted or exchanged (by the holder or by the issuer) into shares of the underlying common stock (or cash or securities of equivalent value) at a stated exchange ratio. A convertible security may also be called for redemption or conversion by the issuer after a particular date and under certain circumstances (including a specified price) established upon issue. If a convertible security held by a Fund is called for redemption or conversion, the Fund could be required to tender it for redemption, convert it into the underlying common stock, or sell it to a third party.

Each Fund may invest in bonds, including corporate bonds; high yield debt securities; sovereign debt;[14] and U.S. Government obligations.[15]

Each Fund may invest in Variable Rate Demand Obligations (''VRDOs''). VRDOs are short-term tax exempt fixed income instruments whose yield is reset on a periodic basis. VRDO securities tend to be issued with long maturities of up to 30 or 40 years; however, they are considered short-term instruments because they include a put feature which coincides with the periodic yield reset. For example, a VRDO whose yield resets weekly will have a put feature that is exercisable upon seven days notice. VRDOs are put back to a bank or other entity that serves as a liquidity provider, who then tries to resell the VRDOs or, if unable to resell, holds them in its own inventory. VRDOs are generally supported by either a Letter of

[10] Each master fund is registered under the 1940 Act.

[11] The diversification standard is set forth in Section 5(b)(1) of the 1940 Act.

[12] *See* Form N–1A, Item 9. The Commission has taken the position that a fund is concentrated if it invests more than 25% of the value of its total assets in any one industry. *See, e.g.,* Investment Company Act Release No. 9011 (October 30, 1975), 40 FR 54241 (November 21, 1975).

[13] 26 U.S.C. 851 *et seq.*

[14] Sovereign debt obligations are issued or guaranteed by foreign governments or their agencies. Sovereign debt may be in the form of conventional securities or other types of debt instruments such as loans or loan participations. Governmental entities responsible for repayment of the debt may be unable or unwilling to repay principal and pay interest when due, and may require renegotiation or reschedule of debt payments. In addition, prospects for repayment of principal and payment of interest may depend on political as well as economic factors. Although some sovereign debt, such as Brady Bonds, is collateralized by U.S. Government securities, repayment of principal and payment of interest is not guaranteed by the U.S. Government.

[15] U.S. Government obligations are a type of bond and include securities issued or guaranteed as to principal and interest by the U.S. Government, its agencies or instrumentalities.

Credit or a Stand-by Bond Purchase Agreement to provide credit enhancement.

The Funds may invest in inflation-protected public obligations, commonly known as ''TIPS,'' of the U.S. Treasury, as well as TIPS of major governments and emerging market countries, excluding the United States. TIPS are a type of security issued by a government that are designed to provide inflation protection to investors.

The Funds may conduct foreign currency transactions on a spot (*i.e.,* cash) or forward basis (*i.e.,* by entering into forward contracts to purchase or sell foreign currencies).

Each Fund may invest in repurchase agreements with commercial banks, brokers or dealers to generate income from its excess cash balances and to invest securities lending cash collateral. A repurchase agreement is an agreement under which a Fund acquires a financial instrument (*e.g.,* a security issued by the U.S. government or an agency thereof, a banker's acceptance or a certificate of deposit) from a seller, subject to resale to the seller at an agreed upon price and date (normally, the next business day). A repurchase agreement may be considered a loan collateralized by securities.

Each Fund may enter into reverse repurchase agreements, which involve the sale of securities with an agreement to repurchase the securities at an agreed-upon price, date and interest payment and have the characteristics of borrowing.

Each Fund may invest in commercial paper. Commercial paper consists of short-term, promissory notes issued by banks, corporations and other entities to finance short-term credit needs. These securities generally are discounted but sometimes may be interest bearing.

In addition to repurchase agreements, each Fund may invest in short-term instruments, including money market instruments, (including money market funds advised by the Adviser), repurchase agreements, cash and cash equivalents, on an ongoing basis to provide liquidity or for other reasons.

In certain situations or market conditions, a Fund may (either directly or through the corresponding Portfolio) temporarily depart from its normal investment policies and strategies provided that the alternative is consistent with the Fund's investment objective and is in the best interest of the Fund.[16] For example, a Fund may hold a higher than normal proportion of its assets in cash in times of extreme market stress. Each Fund may (either directly or through its investments in its corresponding Portfolio) borrow money from a bank as permitted by the 1940 Act or other governing statute, by applicable rules thereunder, or by Commission or other regulatory agency with authority over the Fund, but only for temporary or emergency purposes.

In addition to ETPs, each Fund may invest in the securities of other investment companies, including money market funds, subject to applicable limitations under Section 12(d)(1) of the 1940 Act. A Fund may also invest in the securities of other investment companies if such securities are the only investment securities held by the Fund, such as through a master-feeder arrangement. Each Fund will pursue its respective investment objective through such an arrangement. To the extent allowed by law, regulation, each Fund's investment restrictions and the Trust's exemptive relief under the 1940 Act, a Fund may invest its assets in securities of investment companies that are money market funds, including those advised by the Adviser or otherwise affiliated with the Adviser, in excess of the limits discussed above.

The Funds may purchase U.S. exchange listed common stocks and preferred securities of foreign corporations, as well as U.S. registered, dollar-denominated bonds of foreign corporations, governments, agencies and supra-national entities.

A Fund's investments in common stock of foreign corporations may also be in the form of American Depositary Receipts (''ADRs''), Global Depositary Receipts (''GDRs'') and European Depositary Receipts (''EDRs'') (collectively ''Depositary Receipts''). [17] Depositary Receipts are receipts, typically issued by a bank or trust company, which evidence ownership of underlying securities issued by a foreign corporation. For ADRs, the depository is typically a U.S. financial institution and the underlying securities are issued by a foreign issuer. For other Depositary Receipts, the depository may be a foreign or a U.S. entity, and the underlying securities may have a foreign or a U.S. issuer. Depositary Receipts will not necessarily be denominated in the same currency as their underlying securities. Generally, ADRs, in registered form, are designed for use in the U.S. securities market, and EDRs, in bearer form, are designated for use in European securities markets. GDRs are tradable both in the United States and in Europe and are designed for use throughout the world. Each Fund may invest up to 10% of its assets in unsponsored Depositary Receipts. The issuers of unsponsored Depositary Receipts are not obligated to disclose material information in the United States, and, therefore, there may be less information available regarding such issuers and there may not be a correlation between such information and the market value of the Depositary Receipts.

Each Fund may invest in the aggregate up to 15% of its net assets (taken at the time of investment) in: (1) Illiquid securities, (2) Rule 144A securities, and (3) loan participation interests. An illiquid asset is any asset which may not be sold or disposed of in the ordinary course of business within seven days at approximately the value at which a Fund has valued the investment.[18]

In accordance with the Exemptive Order, the Funds will not invest in options, futures or swaps. Each Fund's investments will be consistent with its respective investment objective and will not be used to enhance leverage.

Except for ETPs that may hold non-U.S. issues and Depositary Receipts,[19] the Funds will not otherwise invest in non-U.S.-registered issues.

Creations and Redemptions

Each Fund will issue and redeem Shares only in Creation Units at the net asset value (''NAV'') next determined

[16] Such situations and conditions include, but are not limited to, trading halts in the equities or fixed income markets or disruptions in the financial markets generally; operational issues causing dissemination of inaccurate market information; or force majeure type events such as systems failure, natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption or any similar intervening circumstance.

[17] The foreign equity securities in which the Funds may invest will be limited to securities that trade in markets that are members of the Intermarket Surveillance Group (''ISG''), which includes all U.S. national securities exchanges and certain foreign exchanges, or are parties to a comprehensive surveillance sharing agreement with the Exchange. *See* note 27, *infra.*

[18] The Commission has stated that long-standing Commission guidelines have required open-end funds to hold no more than 15% of their net assets in illiquid securities and other illiquid assets. *See* Investment Company Act Release No. 28193 (March 11, 2008), 73 FR 14617 (March 18, 2008), footnote 34. *See also,* Investment Company Act Release No. 5847 (October 21, 1969), 35 FR 19989 (December 31, 1970) (Statement Regarding ''Restricted Securities''); Investment Company Act Release No. 18612 (March 12, 1992), 57 FR 9828 (March 20, 1992) (Revisions of Guidelines to Form N–1A). A fund's portfolio security is illiquid if it cannot be disposed of in the ordinary course of business within seven days at approximately the value ascribed to it by the ETF. *See* Investment Company Act Release No. 14983 (March 12, 1986), 51 FR 9773 (March 21, 1986) (adopting amendments to Rule 2a-7 under the 1940 Act); Investment Company Act Release No. 17452 (April 23, 1990), 55 FR 17933 (April 30, 1990) (adopting Rule 144A under the Securities Act of 1933).

[19] *See* note 17, *supra,* and note 27, *infra.*

after receipt of an order on a continuous basis every day except weekends and specified holidays. The NAV of a Fund will be determined once each business day, normally 4 p.m. Eastern Time. Creation Unit sizes will be 50,000 Shares per Creation Unit. The Trust will issue and sell Shares of each Fund only in Creation Units on a continuous basis, without a sales load (but subject to transaction fees), at their NAV per Share next determined after receipt of an order, on any business day, in proper form pursuant to the terms of the authorized participant agreement (''Participant Agreement'').

The consideration for purchase of a Creation Unit of each Fund generally will consist of either (i) The in-kind deposit of a designated portfolio of securities held by the corresponding master fund (''Deposit Securities'') per each Creation Unit and the Cash Component (defined below), computed as described below or (ii) the cash value of the Deposit Securities (''Deposit Cash'') and the ''Cash Component,'' computed as described below. When accepting purchases of Creation Units for cash, a Fund may incur additional costs associated with the acquisition of Deposit Securities that would otherwise be provided by an in-kind purchaser. Together, the Deposit Securities or Deposit Cash, as applicable, and the Cash Component constitute the ''Fund Deposit,'' which represents the minimum initial and subsequent investment amount for a Creation Unit of any Fund. The ''Cash Component'' is an amount equal to the difference between the NAV of the Shares (per Creation Unit) and the market value of the Deposit Securities or Deposit Cash, as applicable. If the Cash Component is a positive number (*i.e.,* the NAV per Creation Unit exceeds the market value of the Deposit Securities or Deposit Cash, as applicable), the Cash Component shall be such positive amount. If the Cash Component is a negative number (*i.e.,* the NAV per Creation Unit is less than the market value of the Deposit Securities or Deposit Cash, as applicable), the Cash Component will be such negative amount and the creator will be entitled to receive cash in an amount equal to the Cash Component. The Cash Component serves the function of compensating for any differences between the NAV per Creation Unit and the market value of the Deposit Securities or Deposit Cash, as applicable.

The Custodian, through the National Securities Clearing Corporation (''NSCC''), will make available on each business day, immediately prior to the opening of business on the Exchange's Core Trading Session (9:30 a.m., Eastern Time), the list of the names and the required number of shares of each Deposit Security or the required amount of Deposit Cash, as applicable, to be included in the current Fund Deposit (based on information at the end of the previous business day) for a Fund. Such Fund Deposit is subject to any applicable adjustments as described in the Registration Statement, in order to effect purchases of Creation Units of a Fund until such time as the next-announced composition of the Deposit Securities or the required amount of Deposit Cash, as applicable, is made available.

Shares may be redeemed only in Creation Units at their NAV next determined after receipt of a redemption request in proper form by a Fund through the Transfer Agent and only on a business day.

With respect to each Fund, the Custodian, through the NSCC, will make available immediately prior to the opening of business on the Exchange (9:30 a.m. Eastern Time) on each business day, the list of the names and share quantities of each Fund's portfolio securities that will be applicable (subject to possible amendment or correction) to redemption requests received in proper form (as defined below) on that day (''Fund Securities''). Fund Securities received on redemption may not be identical to Deposit Securities.

Redemption proceeds for a Creation Unit will be paid either in-kind or in cash or a combination thereof, as determined by the Trust. With respect to in-kind redemptions of a Fund, redemption proceeds for a Creation Unit will consist of Fund Securities as announced by the Custodian on the business day of the request for redemption received in proper form plus cash in an amount equal to the difference between the NAV of the Shares being redeemed, as next determined after a receipt of a request in proper form, and the value of the Fund Securities (''Cash Redemption Amount''), less a fixed redemption transaction fee and any applicable additional variable charge as set forth in the Registration Statement. In the event that the Fund Securities have a value greater than the NAV of the Shares, a compensating cash payment equal to the differential will be required to be made by or through an authorized participant by the redeeming shareholder. Notwithstanding the foregoing, at the Trust's discretion, an authorized participant may receive the corresponding cash value of the securities in lieu of the in-kind securities value representing one or more Fund Securities.

The creation/redemption order cut-off time for Funds is expected to be 4 p.m. Eastern Time for purchases of Shares. On days when the Exchange closes earlier than normal, a Fund may require orders for Creation Units to be placed earlier in the day.

Net Asset Value

The NAV per Share for each Fund of the Trust will be computed by dividing the value of the net assets of such Fund (*i.e.,* the value of its total assets less total liabilities) by the total number of Shares outstanding, rounded to the nearest cent. Expenses and fees, including the management fees, are accrued daily and taken into account for purposes of determining NAV. The NAV of a Fund will be calculated by the Custodian and determined at the close of the regular trading session on the New York Stock Exchange (ordinarily 4 p.m. Eastern Time) on each day that such exchange is open, provided that fixed-income assets (and, accordingly, a Fund's NAV) may be valued as of the announced closing time for trading in fixed-income instruments on any day that the Securities Industry and Financial Markets Association (or the applicable exchange or market on which a Fund's investments are traded) announces an early closing time. Creation/redemption order cut-off times may also be earlier on such days, but in any event earlier than the NAV calculation time.

In calculating a Fund's NAV per Share, such Fund's investments will generally be valued using market valuations. A market valuation generally means a valuation (i) Obtained from an exchange, a pricing service, or a major market maker (or dealer), (ii) based on a price quotation or other equivalent indication of value supplied by an exchange, a pricing service, or a major market maker (or dealer) or (iii) based on amortized cost. In the case of shares of other funds that are not traded on an exchange, a market valuation means such fund's published NAV per share. The Adviser may use various pricing services, or discontinue the use of any pricing service, as approved by the Funds' Board of Directors from time to time. A price obtained from a pricing service based on such pricing service's valuation matrix may be considered a market valuation. Any assets or liabilities denominated in currencies other than the U.S. dollar will be converted into U.S. dollars at the current market rates on the date of valuation as quoted by one or more sources.

In the event that current market valuations are not readily available or such valuations do not reflect current market value, the Trust's procedures require the Trust's Pricing and Investment Committee to determine a security's fair value if a market price is not readily available.[20] In determining such value the Pricing and Investment Committee may consider, among other things, (i) Price comparisons among multiple sources, (ii) a review of corporate actions and news events, and (iii) a review of relevant financial indicators (*e.g.,* movement in interest rates, and market indices). In these cases, the applicable Fund's NAV may reflect certain portfolio securities' fair values rather than their market prices. Fair value pricing involves subjective judgments and it is possible that the fair value determination for a security is materially different than the value that could be realized upon the sale of the security.

The Shares will conform to the initial and continued listing criteria under NYSE Arca Equities Rule 8.600. The Exchange represents that, for initial and/or continued listing, the Funds will be in compliance with Rule 10A–3 under the Exchange Act,[21] as provided by NYSE Arca Equities Rule 5.3. A minimum of 100,000 Shares for each Fund will be outstanding at the commencement of trading on the Exchange. The Exchange will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time.

Availability of Information

The Funds' Web site (*http://www.spdrs.com*), which will be publicly available prior to the public offering of Shares, will include a form of the prospectus for the Funds that may be downloaded. The Funds' Web site will include additional quantitative information updated on a daily basis, including, for the Funds, (1) Daily trading volume, the prior business day's reported closing price, NAV and mid-point of the bid/ask spread at the time of calculation of such NAV (''Bid/Ask Price''),[22] and a calculation of the premium and discount of the Bid/Ask Price against the NAV, and (2) data in chart format displaying the frequency distribution of discounts and premiums of the daily Bid/Ask Price against the NAV, within appropriate ranges, for each of the four previous calendar quarters. On each business day, before commencement of trading in Shares in the Core Trading Session on the Exchange, the Funds will disclose on their Web site the Disclosed Portfolio as defined in NYSE Arca Equities Rule 8.600(c)(2) that will form the basis for the Funds' calculation of NAV at the end of the business day.[23]

On a daily basis, the Adviser will disclose for each portfolio security or other financial instrument of the Funds and of the Portfolios the following information on the Funds' Web site: Ticker symbol (if applicable), name of security or financial instrument, number of shares or dollar value of financial instruments held in the portfolio, and percentage weighting of the security or financial instrument in the portfolio. The Web site information will be publicly available at no charge.

In addition, a basket composition file, which includes the security names and share quantities required to be delivered in exchange for a Fund's Shares, together with estimates and actual cash components, will be publicly disseminated daily prior to the opening of the NYSE via NSCC. The basket represents one Creation Unit of each Fund.

Investors can also obtain the Trust's Statement of Additional Information (''SAI''), the Funds' Shareholder Reports, and the Trust's Form N–CSR and Form N–SAR, filed twice a year. The Trust's SAI and Shareholder Reports are available free upon request from the Trust, and those documents and the Form N–CSR and Form N–SAR may be viewed on-screen or downloaded from the Commission's Web site at *http://www.sec.gov.* Information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. Information regarding the previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers. Quotation and last sale information for the Shares will be available via the Consolidated Tape Association (''CTA'') high-speed line and, for the ETPs, will be available from the national securities exchange on which they are listed. In addition, the Indicative Optimized Portfolio Value (''IOPV''),[24] which is the Portfolio Indicative Value as defined in NYSE Arca Equities Rule 8.600 (c)(3), will be widely disseminated at least every 15 seconds during the Core Trading Session by one or more major market data vendors.[25] The dissemination of the Portfolio Indicative Value, together with the Disclosed Portfolio, will allow investors to determine the value of the underlying portfolio of the Funds and of the Portfolios on a daily basis and to provide a close estimate of that value throughout the trading day. The intra-day, closing and settlement prices of the portfolio securities are also readily available from the national securities exchanges trading such securities, automated quotation systems, published or other public sources, or on-line information services such as Bloomberg or Reuters.

Additional information regarding the Trust and the Shares, including investment strategies, risks, creation and redemption procedures, fees, portfolio holdings disclosure policies, distributions and taxes is included in the Registration Statement. All terms relating to the Funds that are referred to, but not defined in, this proposed rule change are defined in the Registration Statement.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Funds.[26] Trading in Shares of the Funds will be halted if the circuit breaker parameters in NYSE Arca Equities Rule 7.12 have been reached. Trading also may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) The extent to which trading

[20] The Trust's Pricing and Investment Committee has implemented procedures designed to prevent the use and dissemination of material, non-public information regarding the Portfolios and the Funds.

[21] 17 CFR 240.10A–3.

[22] The Bid/Ask Price of the Funds is determined using the midpoint of the highest bid and the lowest offer on the Exchange as of the time of calculation of the Funds' NAV. The records relating to Bid/Ask Prices will be retained by the Funds and their service providers.

[23] Under accounting procedures followed by the Funds, trades made on the prior business day (''T'') will be booked and reflected in NAV on the current business day (''T+1''). Accordingly, the Funds will be able to disclose at the beginning of the business day the portfolio that will form the basis for the NAV calculation at the end of the business day.

[24] The IOPV calculations will be estimates of the value of the Funds' NAV per Share using market data converted into U.S. dollars at the current currency rates. The IOPV price will be based on quotes and closing prices from the securities' local market and may not reflect events that occur subsequent to the local market's close. Premiums and discounts between the IOPV and the market price may occur. This should not be viewed as a ''real-time'' update of the NAV per Share of the Funds, which will be calculated only once a day.

[25] Currently, it is the Exchange's understanding that several major market data vendors display and/or make widely available Portfolio Indicative Values published on CTA or other data feeds.

[26] *See* NYSE Arca Equities Rule 7.12, Commentary .04.

is not occurring in the securities and/or the financial instruments comprising the Disclosed Portfolio of the Funds; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Trading in the Shares will be subject to NYSE Arca Equities Rule 8.600(d)(2)(D), which sets forth circumstances under which Shares of the Funds may be halted.

Trading Rules

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. Shares will trade on the NYSE Arca Marketplace from 4 a.m. to 8 p.m. Eastern Time in accordance with NYSE Arca Equities Rule 7.34 (Opening, Core, and Late Trading Sessions). The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in NYSE Arca Equities Rule 7.6, Commentary .03, the minimum price variation (''MPV'') for quoting and entry of orders in equity securities traded on the NYSE Arca Marketplace is $0.01, with the exception of securities that are priced less than $1.00 for which the MPV for order entry is $0.0001.

Surveillance

The Exchange intends to utilize its existing surveillance procedures applicable to derivative products (which include Managed Fund Shares) to monitor trading in the Shares. The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable Federal securities laws.

The Exchange's current trading surveillance focuses on detecting securities trading outside their normal patterns. When such situations are detected, surveillance analysis follows and investigations are opened, where appropriate, to review the behavior of all relevant parties for all relevant trading violations.

The Exchange may obtain information via the ISG from other exchanges that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.[27] In addition, the Exchange could obtain information from the U.S. exchanges on which the ETPs are listed and traded.

In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

Information Bulletin

Prior to the commencement of trading, the Exchange will inform its Equity Trading Permit (''ETP'') Holders in an Information Bulletin (''Bulletin'') of the special characteristics and risks associated with trading the Shares. Specifically, the Bulletin will discuss the following: (1) The procedures for purchases and redemptions of Shares in Creation Unit Aggregations (and that Shares are not individually redeemable); (2) NYSE Arca Equities Rule 9.2(a), which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Shares; (3) the risks involved in trading the Shares during the Opening and Late Trading Sessions when an updated Portfolio Indicative Value will not be calculated or publicly disseminated; (4) how information regarding the Portfolio Indicative Value is disseminated; (5) the requirement that ETP Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (6) trading information.

In addition, the Bulletin will reference that the Funds are subject to various fees and expenses described in the Registration Statement. The Bulletin will discuss any exemptive, no-action, and interpretive relief granted by the Commission from any rules under the Exchange Act. The Bulletin will also disclose that the NAV for the Shares will be calculated after 4 p.m. Eastern Time each trading day.

2. Statutory Basis

The basis under the Exchange Act for this proposed rule change is the requirement under Section 6(b)(5)[28] that an exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange pursuant to the initial and continued listing criteria in NYSE Arca Equities Rule 8.600. The Exchange has in place surveillance procedures that are adequate to properly monitor trading in the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable Federal securities laws. The Adviser has implemented a ''fire wall'' with respect to its affiliated broker-dealer regarding access to information concerning the composition and/or changes to the Funds' portfolios. In addition, the Trust's Pricing and Investment Committee has implemented procedures designed to prevent the use and dissemination of material, non-public information regarding the Portfolios and the Funds. The Exchange may obtain information via ISG from other exchanges that are members of ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement. The ETPs held by the Funds will be traded on U.S. national securities exchanges and will be subject to the rules of such exchanges, as approved by the Commission. Except for ETPs that may hold non-U.S. issues, the Funds will not otherwise invest in non-U.S.-registered issues.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that the Exchange will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time. In addition, a large amount of information is publicly available regarding the Funds and the Shares, thereby promoting market transparency. The Funds' portfolio holdings will be disclosed on their Web site daily after the close of trading on the Exchange and prior to the opening of trading on the Exchange the following day. Moreover, the IOPV will be widely disseminated by one or more major market data vendors at least every 15 seconds during the Exchange's Core Trading Session. On each business day, before commencement of trading in Shares in the Core Trading Session on the Exchange, the Funds will disclose on their Web site the Disclosed Portfolio that will form the basis for the Funds' calculation of NAV at the end of the business day. Information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services, and quotation and last sale information will be available via the CTA high-speed line. The Web

[27] For a list of the current members of ISG, *see http://www.isgportal.org*. The Exchange notes that not all components of the Disclosed Portfolio for the Funds may trade on markets that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

[28] 15 U.S.C. 78f(b)(5).

site for the Funds will include a form of the prospectus for the Funds and additional data relating to NAV and other applicable quantitative information. Moreover, prior to the commencement of trading, the Exchange will inform its ETP Holders in an Information Bulletin of the special characteristics and risks associated with trading the Shares. Trading in Shares of the Funds will be halted if the circuit breaker parameters in NYSE Arca Equities Rule 7.12 have been reached or because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable, and trading in the Shares will be subject to NYSE Arca Equities Rule 8.600(d)(2)(D), which sets forth circumstances under which Shares of the Funds may be halted. In addition, as noted above, investors will have ready access to information regarding the Funds' holdings, the IOPV, the Disclosed Portfolio, and quotation and last sale information for the Shares.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of additional types of actively-managed exchange-traded products that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures relating to trading in the Shares and may obtain information via ISG from other exchanges that are members of ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement. In addition, as noted above, investors will have ready access to information regarding the Funds' holdings, the IOPV, the Disclosed Portfolio, and quotation and last sale information for the Shares.

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

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) As the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission shall:

(A) By order approve or disapprove such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2011–85 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2011–85. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–NYSEArca–2011–85 and should be submitted on or before December 28, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[29]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–31335 Filed 12–6–11; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65858; File No. SR–NASDAQ–2011–162]

Self-Regulatory Organizations; NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to the Customer Rebate To Add Liquidity

December 1, 2011.

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 November 29, 2011, The NASDAQ Stock Market LLC (''NASDAQ'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. 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 Exchange proposes to modify Exchange Rule 7050 governing pricing for NASDAQ members using the NASDAQ Options Market (''NOM''), NASDAQ's facility for executing and routing standardized equity and index options. Specifically, NOM proposes to amend the applicability of the Customer

[29] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Rebate to Add Liquidity for the Penny Pilot[3] Options (''Penny Options'').

While changes pursuant to this proposal are effective upon filing, the Exchange has designated these changes to be operative for transactions on December 1, 2011.

The text of the proposed rule change is available on the Exchange's Web site at *http://www.nasdaq.cchwallstreet.com*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

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 Exchange 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

NASDAQ is proposing to modify Exchange Rule 7050 governing the rebates and fees assessed for option orders entered into NOM. Specifically, the Exchange is proposing to allow NOM Participants to qualify for the Customer Rebate to Add Liquidity in Penny Options, at Tier 6, if a NASDAQ member[4] under common ownership with a NOM Participant qualifies for credit under the Investor Support Program (''ISP'') set forth in Rule 7014.[5] The Exchange believes the existing monthly volume thresholds have incentivized firms that route Customer orders to the Exchange to increase Customer order flow to the Exchange. The Exchange desires to continue to encourage firms that route Customer orders to increase Customer order flow to the Exchange by offering an opportunity for NOM Participants to qualify for the Customer rebate in Tier 6 by allowing a NASDAQ member under common ownership with the NOM Participant to qualify for the credit under ISP as required by Tier 6. Common ownership shall mean 75% common ownership between the NOM Participant and the NASDAQ member who qualifies for the ISP.

The Exchange currently pays a Customer Rebate to Add Liquidity in Penny Options based on six volume tiers as follows:[6]

	Monthly volume	Rebate to add liquidity
Tier 1	Participant adds Customer liquidity of up to 24,999 contracts per day in a month.	$0.26
Tier 2	Participant adds Customer liquidity of 25,000—59,999 contracts per day in a month.	0.36
Tier 3	Participant adds Customer liquidity of 60,000—124,999 contracts per day in a month.	0.38
Tier 4	Participant adds Customer liquidity of 125,000 or more contracts per day in a month.	0.40
Tier 5[a]	Participant adds (1) Customer liquidity of 60,000 or more contracts per day in a month, and (2) NOM Market Maker liquidity of 60,000 or more contracts per day in a month.	0.40
Tier 6	Participant adds Customer liquidity of 25,000 or more contracts per day in a month, and (2) the Participant simultaneously qualifies for credit under the Investor Support Program set forth in Rule 7014.	0.37

Currently, a NOM Participant may qualify for Tier 6 by adding Customer liquidity of 25,000 or more contracts per day in a month and also qualifying for credit under the ISP in the equity market. This would be true of a NASDAQ member who conducts both an options and equities business. There are some NASDAQ members today who separate their business in such a way that they conduct activity through separate but related broker-dealers. The Exchange proposes to permit a NOM Participant, who is transacting 25,000 or more Customer contracts per day in a month, to qualify for Tier 6 if a separate but related broker-dealer under 75% common ownership conducts an equities business and qualifies for credit under the ISP.

The Exchange is not otherwise amending the Customer Rebates to Add Liquidity. While changes pursuant to this proposal are effective upon filing, the Exchange has designated these changes to be operative for transactions on December 1, 2011.

2. Statutory Basis

NASDAQ believes that the proposed rule changes are consistent with the provisions of Section 6 of the Act,[7] in general, and with Section 6(b)(4) of the Act,[8] in particular, in that it 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 NASDAQ operates or controls.

NASDAQ believes that it is reasonable to allow NOM Participants with a certain amount of Customer orders, as

[3] The Penny Pilot was established in March 2008 and in October 2009 was expanded and extended through December 31, 2011. *See* Securities Exchange Act Release Nos. 57579 (March 28, 2008), 73 FR 18587 (April 4, 2008) (SR–NASDAQ–2008–026) (notice of filing and immediate effectiveness establishing Penny Pilot); 60874 (October 23, 2009), 74 FR 56682 (November 2, 2009) (SR–NASDAQ–2009–091) (notice of filing and immediate effectiveness expanding and extending Penny Pilot); 60965 (November 9, 2009), 74 FR 59292 (November 17, 2009) (SR–NASDAQ–2009–097) (notice of filing and immediate effectiveness adding seventy-five classes to Penny Pilot); 61455 (February 1, 2010), 75 FR 6239 (February 8, 2010) (SR–NASDAQ–2010–013) (notice of filing and immediate effectiveness adding seventy-five classes to Penny Pilot); and 62029 (May 4, 2010), 75 FR 25895 (May 10, 2010) (SR–NASDAQ–2010–053) (notice of filing and immediate effectiveness adding seventy-five classes to Penny Pilot). *See also* Exchange Rule Chapter VI, Section 5.

[4] All NOM Participants are required to be [sic] members of the NASDAQ Stock Market LLC.

[5] For a detailed description of the Investor Support Program, *see* Securities Exchange Act Release No. 63270 (November 8, 2010), 75 FR 69489 (November 12, 2010) (NASDAQ–2010–141) (notice of filing and immediate effectiveness) (the ''ISP Filing''). *See also* Securities Exchange Act Release Nos. 63414 (December 2, 2010), 75 FR 76505 (December 8, 2010) (NASDAQ–2010–153) (notice of filing and immediate effectiveness); and 63628 (January 3, 2011), 76 FR 1201 (January 7, 2011) (NASDAQ–2010–154) (notice of filing and immediate effectiveness).

[6] The Exchange adopted these monthly volume achievement tiers in September 2011. *See* Securities Exchange Act Release No. 65317 (September 12, 2011) (SR–NASDAQ–2011–127). The Exchange subsequently offered a monthly volume target for NOM Participants that qualified for Tiers 2 and 6. *See* Securities Exchange Act Release No. 65318 (September 12, 2011) (SR–NASDAQ–2011–124). The Exchange amended the monthly tiers to eliminate certain tiers thereafter. *See* Securities Exchange Act Release No. 65381 (September 22, 2011), 76 FR 60103 (September 28, 2011) (SR–NASDAQ–2011–128).

[7] 15 U.S.C. 78f.

[8] 15 U.S.C. 78f(b)(4).

specified in Tier 6, to qualify for a Customer rebate by allowing a related NASDAQ member to qualify for the ISP. NASDAQ is proposing to accommodate NASDAQ members who prefer to separate their equities and options businesses into separate but related broker-dealers.

NASDAQ believes that the proposal to allow NOM Participants to qualify for the Customer Rebate to Add Liquidity in Penny Options at Tier 6, if a NASDAQ member under common ownership with the NOM Participant qualified for the ISP is equitable and not unfairly discriminatory because it would allow NOM Participants to achieve higher rebates and encourage NASDAQ members who conduct an equities business to add significant liquidity as part of the ISP. It would therefore both encourage greater Customer orders into NOM and greater Customer order flow into the NASDAQ's equity market. The goal of the Investor Support Program is to incentivize members to provide liquidity from individual equity investors to the NASDAQ Market Center.[9] Permitting commonly owned NASDAQ members to qualify for a credit under the ISP in order that the related NOM Participant may qualify for the Customer rebate will bring increased Customer order liquidity and will benefit all Exchange members that participate in those markets. NASDAQ Rule 7018(a) already provides incentives for firms to participate in both NASDAQ's equity market and its options market.

The Exchange operates in a highly competitive market comprised of nine U.S. options exchanges in which sophisticated and knowledgeable market participants can and do send order flow to competing exchanges if they deem fee levels at a particular exchange to be excessive or rebate opportunities to be inadequate. The Exchange believes that the proposed rebate scheme is competitive and similar to other rebates and tiers opportunities in place on other exchanges. The Exchange believes that this competitive marketplace materially impacts the rebates present on the Exchange today and substantially influenced the proposal set forth above.

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 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

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act[10] and paragraph (f)(2) of Rule 19b–4[11] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend 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.

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. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2011–162 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2011–162. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2011–162 and should be submitted on or before December 28, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–31334 Filed 12–6–11; 8:45 am]

BILLING CODE 8011–01–P

[9] The Commission has expressed its concern that a significant percentage of the orders of individual investors are executed at over the counter (''OTC'') markets, that is, at off-exchange markets; and that a significant percentage of the orders of institutional investors are executed in dark pools. *See* Securities Exchange Act Release No. 61358 (January 14, 2010), 75 FR 3594 (January 21, 2010) (Concept Release on Equity Market Structure, ''Concept Release''). In the Concept Release, the Commission has recognized the strong policy preference under the Act in favor of price transparency and displayed markets. The Commission published the Concept Release to invite public comment on a wide range of market structure issues, including high frequency trading and un-displayed, or ''dark,'' liquidity. *See also* Mary L. Schapiro, *Strengthening Our Equity Market Structure* (Speech at the Economic Club of New York, Sept. 7, 2010) (''Schapiro Speech,'' available on the Commission Web site) (comments of Commission Chairman on what she viewed as a troubling trend of reduced participation in the equity markets by individual investors, and that nearly 30 percent of volume in U.S.-listed equities is executed in venues that do not display their liquidity or make it generally available to the public).

[10] 15 U.S.C. 78s(b)(3)(A)(ii).

[11] 17 CFR 240.19b–4(f)(2).

[12] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[License No. 09/79–0454]

Emergence Capital Partners SBIC, L.P.; Notice Seeking Exemption Under Section 312 of the Small Business Investment Act, Conflicts of Interest

Notice is hereby given that Emergence Capital Partners SBIC, L.P., 160 Bovet Road, Suite 300, San Mateo, CA 94402, a Federal Licensee under the Small Business Investment Act of 1958, as amended (''the Act''), in connection

with the financing of a small concern, has sought an exemption under Section 312 of the Act and Section 107.730, Financings which Constitute Conflicts of Interest of the Small Business Administration (''SBA'') Rules and Regulations (13 CFR 107.730). Emergence Capital Partners SBIC, L.P. proposes to provide equity financing to Lithium Technologies, Inc., 6121 Hollis Street, Suite 4, Emeryville, CA 94608 (''Lithium''). The financing is contemplated for working capital and general operating purposes.

The financing is brought within the purview of § 107.730(a)(1) of the Regulations because Emergence Capital Partners, L.P. and Emergence Capital Associates, L.P., Associates of Emergence Capital Partners SBIC, L.P., own more than ten percent of Lithium. Therefore, Lithium is considered an Associate of Emergence Capital Partners SBIC, L.P., and this transaction is considered *Financing an Associate*, requiring prior SBA approval.

Notice is hereby given that any interested person may submit written comments on the transaction within 15 days of the date of this publication to the Associate Administrator for Investment, U.S. Small Business Administration, 409 Third Street SW., Washington, DC 20416.

Dated: November 25, 2011.

Sean J. Greene,

Associate Administrator for Investment.

[FR Doc. 2011–31190 Filed 12–6–11; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[License No. 02/02–0647]

Praesidian Capital Opportunity Fund III, LP; Notice Seeking Exemption Under Section 312 of the Small Business Investment Act, Conflicts of Interest

Notice is hereby given that Praesidian Capital Opportunity Fund III, LP, 419 Park Avenue South, New York, NY 10016, a Federal Licensee under the Small Business Investment Act of 1958, as amended (''the Act''), in connection with the financing of a small concern, has sought an exemption under Section 312 of the Act and Section 107.730, Financings which Constitute Conflicts of Interest of the Small Business Administration (''SBA'') Rules and Regulations (13 CFR 107.730). Praesidian Capital Opportunity Fund III, LP proposes to transfer assets between itself and its Associate Praesidian Capital Opportunity Fund III–A, LP to achieve pro rata allocation of investments between the funds.

The financing is brought within the purview of § 107.730(a) of the Regulations because Praesidian Capital Opportunity Fund III, LP and its Associate Praesidian Capital Opportunity Fund III–A, LP propose to ''self deal'' so the transactions that will effect the proposed transfer require prior SBA approval.

Notice is hereby given that any interested person may submit written comments on the transaction, within fifteen days of the date of this publication, to the Associate Administrator for Investment, U.S. Small Business Administration, 409 Third Street SW., Washington, DC 20416.

Dated: November 16, 2011.

Sean J. Greene,

Associate Administrator for Investment.

[FR Doc. 2011–31193 Filed 12–6–11; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

[License No. 09/09–0463]

Tregaron Opportunity Fund I, L.P.; Notice Seeking Exemption Under Section 312 of the Small Business Investment Act, Conflicts of Interest

Notice is hereby given that Tregaron Opportunity Fund I, L.P., 540 University Avenue, Suite 250, Palo Alto, CA 94301, a Federal Licensee under the Small Business Investment Act of 1958, as amended (''the Act''), in connection with the financing of a small concern, has sought an exemption under Section 312 of the Act and Section 107.730, Financings which Constitute Conflicts of Interest of the Small Business Administration (''SBA'') Rules and Regulations (13 CFR 107.730). Tregaron Opportunity Fund I, L.P. proposes to provide debt financing to PIU Management, LLC, 1860 West University Drive, Suite 108, Tempe, AZ 85281.

The financing is brought within the purview of § 107.730(a)(1) of the Regulations because Nelson E. Matthew and M. Todd Collins, members of the Licensee's General Partner, own Tregaron Investors, LLC, which has a greater than ten percent interest in PIU Management, LLC, and therefore this transaction is considered a financing of an Associate requiring prior SBA approval.

Notice is hereby given that any interested person may submit written comments on the transaction, within fifteen days of the date of this publication, to the Associate Administrator for Investment, U.S. Small Business Administration, 409 Third Street SW., Washington, DC 20416.

Dated: November 21, 2011.

Sean J. Greene,

Associate Administrator for Investment.

[FR Doc. 2011–31195 Filed 12–6–11; 8:45 am]

BILLING CODE P

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA–2011–0096]

Employment Network (EN) Report Card

AGENCY: Social Security Administration.

ACTION: Notice of Webinar and National Teleconference Call Listening Sessions—Announcing Two Opportunities for SSA to Hear Public Comments on Draft Revised Ticket to Work Consumer Employment Network Report Card.

SUMMARY: We are soliciting the input of beneficiaries, recipients, advocates, employment networks (ENs), other professionals, and the general public on the draft revised EN Report Card. An EN is a private or public entity that participates in the Ticket to Work (TTW) program and provides employment services, vocational rehabilitation services, or other support services to Social Security Disability Insurance beneficiaries and Supplemental Security Income (SSI) recipients who are disabled. The EN Report Card is available at: *EN Report Card Page.* Disability beneficiaries and SSI recipients who want help with their work goals may use the EN Report Card to help them make informed choices about how to select ENs under the TTW program.

The EN Report Card contains performance information about ENs. This information comes from our records, EN records, and beneficiary and recipient's satisfaction ratings of their EN.

DATES: In December 2011, there will be two listening sessions—(1) On Friday, December 16, 2011, from 1 p.m. to 2:30 p.m. EST, we will invite ENs, advocates, and other interested TTW program partners to participate in a Webinar and (2) on Monday, December 19, 2011, from 3 p.m. to 4:30 p.m. EST, we will invite our beneficiaries, recipients, the public, and those who cannot make the first date to participate in a National Teleconference Call. Go to *http://socialsecurity.gov/work/* beginning December 9, 2011, for information about

how to register for the Webinar or participate in the National Teleconference Call.

FOR FURTHER INFORMATION CONTACT: Bashiru Kamara, Office of Employment Support Programs, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235–6401, (410) 965–9128, for information about this notice. For information on eligibility or filing for benefits, call our national toll-free number, 1–(800) 772–1213 or TTY 1–(800) 325–0778, or visit our Internet site, Social Security Online, at *http://www.socialsecurity.gov.*

SUPPLEMENTARY INFORMATION: The purpose of the Webinar and National Teleconference Call is to provide a forum for us to obtain input on the draft revised EN Report Card. When we launched the report cards earlier this year, we committed to inviting ideas for improving the initial EN Report Card. We have already received some input from ENs, which we have taken into consideration in the proposed draft revision.

We invite participation in the Webinar and National Teleconference Call from people who have an interest in the rules we use to administer the TTW program, people who apply for or receive disability benefits or SSI payments, members of the public, advocates and organizations who represent parties interested in the TTW program, and others.

This is not a request for written comments and we will not respond to comments you send in response to this Notice. We will accept and consider oral comments through the Webinar and National Teleconference Call. We will then determine whether and how we should adjust the EN Report Card.

Michael J. Astrue,

Commissioner of Social Security.

[FR Doc. 2011–31325 Filed 12–6–11; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice 7656]

Notice of Proposal To Extend the Memorandum of Understanding Between the Government of the United States of America and the Government of the Republic of Cyprus Concerning the Imposition of Import Restrictions on Pre-Classical and Classical Archaeological Objects and Byzantine Period Ecclesiastical and Ritual Ethnological Material

The Government of the Republic of Cyprus has informed the Government of the United States of America of its interest in an extension of the Memorandum of Understanding between the Government of the United States of America and the Government of the Republic of Cyprus Concerning the Imposition of Import Restrictions on Pre-Classical and Classical Archaeological Objects and Byzantine Period Ecclesiastical and Ritual Ethnological Material (MOU).

Pursuant to the authority vested in the Assistant Secretary for Educational and Cultural Affairs, and pursuant to the requirement under 19 U.S.C. 2602(f)(1), an extension of this MOU is hereby proposed.

Pursuant to 19 U.S.C. 2602(f)(2), the views and recommendations of the Cultural Property Advisory Committee regarding this proposal will be requested.

A copy of the MOU, the Designated List of restricted categories of material, and related information can be found at the following Web site: *http://exchanges.state.gov/heritage/culprop.*

Dated: November 30, 2011.

Adam Ereli,

Acting Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2011–31426 Filed 12–6–11; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 7658; Cyprus Docket No. DOS–2011–0135; Peru Docket No. DOS–2011–0136]

Notice of Meeting of the Cultural Property Advisory Committee

There will be a meeting of the Cultural Property Advisory Committee January 17–20, 2012, at the Department of State, Annex 5, 2200 C Street NW., Washington, DC Portions of this meeting will be closed to the public, as discussed below.

During the closed portion of the meeting, the Committee will review the proposal to extend cultural property memoranda of understanding with Cyprus, *Memorandum of Understanding Between the Government of the United States of America and the Government of the Republic of Cyprus Concerning the Imposition of Import Restrictions on Pre-Classical and Classical Archaeological Objects and Byzantine Period Ecclesiastical and Ritual Ethnological Material* [Docket No. DOS–2011–0135], and with Peru *Memorandum of Understanding Between the Government of the United States of America and the Government of the Republic of Peru Concerning the Imposition of Import Restrictions on Archaeological Material From Pre-Hispanic Cultures and Certain Ethnological Material From the Colonial Period of Peru* [Docket No. DOS–2011–0136].

An open session to receive oral public comment on these two proposals will be held on Wednesday, January 18, 2012, 9:00 to 11:30 a.m. EST.

Also during the closed portion of the meeting, the Committee will continue its review of a new cultural property request from the Government of the Republic of Belize seeking import restrictions on Pre-Columbian and Spanish Colonial archaeological material. Please see the link to the Public Summary of this request at *http://exchanges.state.gov/heritage/whatsnew.html.*

The Committee's responsibilities are carried out in accordance with provisions of the Convention on Cultural Property Implementation Act (19 U.S.C. 2601 *et seq.*). The text of the Act and subject MOUs, as well as related information, may be found at *http://exchanges.state.gov/heritage/culprop.html.*

If you wish to attend the open session on January 18, 2012, you should notify the Cultural Heritage Center of the Department of State at (202) 632–6301 no later than 5 p.m. (EST) January 3, 2012, to arrange for admission. Seating is limited. When calling, please specify if you have special accommodation needs.

If you wish to make an oral presentation at the open session, you must request to be scheduled and must submit a written text of their oral comments, ensuring that it is received no later than January 3, 2012, 11:59 p.m. (EST) to allow time for distribution to Committee members prior to the meeting. Oral comments will be limited to allow time for questions from members of the Committee. All oral and written comments must relate specifically to the determinations under Section 303(a)(1) (19 U.S.C. 2602) of the Convention on Cultural Property Implementation Act, pursuant to which the Committee must make findings. This statute can be found at the Web site noted above.

You may also send written comments to the Committee. Again, your comments must relate specifically to the determinations under Section 303(a)(1) (19 U.S.C. 2602) of the Convention on Cultural Property Implementation Act, pursuant to which the Committee must make findings. Addresses: Submit all written materials, including the written texts of oral statements, via regular mail, commercial delivery, or hand delivery;

or electronically through the eRulemaking Portal. If more than three (3) pages, 20 paper copies of written materials must be sent to the address below by commercial delivery. If you have access to the internet and wish to make a comment of three or fewer pages regarding this Public Notice, please use the Federal eRulemaking Portal (see below). Our adoption of this procedure facilitates public participation, implements Section 206 of the E-Government Act of 2002, Public Law 107–347, 116 Stat. 2915, and supports the Department of State's ''Greening Diplomacy'' initiative which aims to reduce the State Department's environmental footprint and reduce costs. Please note that *comments by fax or by email will no longer be accepted.*

Please submit comments only one time.

• *Regular Mail or Commercial Delivery.* Cultural Heritage Center (ECA/P/C), SA–5, Fifth Floor, Department of State, Washington, DC 20522–0505.

• *Hand Delivery.* Cultural Heritage Center (ECA/P/C), Department of State, 2200 C Street NW., Washington, DC 20522–0505.

• *Electronic Delivery.* To submit comments electronically, go to the Federal eRulemaking Portal (*http://www.regulations.gov*), enter the Docket No. DOS–2011–0135 for Cyprus or Docket No. DOS–2011–0136 for Peru, and follow the prompts to submit a comment. For further information, see *http://exchanges.state.gov/heritage/whatsnew.html.*

Are Comments Private? No. Comments submitted in electronic form will be posted on the site *http://www.regulations.gov.* Because the comments cannot be edited to remove any identifying or contact information, the Department of State cautions against including any information in an electronic submission that one does not want publicly disclosed (including trade secrets and commercial or financial information that is privileged or confidential pursuant to 19 U.S.C. 2605(i)(1)). The Department of State requests that any party soliciting or aggregating comments received from other persons for submission to the Department of State inform those persons that the Department of State will not edit their comments to remove any identifying or contact information, and that they therefore should not include any information in their comments that they do not want publicly disclosed.

On Closed Meetings: As noted above, portions of the meeting will be closed pursuant to 5 U.S.C. 552b(c)(9)(B) and 19 U.S.C. 2605(h), the latter of which stipulates that ''The provisions of the Federal Advisory Committee Act shall apply to the Cultural Property Advisory Committee except that the requirements of subsections (a) and (b) of section 10 and 11 of such Act (relating to open meetings, public notice, public participation, and public availability of documents) shall not apply to the Committee, whenever and to the extent it is determined by the President or his designee that the disclosure of matters involved in the Committee's proceedings would compromise the government's negotiation objectives or bargaining positions on the negotiations of any agreement authorized by this title.'' The President's designee has made such a determination.

Dated: November 30, 2011.

Adam Ereli,

Acting Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2011–31408 Filed 12–6–11; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 7657]

Notice of Proposal To Extend the Memorandum of Understanding Between the Government of the United States of America and the Government of the Republic of Peru Concerning the Imposition of Import Restrictions on Archaeological Material From Pre-Hispanic Cultures and Certain Ethnological Material From the Colonial Period of Peru

The Government of the Republic of Peru has informed the Government of the United States of America of its interest in an extension of the Memorandum of Understanding between the Government of the United States of America and the Government of the Republic of Peru Concerning the Imposition of Import Restrictions on Archaeological Material from Pre-Hispanic Cultures and Certain Ethnological Material from the Colonial Period of Peru (MOU).

Pursuant to the authority vested in the Assistant Secretary for Educational and Cultural Affairs, and pursuant to the requirement under 19 U.S.C. 2602(f)(1), an extension of this Memorandum of Understanding is hereby proposed.

Pursuant to 19 U.S.C. 2602(f)(2), the views and recommendations of the Cultural Property Advisory Committee regarding this proposal will be requested.

A copy of the MOU, the Designated List of restricted categories of material, and related information can be found at the following Web site: *http://exchanges.state.gov/heritage/culprop.*

Dated: November 30, 2011.

Adam Ereli,

Acting Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2011–31409 Filed 12–6–11; 8:45 am]

BILLING CODE 4710–05–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Generalized System of Preferences (GSP): Extension of Deadlines for Filing Petitions for the 2011 Annual GSP Product and Country Practices Review

AGENCY: Office of the United States Trade Representative.

ACTION: Notice of extension of the deadline for submission of petitions from the public.

SUMMARY: The deadlines for submission of all petitions for consideration as part of the 2011 Annual GSP Product and Country Practices Review are extended to December 30, 2011.

SUPPLEMENTARY INFORMATION: On November 1, 2011, a notice was published in the **Federal Register** (76 FR 67531) announcing the initiation of the 2011 Annual GSP Product and Country Practices Review and setting out the deadlines for the submission of petitions to modify the list of products that are eligible for duty-free treatment under the GSP program and to modify the GSP status of certain GSP beneficiary developing countries because of country practices. The deadline for submission of country practice petitions and for submission of product petitions, except for those requesting competitive need limitation (CNL) waivers, was December 5, 2011. The deadline for submission of petitions requesting CNL waivers was December 16, 2011. This notice extends the deadlines for the submission of all petitions for the 2011 Annual Review to 5 p.m., December 30, 2011. Decisions on which of the petitions that are submitted are accepted for review will be announced in the **Federal Register** at later dates.

FOR FURTHER INFORMATION CONTACT: Tameka Cooper, GSP Program, Office of the United States Trade Representative, 600 17th Street NW., Washington, DC 20508. The telephone number is (202) 395–6971; the fax number is (202) 395–9674, and the email address is *Tameka_Cooper@ustr.eop.gov.*

Public versions of all documents relating to the 2011 Annual Review will be made available for public viewing in docket USTR–2011–0015 at *www.regulations.gov* upon completion of processing and no later than approximately two weeks after the due date.

William D. Jackson,

Deputy Assistant, U.S. Trade Representative for the Generalized System of Preferences and Chair of the GSP Subcommittee of the Trade Policy Staff Committee, Office of the U.S. Trade Representative.

[FR Doc. 2011–31316 Filed 12–6–11; 8:45 am]

BILLING CODE 3190–w2–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Request for Comments on Japan's Expression of Interest in the Proposed Trans-Pacific Partnership Trade Agreement

AGENCY: Office of the United States Trade Representative.

ACTION: Request for comments.

SUMMARY: Japanese Prime Minister Noda recently announced Japan's intention to begin consultations with the Trans-Pacific Partnership (TPP) countries towards joining the TPP negotiations. The Office of the United States Trade Representative (USTR) is assessing Japan's expression of interest in the TPP negotiations in light of the TPP's high standards for liberalizing trade and specific issues of concern to the United States regarding Japanese barriers to agriculture, services, and manufacturing trade, including non-tariff measures. In conducting its assessment, USTR is seeking public comments on these concerns and all other elements related to Japan's interest in the TPP negotiations.

DATES: Written comments are due by noon, January 13, 2012.

ADDRESSES: *Submissions via on-line: http://www.regulations.gov.* For alternatives to on-line submissions please contact Donald W. Eiss at (202) 395–3475.

FOR FURTHER INFORMATION CONTACT: For questions concerning requirements for written comments, please contact Donald W. Eiss at (202) 395–3475. All other questions regarding this notice should be directed to Michael Beeman, Deputy Assistant U.S. Trade Representative for Japan, at (202) 395–5070.

SUPPLEMENTARY INFORMATION:

On December 14, 2009, after consulting with relevant Congressional committees, USTR notified Congress of the President's intent to initiate negotiations on a TPP trade agreement. These negotiations aim to achieve a high-standard, 21st century agreement with a membership and coverage that provides economically significant market access opportunities for America's workers, farmers, ranchers, service providers, and small businesses and that can expand to include additional countries across the Asia-Pacific region. Currently, the negotiations include Australia, Brunei Darussalam, Chile, Malaysia, New Zealand, Peru, Singapore, and Vietnam, as well as the United States. Further information regarding the TPP negotiations can be found at *http://www.ustr.gov/tpp.*

On November 11, 2011, Japanese Prime Minister Yoshihiko Noda announced Japan's intention to begin consultations with the current TPP participating countries towards joining the TPP negotiations. The Chair of the interagency Trade Policy Staff Committee (TPSC) invites interested persons to provide written comments that will assist USTR in assessing Japan's expression of interest in the TPP negotiations in light of the TPP's high standards for liberalizing trade and specific issues of concern to the United States regarding Japanese barriers to agriculture, services, and manufacturing trade, including non-tariff measures. Commenters may address these issues or any other specific barriers affecting U.S. exports to or investment in Japan. The TPSC Chair invites comments on all of these matters, and, in particular, on the following:

(a) Economic costs and benefits to U.S. producers and consumers of eliminating tariffs and eliminating or reducing non-tariff barriers on goods and services traded with Japan.

(b) Treatment by Japan of specific goods (described by HTSUS numbers), including product-specific import or export interests or barriers.

(c) Adequacy of existing customs measures to ensure that only qualifying imported goods from Japan receive preferential treatment, and appropriate rules of origin for goods entering the United States.

(d) Japanese sanitary and phytosanitary measures or technical barriers to trade that should be addressed.

(e) Existing barriers to trade in services between the United States and Japan that should be addressed.

(f) Relevant electronic commerce issues.

(g) Relevant trade-related intellectual property rights issues.

(h) Relevant investment issues.

(i) Relevant competition-related matters.

(j) Relevant government procurement issues.

(k) Relevant environmental issues.

(l) Relevant labor issues.

(m) Relevant transparency issues.

(n) Relevant issues related to innovation and competitiveness, new technologies and emerging economic sectors, the participation of small- and medium-sized businesses in trade, and the development of efficient production and supply chains.

Public Comment: Requirements for Submissions

Persons submitting written comments must do so in English and must identify (on the first page of the submission) ''Japan's Expression of Interest in the Trans-Pacific Partnership Trade Negotiations.'' In order to be assured of consideration, comments should be submitted by noon, January 13, 2012.

In order to ensure the timely receipt and consideration of comments, USTR strongly encourages commenters to make on-line submissions, using the *http://www.regulations.gov* Web site. Comments should be submitted under the following docket: USTR–2011–0018. To find the docket, enter the docket number in the ''Enter Keyword or ID'' window at the *http://www.regulations.gov* home page and click ''Search.'' The site will provide a search-results page listing all documents associated with this docket. Find a reference to this notice by selecting ''Notices'' under ''Document Type'' on the search-results page, and click on the link entitled ''Submit a Comment.'' (For further information on using the *http://www.regulations.gov* Web site, please consult the resources provided on the web site by clicking on the ''Help'' tab.)

The *http://www.regulations.gov* Web site provides the option of making submissions by filling in a comments field, or by attaching a document. USTR prefers submissions to be provided in an attached document. If a document is attached, it is sufficient to type ''See attached'' in the ''Type comment & Upload File'' field. USTR also prefers submissions in Microsoft Word (.doc) or Adobe Acrobat (.pdf). If the submission is in an application other than those two, please indicate the name of the application in the ''Comments'' field.

For any comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters ''BC''. Any page containing business confidential information must be clearly

marked ''BUSINESS CONFIDENTIAL'' on the top of that page. Filers of submissions containing business confidential information must also submit a public version of their comments. The file name of the public version should begin with the character ''P''. The ''BC'' and ''P'' should be followed by the name of the person or entity submitting the comments or reply comments. Filers submitting comments containing no business confidential information should name their file using the character ''P'', followed by the name of the person or entity submitting the comments.

Please do not attach separate cover letters to electronic submissions; rather, include any information that might appear in a cover letter in the comments themselves. Similarly, to the extent possible, please include any exhibits, annexes, or other attachments in the same file as the submission itself, not as separate files.

USTR strongly urges submitters to file comments through *http://www.regulations.gov*, if at all possible. Any alternative arrangements must be made with Donald W. Eiss in advance of transmitting a comment. Mr. Eiss should be contacted at (202) 395–3475. General information concerning USTR is available at *http://www.ustr.gov*.

Douglas Bell,

Chair, Trade Policy Staff Committee.

[FR Doc. 2011–31322 Filed 12–6–11; 8:45 am]

BILLING CODE 3190–W2–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Request for Comments on Mexico's Expression of Interest in the Proposed Trans-Pacific Partnership Trade Agreement

AGENCY: Office of the United States Trade Representative.

ACTION: Request for comments.

SUMMARY: Mexican Economy Secretary Bruno Ferrari recently stated Mexico's intention to begin consultations with the Trans-Pacific Partnership (TPP) countries towards joining the TPP negotiations. The Office of the United States Trade Representative (USTR) is assessing Mexico's expression of interest in the TPP negotiations in light of the TPP's high standards for liberalizing trade and specific issues of concern to the United States regarding Mexican barriers to agriculture, services, and manufacturing trade, including non-tariff measures. In conducting its assessment, USTR is seeking public comments on these concerns and all other elements related to Mexico's interest in the TPP negotiations.

DATES: Written comments are due by noon, January 13, 2012.

ADDRESSES: Submissions via on-line: *http://www.regulations.gov.* For alternatives to on-line submissions please contact Donald W. Eiss at (202) 395–3475.

FOR FURTHER INFORMATION CONTACT: For questions concerning requirements for written comments, please contact Donald W. Eiss at (202) 395–3475. All other questions regarding this notice should be directed to Kent Shigetomi, Director for Mexico, NAFTA, and the Caribbean, at (202) 395–3412.

SUPPLEMENTARY INFORMATION: On December 14, 2009, after consulting with relevant Congressional committees, USTR notified Congress of the President's intent to initiate negotiations on a TPP trade agreement. These negotiations aim to achieve a high-standard, 21st century agreement with a membership and coverage that provides economically significant market access opportunities for America's workers, farmers, ranchers, service providers, and small businesses and that can expand to include additional countries across the Asia-Pacific region. Currently, the negotiations include Australia, Brunei Darussalam, Chile, Malaysia, New Zealand, Peru, Singapore, and Vietnam, as well as the United States. Further information regarding the TPP negotiations can be found at *http://www.ustr.gov/tpp.*

On November 13, 2011, Mexican Economy Secretary Bruno Ferrari stated Mexico's intention to begin consultations with the current TPP participating countries towards joining the TPP negotiations. The Chair of the interagency Trade Policy Staff Committee (TPSC) invites interested persons to provide written comments that will assist USTR in assessing Mexico's expression of interest in the TPP negotiations in light of the TPP's high standards for liberalizing trade and specific issues of concern to the United States regarding Mexican barriers to agriculture, services, and manufacturing trade, including non-tariff measures. Commenters may address these issues or any other specific barriers affecting U.S. exports to or investment in Mexico. The TPSC Chair invites comments on all of these matters, and, in particular, on the following:

(a) Economic costs and benefits to U.S. producers and consumers of eliminating tariffs and eliminating or reducing non-tariff barriers on goods and services traded with Mexico.

(b) Treatment by Mexico of specific goods (described by HTSUS numbers), including product-specific import or export interests or barriers.

(c) Adequacy of existing customs measures to ensure that only qualifying imported goods from Mexico receive preferential treatment, and appropriate rules of origin for goods entering the United States.

(d) Mexican sanitary and phytosanitary measures or technical barriers to trade that should be addressed.

(e) Existing barriers to trade in services between the United States and Mexico that should be addressed.

(f) Relevant electronic commerce issues.

(g) Relevant trade-related intellectual property rights issues.

(h) Relevant investment issues.

(i) Relevant competition-related matters.

(j) Relevant government procurement issues.

(k) Relevant environmental issues.

(l) Relevant labor issues.

(m) Relevant transparency issues.

(n) Relevant issues related to innovation and competitiveness, new technologies and emerging economic sectors, the participation of small- and medium-sized businesses in trade, and the development of efficient production and supply chains.

Public Comment: Requirements for Submissions

Persons submitting written comments must do so in English and must identify (on the first page of the submission) ''Mexico's Expression of Interest in the Trans-Pacific Partnership Trade Negotiations.'' In order to be assured of consideration, comments should be submitted by noon, January 13, 2012.

In order to ensure the timely receipt and consideration of comments, USTR strongly encourages commenters to make on-line submissions, using the *http://www.regulations.gov* Web site. Comments should be submitted under the following docket: USTR–2011–0020. To find the docket, enter the docket number in the ''Enter Keyword or ID'' window at the *http://www.regulations.gov* home page and click ''Search.'' The site will provide a search-results page listing all documents associated with this docket. Find a reference to this notice by selecting ''Notices'' under ''Document Type'' on the search-results page, and click on the link entitled ''Submit a Comment.'' (For further information on using the *http://www.regulations.gov* Web site, please consult the resources provided on the Web site by clicking on the ''Help'' tab.)

The *http://www.regulations.gov* Web site provides the option of making submissions by filling in a comments field, or by attaching a document. USTR prefers submissions to be provided in an attached document. If a document is attached, it is sufficient to type ''See attached'' in the ''Type comment & Upload File'' field. USTR also prefers submissions in Microsoft Word (.doc) or Adobe Acrobat (.pdf). If the submission is in an application other than those two, please indicate the name of the application in the ''Comments'' field.

For any comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters ''BC''. Any page containing business confidential information must be clearly marked ''BUSINESS CONFIDENTIAL'' on the top of that page. Filers of submissions containing business confidential information must also submit a public version of their comments. The file name of the public version should begin with the character ''P''. The ''BC'' and ''P'' should be followed by the name of the person or entity submitting the comments or reply comments. Filers submitting comments containing no business confidential information should name their file using the character ''P'', followed by the name of the person or entity submitting the comments.

Please do not attach separate cover letters to electronic submissions; rather, include any information that might appear in a cover letter in the comments themselves. Similarly, to the extent possible, please include any exhibits, annexes, or other attachments in the same file as the submission itself, not as separate files.

USTR strongly urges submitters to file comments through *http://www.regulations.gov,* if at all possible. Any alternative arrangements must be made with Donald W. Eiss in advance of transmitting a comment. Mr. Eiss should be contacted at (202) 395–3475. General information concerning USTR is available at *http://www.ustr.gov.*

Douglas Bell,

Chair, Trade Policy Staff Committee.

[FR Doc. 2011–31318 Filed 12–6–11; 8:45 am]

BILLING CODE 3190–W2–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Request for Comments on Canada's Expression of Interest in the Proposed Trans-Pacific Partnership Trade Agreement

AGENCY: Office of the United States Trade Representative.

ACTION: Request for comments.

SUMMARY: Canadian Prime Minister Stephen Harper recently stated Canada's intention to begin consultations with the Trans-Pacific Partnership (TPP) countries towards joining the TPP negotiations. The Office of the United States Trade Representative (USTR) is assessing Canada's expression of interest in the TPP negotiations in light of the TPP's high standards for liberalizing trade and specific issues of concern to the United States regarding Canadian barriers to agriculture, services, and manufacturing trade, including non-tariff measures. In conducting its assessment, USTR is seeking public comments on these concerns and all other elements related to Canada's interest in the TPP negotiations.

DATES: Written comments are due by noon, January 13, 2012.

ADDRESSES: *Submissions via on-line: http://www.regulations.gov.* For alternatives to on-line submissions please contact Donald W. Eiss at (202) 395–3475.

FOR FURTHER INFORMATION CONTACT: For questions concerning requirements for written comments, please contact Donald W. Eiss at (202) 395–3475. All other questions regarding this notice should be directed to Mary T. Smith, Director for Canada, at (202) 395–3412.

SUPPLEMENTARY INFORMATION:

On December 14, 2009, after consulting with relevant Congressional committees, USTR notified Congress of the President's intent to initiate negotiations on a TPP trade agreement. These negotiations aim to achieve a high-standard, 21st century agreement with a membership and coverage that provides economically significant market access opportunities for America's workers, farmers, ranchers, service providers, and small businesses and that can expand to include additional countries across the Asia-Pacific region. Currently, the negotiations include Australia, Brunei Darussalam, Chile, Malaysia, New Zealand, Peru, Singapore, and Vietnam, as well as the United States. Further information regarding the TPP negotiations can be found at *http://www.ustr.gov/tpp.*

On November 13, 2011, Canadian Prime Minister Stephen Harper stated Canada's interest in joining the TPP negotiations. The Chair of the interagency Trade Policy Staff Committee (TPSC) invites interested persons to provide written comments that will assist USTR in assessing Canada's expression of interest in the TPP negotiations in light of the TPP's high standards for liberalizing trade and specific issues of concern to the United States regarding Canadian barriers to agriculture, services, and manufacturing trade, including non-tariff measures. Commenters may address these issues or any other specific barriers affecting U.S. exports to or investment in Canada. The TPSC Chair invites comments on all of these matters, and, in particular, on the following:

(a) Economic costs and benefits to U.S. producers and consumers of eliminating tariffs and eliminating or reducing non-tariff barriers on goods and services traded with Canada.

(b) Treatment by Canada of specific goods (described by HTSUS numbers), including product-specific import or export interests or barriers.

(c) Adequacy of existing customs measures to ensure that only qualifying imported goods from Canada receive preferential treatment, and appropriate rules of origin for goods entering the United States.

(d) Canadian sanitary and phytosanitary measures or technical barriers to trade that should be addressed.

(e) Existing barriers to trade in services between the United States and Canada that should be addressed.

(f) Relevant electronic commerce issues.

(g) Relevant trade-related intellectual property rights issues.

(h) Relevant investment issues.

(i) Relevant competition-related matters.

(j) Relevant government procurement issues.

(k) Relevant environmental issues.

(l) Relevant labor issues.

(m) Relevant transparency issues.

(n) Relevant issues related to innovation and competitiveness, new technologies and emerging economic sectors, the participation of small- and medium-sized businesses in trade, and the development of efficient production and supply chains.

Public Comment: Requirements for Submissions

Persons submitting written comments must do so in English and must identify (on the first page of the submission) ''Canada's Expression of Interest in the

Trans-Pacific Partnership Trade Negotiations.'' In order to be assured of consideration, comments should be submitted by noon, January 13, 2012.

In order to ensure the timely receipt and consideration of comments, USTR strongly encourages commenters to make on-line submissions, using the *http://www.regulations.gov* Web site. Comments should be submitted under the following docket: USTR–2011–0019. To find the docket, enter the docket number in the ''Enter Keyword or ID'' window at the *http://www.regulations.gov* home page and click ''Search.'' The site will provide a search-results page listing all documents associated with this docket. Find a reference to this notice by selecting ''Notices'' under ''Document Type'' on the search-results page, and click on the link entitled ''Submit a Comment.'' (For further information on using the *http://www.regulations.gov* Web site, please consult the resources provided on the Web site by clicking on the ''Help'' tab.)

The *http://www.regulations.gov* Web site provides the option of making submissions by filling in a comments field, or by attaching a document. USTR prefers submissions to be provided in an attached document. If a document is attached, it is sufficient to type ''See attached'' in the ''Type comment & Upload File'' field. USTR also prefers submissions in Microsoft Word (.doc) or Adobe Acrobat (.pdf). If the submission is in an application other than those two, please indicate the name of the application in the ''Comments'' field.

For any comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters ''BC.'' Any page containing business confidential information must be clearly marked ''BUSINESS CONFIDENTIAL'' on the top of that page. Filers of submissions containing business confidential information must also submit a public version of their comments. The file name of the public version should begin with the character ''P.'' The ''BC'' and ''P'' should be followed by the name of the person or entity submitting the comments or reply comments. Filers submitting comments containing no business confidential information should name their file using the character ''P,'' followed by the name of the person or entity submitting the comments.

Please do not attach separate cover letters to electronic submissions; rather, include any information that might appear in a cover letter in the comments themselves. Similarly, to the extent possible, please include any exhibits, annexes, or other attachments in the same file as the submission itself, not as separate files.

USTR strongly urges submitters to file comments through *http://www.regulations.gov*, if at all possible. Any alternative arrangements must be made with Donald W. Eiss in advance of transmitting a comment. Mr. Eiss should be contacted at (202) 395–3475. General information concerning USTR is available at *http://www.ustr.gov.*

Douglas Bell,

Chair, Trade Policy Staff Committee.

[FR Doc. 2011–31317 Filed 12–6–11; 8:45 am]

BILLING CODE 3190–W2–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Denial of Motor Vehicle Defect Petition

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

ACTION: Denial of a petition for a defect investigation.

SUMMARY: This notice sets forth the reasons for the denial of a petition Defect Petition (DP) 10–004 submitted by Ms. Lalitha Seetharaman (petitioner) with the assistance of Emerick Bohmer to NHTSA by a letter received on November 5, 2010, under 49 CFR part 552. The petitioners request an investigation of brake failure in model year 2005 Honda Accord Hybrid vehicles.

FOR FURTHER INFORMATION CONTACT: Mr. Derek Rinehardt, Vehicle Controls Division, Office of Defects Investigation, NHTSA, 1200 New Jersey Avenue SE., Washington, DC 20590. Telephone (202) 366–3642. Email *derek.rinehardt@dot.gov*.

SUPPLEMENTARY INFORMATION:

Section—1.0 Introduction

Interested persons may petition NHTSA requesting that the agency initiate an investigation to determine whether a motor vehicle or item of replacement equipment does not comply with an applicable motor vehicle safety standard or contains a defect that relates to motor vehicle safety. 49 CFR 552.1. Upon receipt of a properly filed petition the agency conducts a technical review of the petition, material submitted with the petition, and any additional information. § 552.6. After considering the technical review and taking into account appropriate factors, which may include, among others, allocation of agency resources, agency priorities, and the likelihood of success in litigation that might arise from a determination of a noncompliance or a defect related to motor vehicle safety, the agency will grant or deny the petition. § 552.8.

Petition Review—DP10–004

Section—2.0 Background Information

Ms. Lalitha Seetharaman of Newton, Pennsylvania (sometimes referred to as ''Petitioner''), with the assistance of Mr. Emerick Bohmer, a friend of about a year, filed a petition on November 5, 2010 with NHTSA alleging that she was the driver of a model year (MY) 2005 Honda Accord Hybrid (subject vehicle), VIN JHMCN36425C005487, that experienced a brake failure. The petition states that the incident allegedly occurred on July 23, 2005, while braking and, at the same time, driving over rumble strips adjacent to her lane of travel on highway I–195 in New Jersey. In her petition, Ms. Seetharaman further alleges the brake failure resulted in a crash, fatally injuring her husband, Mr. Gautama Saroop (the front seat passenger), severely injuring the petitioner (the driver), and severely injuring the two occupants of a MY 1990 Ford Tempo vehicle that was struck by the petitioner's vehicle.

In March of 2005, four months prior to the crash, Ms. Seetharaman purchased the subject vehicle as a birthday present for her husband. On the evening of the crash, Ms. Seetharaman, who also owns a 1999 Mazda Protégé as her normal usage vehicle, was driving the subject vehicle with her husband as the passenger from their home in Newtown, PA to Bellmawr, NJ. The events leading to the crash and the crash itself are described by Ms. Seetharaman in the petition document and in a vehicle owner questionnaire (VOQ) 10329383 submitted to NHTSA. The two documents contain similar summaries of the event. The Defect Petition, at page 39, states:

> While traveling East on I–195, I saw that a Police Officer had a vehicle pulled over on the right shoulder of the highway. I moved over to the left lane in order to decrease any chance of an accident with the stopped vehicles. When I did, I crossed onto the rumble strip on the left side of the highway. I applied the brakes while on the rumble strip to bring the vehicle under control, and nothing happened (no brakes) and the vehicle accelerated uncontrollably.
>
> I tried to bring the vehicle back on the highway. Both my husband and myself were hoping something would bring the vehicle under control. In a desperate attempt to bring the vehicle under control my husband pulled the emergency brake. Upon pulling the

emergency brake, instead of helping to slow down the vehicle, the vehicle further became uncontrollable and started moving in the wrong direction. I clearly remember in the last moments before the vehicle went out of control screaming 'Brakes! Brakes!'

The vehicle then began to go sideways before going across the grass median. I later learned from the police report that we went into the westbound lane of the highway where we were immediately struck on the passenger side by a vehicle-traveling west. The vehicle that hit us was then struck from behind by another vehicle.[1]

In addition to Ms. Seetharaman's verbatim recollection of events of the crash, in multiple interviews with the petitioner, she supplements the account of the crash with the following information:

(1) Ms. Seetharaman was in a coma for 4 months as a result of injuries suffered during the crash.

(2) The delay in filing the petition was due to the extensive recuperation period from the injuries Ms. Seetharaman suffered in the accident.

(3) The subject vehicle had not been serviced since Ms. Seetharaman and her husband took ownership of the vehicle 4 months prior to the crash.

(4) Ms. Seetharaman stated that the reason for braking was a result of seeing the police traffic stop. There was no traffic immediately in front of her.

(5) She was not using the cruise control feature at the time of the incident.

(6) Mr. Saroop (the petitioner's husband) was the primary driver of the subject vehicle prior to the crash and used the subject vehicle primarily to travel back and forth to work. The petitioner was operating the vehicle the day of the crash because her husband had an eye stigmatism and didn't see well in the evenings.

(7) The petitioner was charged with reckless driving however the charges were dismissed.

(8) In 2006, the subject vehicle involved in the crash was disposed of by Ms. Seetharaman's insurance company.

Section 3.0—Police Accident Report Based Crash Details

As supporting documentation, the petitioner submitted to the NHTSA a copy of the New Jersey State Police accident report.[2] Based on the report, the crash occurred on July 23, 2005 at 5:48 p.m. near mile post 2.3 on Interstate I–195 in Hamilton Twp, New Jersey. At the time of crash, the weather was approximately 84 °F and clear.[3] The first responding officer, who was just completing a traffic stop, witnessed the crash and the sequence of events just prior to the crash. An account of the crash appears in the police accident report prepared by the responding police officer:

On this date I was on a routine traffic stop on 1–195 eastbound at milepost 2.5 at 1745 hours. As I completed the traffic stop and proceeded to my patrol vehicle SPA288, I witnessed Vehicle #1 [Petitioner's vehicle] traveling eastbound on 1–195 towards my location out of control. Vehicle #1 swerved over the left side rumble strip came back into the left lane, accelerated back over the left side rumble strip off the roadway through the grass median (shrubbery) and into westbound traffic. Immediately as Vehicle #1 entered the left lane of westbound traffic it was struck on the passenger side by Vehicle #2. On impact, Vehicle #1 overturned and Vehicle #2 was struck from behind by Vehicle #3. The accident occurred at 1748 hours and traffic was moderate heading eastbound and westbound. There were no other vehicles traveling in the area of Vehicle #1 when it left the roadway. I immediately notified communications while moving my vehicle closer to the accident scene. The driver and passenger in Vehicle #1 were unconscious and unresponsive. The driver and passenger in Vehicle #2 were also unconscious and unresponsive. The driver of Vehicle #3 exited her vehicle and I advised her to remain on the shoulder of roadway. Emergency Services were dispatched to the scene immediately.

Figure 1 contains a graphical account of the crash as noted by the responding officer in the police accident report.

[1] The petition document titled ''INBC–DP10004–45020P.pdf can be found at *http://www-odi.nhtsa.dot.gov/defects/* in the public file of this Defect Petition Analysis, DP10–004.

[2] The police accident report can be found at *http://www-odi.nhtsa.dot.gov/defects/* in the public file of this Defect Petition Analysis, DP10–004, on pages 25 through 33 of the defect petition document titled ''INBC–DP10004–45020P.pdf''.

[3] Historical Information based on weather conditions at the crash location documented on *http://www.wunderground.com.* Interviewing the petitioner she also noted the conditions were clear on the day of the incident.

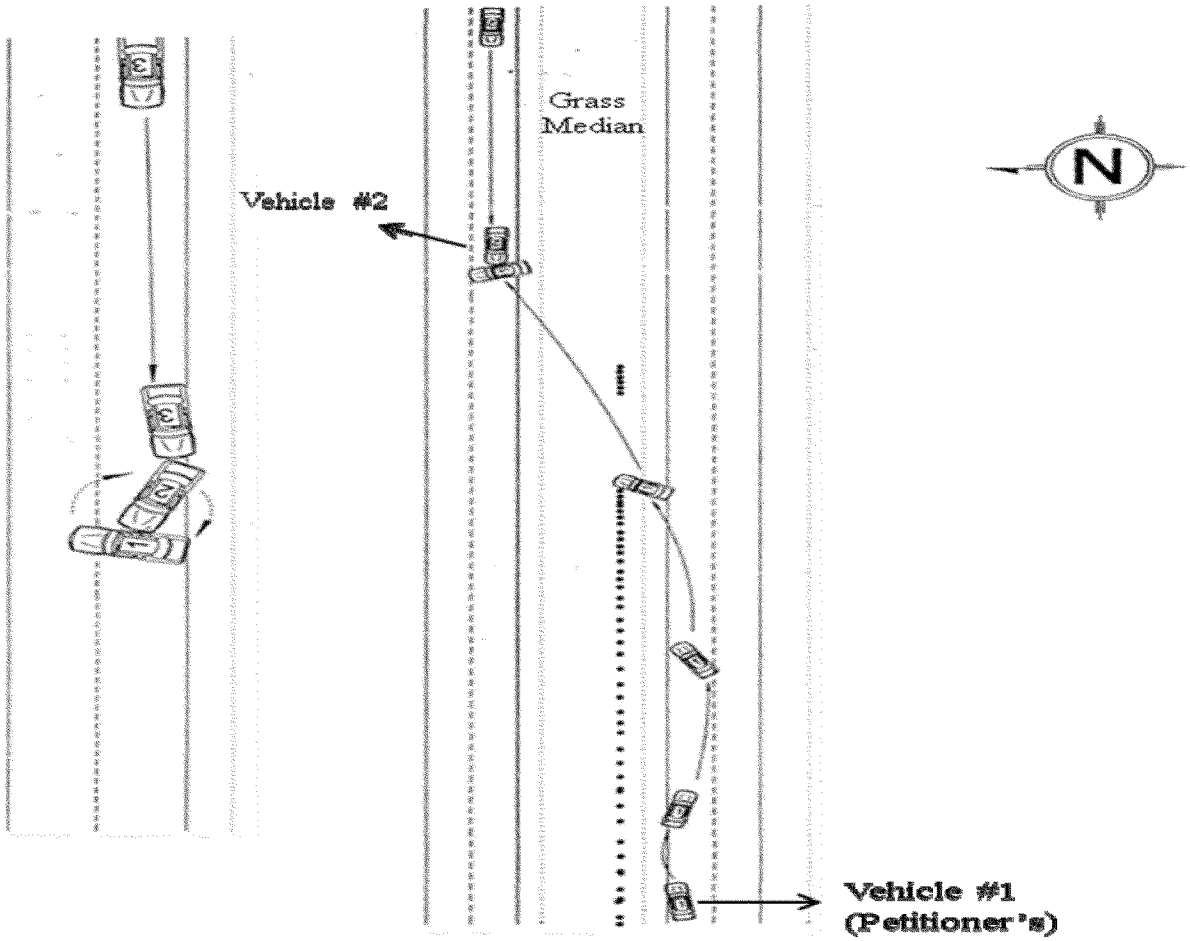

Figure 1

Section 4.0—Petition Allegation Discussion

In DP10–004, the petitioner identifies MY 2005 Honda Accord Hybrids as the subject vehicles and requests that NHTSA investigate and recall all Honda Civic Hybrid vehicles for a braking defect alleged to be similar to the defect addressed by recall 10V–039 (MY 2010 Toyota Prius vehicles).[4] In the defect petition, the petitioner makes six allegations, each of which is individually addressed herein.

Allegation 1: The Petitioner Alleges That She ''Applied the Brakes While on the Rumble Strips To Bring the Vehicle Under Control, and Nothing Happened (No Brakes).'' The Petitioner Further Alleges ''the Vehicle Accelerated Uncontrollably''[5]

As the crash occurred in July of 2005 and the vehicle was indisposed at the time the petition was filed nearly 5 years after the crash, NHTSA was not able to conduct a vehicle inspection of the subject vehicle. NHTSA conducted vehicle testing on an exemplar subject vehicle at its Vehicle Research and Testing Center (VRTC) in East Liberty, OH. NHTSA could not replicate a brake failure similar to that described by the petitioner in testing of an exemplar vehicle. Results of the testing are summarized in Section 6.0 of this report. Complete testing results are also available in the public file of this defect petition.

With regard to the petitioner's association of the incident she experienced and the defect condition addressed by Toyota in recall 10V–039, significant differences are noted between the subject and recalled vehicles: (1) The vehicles use fundamentally different hybrid systems, including different hybrid and brake system architectures and brake control logic; (2) the condition addressed by Toyota in recall 10V–039 was associated with slight differences in brake line pressure caused by switching of the brake hydraulic circuit from linear to hydraulic mode following antilock brake (ABS) activation; and (3) the brake hydraulic circuit in the subject vehicles does not change when ABS is activated. The Toyota Prius braking complaints associated with the condition addressed by recall 10V–039 described symptoms related to brief disruptions in expected braking decelerations following ABS activation. None of the associated

[4] Details of recall 10V–039 can be found at *http://www-odi.nhtsa.dot.gov/recalls/recallsearch.cfm.*

[5] Allegation noted by the petitioner on page 39 of the defect petition document titled ''INBC–DP10004–45020P.pdf'' in the public file of DP10–004. The file can be found at *http://www-odi.nhtsa.dot.gov/defects/*

Toyota complaints alleged an uncontrollable acceleration event.

Allegation 2: The Petitioner Alleges That the Police Accident Report Shows That, Aside From the Alleged Defect in the Subject Vehicle, There Were No Other Contributing Factors to the Crash [6]

The police accident report does not mention or suggest a vehicle-based defect existed or contributed to the subject vehicle's crash. Rather, in the Police Accident report,[7] the investigating police officer, who was also a witness to the crash, states:

> As I completed the traffic stop and proceeded to my patrol vehicle SPA288, I witnessed Vehicle #1 traveling eastbound on 1–195 towards my location out of control. Vehicle #1 swerved over the left side rumble strip~ came back into the left lane, accelerated back over the left side rumble strip off the roadway through the grass median (shrubbery) and into westbound traffic. Immediately as Vehicle #1 entered the left lane of westbound traffic it was struck on the passenger side by Vehicle #2. On impact, Vehicle #1 overturned and Vehicle #2 was struck from behind by Vehicle #3. The accident occurred at 1748 hours and traffic was moderate heading eastbound and westbound. There were no other vehicles traveling in the area of Vehicle #1 when it left the roadway.

The police accident report notes that the petitioner's vehicle ''swerved over the left side rumble strip~ came back into the left lane, accelerated back over the left side rumble strip off the roadway.'' This statement suggests the vehicle may have been out of control ('swerved') prior to traveling over the rumble strips.

Allegation 3: The Petitioner Asserts That the Honda's Integrated Motor Assist (IMA) Technology Used in the Honda Accord Hybrid and the Honda Civic Hybrid Have Identical Designs [8]

The IMA technologies used by Honda in the Accord Hybrid and Civic Hybrid models have some similarities; however, several differences exist with regard to brake control. In fact, within the Honda Civic Hybrid model, differences exist between the first generation (MY 2003–2005) and the second generation (MY 2006–2011). All of Honda Hybrid vehicles discussed in this defect petition analysis utilizes a different braking strategy than that in the Toyota Prius.

Braking Function in Honda Hybrid Vehicles

Because the petitioner alleged a braking failure prior to the crash, this section will give a brief overview of the brake system function during normal and ABS braking events.

Braking Function in a Non-ABS Braking Event

The braking strategy for all three Honda Hybrid models have similarities incorporating regenerative braking (the electric motor is used as a generator to supplement braking while recharging the vehicle's batteries), in addition to traditional hydraulic braking. The models differ in the integration of the regenerative braking system into the overall braking system. These differences are as follows:

1. Honda Accord Hybrid (Manufactured Only During MY 2005–2007)

When the accelerator pedal is off (not depressed), a regenerative braking force equivalent to internal combustion engine braking is generated (Accelerator off regeneration). When the brake is operated, the regenerative braking force is increased proportional to operation amount (master cylinder hydraulic pressure). Regenerative braking force varies according to vehicle speed. The maximum regenerative deceleration during brake on regeneration varies according to the amount of brake operation (master cylinder hydraulic pressure).

2. Honda Civic Hybrid 1st Generation (MY 2003–2005)

When the accelerator pedal is off, the regenerative braking force equivalent to the engine brake is generated (Accelerator off regeneration). Differing from the Honda Accord Hybrid, when the brake is operated, regenerative braking force is increased when brake lamp switch is on (Brake on regeneration). Regenerative braking force varies according to vehicle speed.

3. Honda Civic Hybrid 2nd Generation (MY 2006–2011)

When the accelerator pedal is off, the regenerative braking force equivalent to the engine brake is generated (Accelerator off regeneration). Like the Civic 1st generation, when the brake pedal is operated, regenerative braking force is increased when the brake lamp switch is on. (Brake on regeneration). However, this model differs from the Accord and 1st generation Civic models in that the regenerative braking force is increased according to the amount of brake operation, and hydraulic braking force equivalent to regenerative braking force is controlled in the direction of reduction to generate braking force required by the driver by both regeneration and hydraulic braking (Cooperative regeneration). The regenerative braking force varies according to vehicle speed.

Braking Function in an ABS Braking Event

Traveling over rumble strips while braking, as the petitioner alleges preceded her crash, may cause wheel slip and activate the ABS (as was shown in testing conducted by NHTSA summarized in Section 6.0 of this document). However, in all Honda Hybrids referenced herein, the reduction in braking force is designed to be an insignificant amount when the ABS is activated. The hydraulic braking, which is controlled by the ABS, is still present. As previously discussed, the brake hydraulic circuit is not changed/switched when ABS is activated, which was the condition addressed by the Prius recall. The petitioner alleges that, in her incident, there were ''no brakes'' and the vehicle accelerated uncontrollably. The petitioner's allegation of a ''loss'' of braking and subsequent acceleration is at odds with NHTSA testing and the design of the braking system in the subject vehicles.

1. Honda Accord Hybrid (MY 2005–2007)

When the ABS is activated, the regenerative braking force is reduced and the ABS is controlled by hydraulic braking. While the ABS is active, the reduced regenerative braking force is maintained until the brake is released/vehicle stops. The reduction of regenerative braking force amounts to a relatively small portion of the total brake force (hydraulic braking + regenerative braking). The hydraulic braking system is very similar to the traditional hydraulic system in the standard Accord models.

2. Honda Civic Hybrid 1st Generation (MY 2003–2005)

Differing from the Accord Hybrid, when the ABS is activated, the regenerative braking is stopped and the ABS is controlled by hydraulic brake. While the ABS is working, the stopped regenerative braking condition is maintained until the brake is released/vehicle stops. When a certain brake

[6] Allegation noted by the petitioner on page 6 of the defect petition document titled ''INBC–DP10004–45020P.pdf'' in the public file of DP10–004. The file can be found at *http://www-odi.nhtsa.dot.gov/defects/.*

[7] The police officer's full statement can be found on page 27 of a document titled ''INBC–DP10004–45020P.pdf'' at *http://www.odi.nhtsa.dot.gov/defects/* in the public file of this Defect Petition Analysis, DP10–004.

[8] Allegation noted by the petitioner on page 2 of the defect petition document titled ''INBC–DP10004–45020P.pdf'' in the public file of DP10–004. The file can be found at *http://www-odi.nhtsa.dot.gov/defects/.*

pedal effort is maintained while ABS is active, the total braking force is reduced by a relatively small amount equal to the reduction of regenerative braking force.

3. Honda Civic Hybrid 2nd Generation (MY 2006–2011)

When the ABS is activated, the brake ON regenerative braking ceases and the accelerator off regenerative braking force is reduced. The ABS is controlled by the hydraulic braking system. While the ABS is active, the reduced regenerative braking force is maintained until the brake is released/vehicle stops. When a certain brake pedal effort is maintained while ABS is active the total braking force is reduced by a relatively small amount equal to the reduction of the regenerative braking force.

In summary, all the Honda Hybrid models discussed herein maintain traditional hydraulic braking functionality in the case of non-ABS braking events or ABS braking events. The reduction or cessation (in the case of the 1st generation Honda Civic) in regenerative braking is a small portion of the total braking force. As stated and explained above, the petitioner's allegation of a ''loss'' of braking is inconsistent with the design of the braking system in the subject vehicles.

Allegation 4: The Petitioner Asserts That the Number of Honda Complaints as Compared to the Number of Toyota Prius Complaints Received by NHTSA Is Lower Because the Braking Problem Has Been Largely Ignored by Honda Hybrid Owners Due to the Lack of Media Coverage [9]

The Office of Defects Investigation (ODI) opened investigation PE10–006 on February 3, 2010 to investigate consumer allegations of momentary disruptions in expected vehicle decelerations during brake applications while traveling over a road disturbance such as a pothole or a bump in the road in 3rd generation (MY 2010) Toyota Prius Hybrid vehicles. The number of Prius complaints before the media coverage is more than all of the Honda Hybrid models combined. This fact does not support the petitioner's allegation that media coverage increased the number of Prius complaints and that the lack of media coverage explains the small number of the Honda Hybrid models complaints.

As noted in Table 1, prior to February 3, 2010 (before PE10–006 was opened) and before there was any significant media coverage regarding the braking defect (highlighted in NHTSA Recall number 10V–039) in Toyota Prius vehicles, there was only one (1) similar complaint to NHTSA involving a Honda Hybrid vehicle (Honda Civic Hybrid) that was similar in nature to the Toyota Prius braking issue. During this time, there were no similar complaints related to the subject vehicles (Honda Accord Hybrids).

	Complaints Received by NHTSA prior to 2/3/2010				
		Vehicle Population	"Loss" of brakes while braking over a road disturbance or slippery road surfaces		
			Complaints to NHTSA	Complaint Rates (/100K)	Alleged Crashes
Honda	Honda Accord Hybrid (MY 2005 - 07)	27,166	0	**0.0**	0
Honda	Honda Civic Hybrid 1st Gen (MY 2003 - 05)	82,294	0	**0.0**	0
Honda	Honda Civic Hybrid 2nd Gen (MY 2006 -10)	122,657	1	**3.3**	0
Toyota	Recalled Toyota Prius 3rd Generation (MY 2010)	148,683	124	**83.4**	4

Table 1

By contrast, before February 3, 2010, NHTSA received 124 complaints related to braking in MY 2010 Toyota Prius vehicles. The Honda Hybrid vehicles had up to 7 years of field exposure but only one complaint prior to the recall of the Toyota Prius.

The effect of publicity was not reflected in complaints to NHTSA until February 3, 2010. Subsequently, over a two day period February 3rd and 4th, over 700 complaints were received by the NHTSA related to braking issues in MY 2010 Toyota Prius vehicles.

Allegation 5: The Petitioner Asserts That Technical Service Bulletin (TSB) 05038 [10] *May Be Related to the Alleged Brake Failure Incident That Is the Subject of the Petition. Further, the Petitioner Also Suggests That if Honda Was Aware of a Problem With the Hybrid Braking System on its Vehicle Prior to the Issuance of TSB 05038 This Would Be a Violation of the Tread Act* [11]

By way of background, in November of 2005, Honda mailed owner notification letters of a product update in MY 2005 Honda Accord Hybrid vehicles identified as TSB 05038. In the letter, Honda states:

> The problem: The computer software in your vehicle needs to be updated. Without the update, a technician, using a scan tool in generic mode on your vehicle could cause damage to your vehicle's electric motor battery and/or cause the engine computer to falsely signal engine misfires.

The problem addressed by TSB 05038 could occur if a scan tool was previously used by a service technician.

[9] Allegation noted by the petitioner on page 5 of the defect petition document titled ''INBC–DP10004–45020P.pdf'' in the public file of DP10–004. The file can be found at *http://www-odi.nhtsa.dot.gov/defects/*.

[10] See public file of DP10–004 at *http://www-odi.nhtsa.dot.gov/defects/* for copy of the TSB.

[11] Allegation noted by the petitioner on page 3 of the defect petition document titled ''INBC–DP10004–45020P.pdf'' in the public file of DP10–004. The file can be found at *http://www-odi.nhtsa.dot.gov/defects/*.

In multiple ODI interviews with the petitioner, the petitioner noted that the vehicle was purchased on March 23, 2005, and that, until the crash on July 23, 2005, the vehicle was not taken to a dealer for routine maintenance or any other repairs. Thus, a scan tool was not used between the time the petitioner and her husband took ownership of the vehicle and the crash. In addition, the potential consequences of the TSB condition are not related to the defect alleged by the petitioner or any other aspect of vehicle brake system performance.

The defect petition notes and interviews with the petitioner confirm that there were no signs of an engine misfire condition or any warning of a low battery condition. Based on all of these factors, it is unlikely that the conditions described in TSB 05038 have relevance to the crash on July 23, 2005.

The defect petition suggests that the Transportation Recall Enhancement, Accountability, and Documentation Act, commonly referred to as the TREAD Act, is what obligates the manufacturer to report a TSB to NHTSA. In fact, the reporting requirement for TSBs predates the TREAD Act [12]. In conformance with the regulation, Honda submitted a copy of the TSB to NHTSA in November of 2005.

Allegation 6: Prior to the Petitioner's Crash on July 23, 2005, NHTSA Had Received Two Complaints Regarding Braking Problems With Honda Hybrid Vehicles When Braking on Bump, or Uneven Surfaces (ODI# 10315534, & 10311198). In the Following Months, There Were Two Additional Complaints (ODI# 10306871, & 10307268), One of Which Resulted in a Crash. NHTSA Is Uncertain if Honda Had Knowledge of the Fatal Crash in a Fifth Complaint Belonging to the Petitioner (ODI# 10329383) [13]

This section separately reviews each of these five complaints.

ODI# 10315534

On March 3, 2010 NHTSA received this complaint, involving a MY 2003 Honda Civic Hybrid. The incident date noted in this complaint was January 1, 2003, nearly 7 years before the complaint was filed with the NHTSA. Also, contrary to the petitioner's assertion that the complaint was received by the NHTSA prior to her crash in 2005, the complaint was filed with the NHTSA more than 4 years after the petitioner's crash.

The complaint description stated:

> Braking while on a bumpy road occasionally results in a delay of the braking action. We thought this was part of the ABS system, but there was no ABS ''feel'' in the brake pedal. With the Toyota problem description, we now feel it may be a similar problem. Only occurs while braking on rough pavement.

ODI# 10311198

On February 17, 2010 NHTSA received this complaint, involving a MY 2005 Honda Civic Hybrid. The incident date noted in this complaint was June 8, 2005, more than 4 years before the complaint was filed with the NHTSA. Also, contrary to the petitioner's assertion that the complaint was received by the NHTSA prior to her crash in 2005, the complaint was filed with the NHTSA more than 4 years after the petitioner's crash.

The complaint description stated:

> The contact owns a 2005 Honda Civic Hybrid. The contact stated as he is coming to a stop and stepped on his brakes or hit a bump he loses his brakes it felt as if there is no brakes. The vehicle was taken to the dealer and contact was told this is normal. The manufacture was also call and inform contact they will give him a return call but they never did.* * *The consumer stated the problem has been persistent since the vehicle was purchased and still continues.

ODI# 10306871

On February 6, 2010, NHTSA received this complaint, involving a MY 2003 Honda Civic Hybrid. The incident date noted in the complaint was August 15, 2005, more than 4 years before the complaint was filed with the NHTSA. Also, contrary to the petitioner's assertion that the complaint was received by the NHTSA prior to her crash in 2005, the complaint was filed with the NHTSA more than 4 years after the petitioner's crash.

The complaint description stated:

> I wish to make notice to NHTSA that the issue in braking for Prius vehicles would seem to me to be related, in general, to hybrids, built in Japan, and not just Toyota. I have an '03 Honda Civic hybrid, and it has issues. It has been in an accident back in '05 and what was the issue? Braking! The car went out of control under heavy braking (though all these vehicles have 4 whl ABS) in an ''animal-avoidance'' attempt. I ended up careening side-wise sliding until colliding with a utility pole, at the passenger side ''a'' pillar. Raccoon didn't survive. I had noticed on several occasions that the abs, upon encountering bumps or jolts of any significant degree, will ''cut-out'' momentarily, and further, the ''engine-braking'' associated with the hybrid motor-generator also cuts out and does not return (until after the stop has been concluded using only the available braking methods left) (no abs ''chatter'' is to be observed in these scenarios). The phenomenon is definitely reproducible; I have often found that such bumps are virtually unavoidable on certain places I commonly drive near my home. It is such an issue that I have learned to try to compensate for that when driving over these bumpy places, but one can't compensate when encountering same in a new, unfamiliar area/situation.
>
> Please do look into the concept that it could be more of a Japanese made ABS system-fault, (possibly including engine-regenerative braking system) rather than a Toyota-only thing. I would request that my note be acknowledged, myself be contacted so as to provide any further info needed, and my contact info be retained so as to be contacted regarding subsequent resolutions, ie recalls/legal cases/settlements. By the way, I had not ''collision'' insurance, thus I paid to repair my HCH [Honda Civic Hybrid] post that accident. I still drive the car today, though anyone would have called it ''totaled''. Tires—were the same set installed as OEM, were at least 60% even at 51k, they readily wore out afterwards-post-acc alignment issues.

ODI made several unsuccessful attempts to contact this complainant in order to obtain additional information on the incident. After finally making contact with the consumer approximately 5 months after the initial attempt, the consumer stated that he did not recall many of the incident's details. The complaint stated that, preceding the alleged crash, the driver was making an ''animal avoidance'' maneuver that resulted in the vehicle careening side-ways and sliding until eventually colliding with a utility pole. The complaint does not mention the vehicle travelling over a road disturbance or road conditions that may have trigged the ABS to function. In this incident, ODI has no basis upon which to determine whether the alleged crash could have involved a brake related failure.

ODI# 10307268

This complaint was filed with NHTSA on 2/7/2010 involving a MY 2005 Honda Civic hybrid. The incident date noted in the complaint was 9/01/2005 was noted, more than 4 years before the complaint was filed with the NHTSA. Also, contrary to the petitioner's assertion that the complaint was received by the NHTSA prior to her crash in 2005, the complaint was filed

[12] Technical Service Bulletins fit into a category of communications sent to more than one manufacturer, distributor, dealer, lessor, lessee, or purchaser regarding any defect, regardless of safety-relatedness, in a vehicle or item of equipment. Prior to 2002, the requirement to submit this information was found in 49 CFR 573.8. With the passage of the TREAD Act, the § 573.8 requirement was moved from Part 573 to Part 579. 67 FR 45873, 45824 (July 10, 2002). It now appears at 49 CFR 579.5.

[13] Allegation noted by the petitioner on page 3 of the defect petition document titled ''INBC–DP10004–45020P.pdf'' in the public file of DP10–004. The file can be found at *http://www-odi.nhtsa.dot.gov/defects/*.

with the NHTSA more than 4 years after the petitioner's crash.

The complaint description stated:

There was a ''momentary loss of braking capability while traveling over an uneven road surface, pot hole or bump.''

ODI was able to contact the consumer for further information regarding the incident. In response to a survey sent by ODI to obtain more details about the incident described in the complaint, the complainant stated: ''I am still driving the car and have not had any problems with the brakes, so it probably is not a problem. Sometimes it feels like the car will not stop, but it always does.''

ODI# 10329383

On May 8, 2010, the petitioner filed this complaint. The details of this complaint are discussed in detail Section 2 and Section 3 of this document.

In summary, the petitioner's assertion that the complaints reviewed in this section were received by the NHTSA prior to or shortly after her incident is not accurate. Rather the complaints were received by the NHTSA years after the incident dates and just after the opening of the Toyota Prius investigation PE10–006.

Section 5.0—NHTSA Field Experience Analysis

[1]. Petitioner Identified Complaints to NHTSA

As supporting information, the petition included twenty four complaints filed with NHTSA as summarized in Table 2:

Petitioner Referenced Complaints				
Model	Complaints	Complaint Nature		
		Brake Related with Reference of Road Disturbance while Braking (Pothole, etc.)	Other Brake Related	Non Brake Related
Honda Accord Hybrid (MY 2005 - 07)	2	2	0	0
Honda Civic Hybrid 1st Gen (MY 2003 - 05)	11	7	2	2
Honda Civic Hybrid 2nd Gen (MY 2006 -10)	11	2	6	3
Total	**24**	**11**	**8**	**5**

Table 2

Analysis of these complaints reveals that only two involve MY 2005 Honda Accord Hybrid vehicles. One of the two is the complaint filed by the petitioner. Eleven of the total 24 complaints allege an issue with the brakes not performing as expected while braking over a road disturbance (*e.g.,* a pothole, bump or railroad tracks,). The statements regarding braking in these complaints are similar to complaints regarding braking in third generation Toyota Prius vehicles. Only one of these eleven complaints alleges a crash occurred caused by a brake failure while simultaneously braking and traveling over a road disturbance; this one complaint was the petitioner's complaint.

[2]. Current Complaints to NHTSA (as of October 2011)

NHTSA has conducted a more exhaustive search of its complaint database that went beyond what the petitioner submitted for braking complaints similar to those identified in the Toyota Prius investigation. For example, additional complaints were found using a keyword search of the description field of the complaints for the word ''hybrid'' where a vehicle model was absent or improperly coded as a standard model). In total, three complaints filed by Honda Accord Hybrid owners (including the petitioner's complaint) were found to be similar to complaints regarding braking in third generation Toyota Prius vehicles.

DP10-004 Field Experience - NHTSA Complaints				
	Population	Reduction of Braking / Accel while braking over Road Disturbances		
		VOQs	Rates (/100K)	Crashes
Honda Accord Hybrid (MY 2005 - 07)	27,166	3	**11.0**	1
Honda Civic Hybrid 1st Gen (MY 2003 - 05)	82,294	9	**10.9**	1
Honda Civic Hybrid 2nd Gen (MY 2006 -10)	122,657	2	**3.3**	0
Toyota Prius 3rd Gen (MY 2010)	133,459	1,126*	**843.7**	33

* Complaints at the time of recall 2/9/2010

Table 3

By contrast, on February 9, 2010, when Toyota announced a safety recall for the 3rd generation Toyota Prius, NHTSA had received 1,126 complaints including 33 alleged crashes related to the consumer's perception of a momentary loss of braking while simultaneously braking and driving over road disturbances. The complaint rate for Prius far exceeded that of all the Honda Hybrid vehicles not only separately, but also combined.

[3]. Honda Complaint/Warranty Claim Data Summary

In ODI's Information Request letter to Honda, the alleged defect was broadly written as a ''reduction in braking performance and/or braking failures.''

Based on this alleged defect definition, Honda searched its consumer complaint and warranty claim databases for related complaints and warranty claims. ODI's analysis of the Honda data (summarized in tables 4 and 5) produced one complaint and no warranty claims similar to the Toyota Prius problem of a momentary reduction of braking while braking over road disturbances.

DP10-004 Field Experience - Honda Complaints				
	Population	Reduction of Braking / Accel while braking over Road Disturbances		
		Manf	Rates (/100K)	Crashes
Honda Accord Hybrid (MY 2005 - 07)	27,166	0	**0.0**	0
Honda Civic Hybrid 1st Gen (MY 2003 - 05)	82,294	1	**1.2**	0
Honda Civic Hybrid 2nd Gen (MY 2006 -10)	122,657	0	**0.0**	0

Table 4

DP10-004 Field Experience - Honda Warranty Claim Data			
	Population	Reduction of Braking / Accel while braking over Road Disturbances	
		Manf	Rates (%)
Honda Accord Hybrid (MY 2005 - 07)	27,166	0	**0.0**
Honda Civic Hybrid 1st Gen (MY 2003 - 05)	82,294	0	**0.0**
Honda Civic Hybrid 2nd Gen (MY 2006 -10)	122,657	0	**0.0**

Table 5

Section 6.0—NHTSA Vehicle Testing

In order to better understand the braking characteristics when the ABS is engaged in the subject vehicle, NHTSA acquired a MY 2005 Honda Accord Hybrid for testing purposes. The vehicle was tested in Ohio at NHTSA's Vehicle Research Testing Center (VRTC) on a variety of road surfaces, including rumble strips and split coefficient of friction surfaces (asphalt/epoxy), that could trigger the ABS system to function. The results of the testing can be found in the public file associated with this Petition analysis.[14]

In short, the testing showed that the Honda Accord hybrid brake system (including the ABS) is a robust system that worked in all of the following simulated road surfaces and situations: momentary perturbations, continuous rumble strips, braking then entering a rumble strip, and asphalt/epoxy split-coefficient situations. Moreover, the crash was preceded by the use of the parking brake.

The petitioner's account of the events just preceding the crash states:

> In a desperate attempt to bring the vehicle under control my husband pulled the emergency brake. Upon pulling the emergency brake, instead of helping to slow down the vehicle, the vehicle further became uncontrollable and started moving in the wrong direction.

The responding police officer's account of the events preceding the crash states:

> Vehicle #1 swerved over the left side rumble strip—came back into the left lane, accelerated back over the left side rumble strip off the roadway through the grass median (shrubbery) and into westbound traffic.

Because the petitioner noted that her husband applied the parking brake (located between the driver and the passenger) during the sequence of events just prior to the crash, a portion of the VRTC testing was designed to show the effects of applying the parking brake. The testing showed that the

[14] The complete testing report for DP10–004 can be found at *http://www-odi.nhtsa.dot.gov/defects/*.

application of the parking brake while on a rumble strip or split-coefficient of friction surface results in a high rate of vehicle yaw (angle change rotating around the vertical axis) that is uncontrollable because the locking of the rear wheel decreases its ability to resist lateral forces.

Based upon the inspections and tests of a 2005 Honda Accord hybrid vehicle and the allegations by the petitioner of a brake failure, the following conclusions were noted by VRTC.

(1) The Honda Accord hybrid brake system and ABS was found to be a robust system that could easily handle momentary perturbations, continuous rumble strips, braking then entering a rumble strip, and asphalt/epoxy split-co situations.

(2) Since a locked rear wheel cannot resist lateral forces, the application of the parking brake while on a rumble strip or split-co surface resulted in a high rate of vehicle yaw that was uncontrollable.

7.0 Conclusion

In our view, additional investigation is unlikely to result in a finding that a defect related to motor vehicle safety exists. Therefore, in view of the need to allocate and prioritize NHTSA's limited resources to best accomplish the agency's safety mission, the petition is denied. This action does not constitute a finding by NHTSA that a safety-related defect does not exist. The agency will take further action if warranted by future circumstances.

Authority: 49 U.S.C. 30162(d); delegations of authority at CFR 1.50 and 501.8.

Issued on: November 22, 2011.

Nancy Lummen Lewis,

Associate Administrator Enforcement.

[FR Doc. 2011–31343 Filed 12–6–11; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35576]

PPL Susquehanna, LLC and Allegheny Electric Cooperative, Inc.—Acquisition Exemption—Pennsylvania Department of Transportation

PPL Susquehanna, LLC, and Allegheny Electric Cooperative, Inc. (collectively PPLS), both noncarriers, have filed a verified notice of exemption under 49 CFR 1150.31. The notice invokes a class exemption from 49 U.S.C. 10901, which requires that authority be obtained from the Board before the acquisition of an active rail line. PPLS seeks the exemption for its purchase, from the Pennsylvania Department of Transportation (PennDOT), of an approximately 7-mile line of railroad (the Line), a portion of the former Bloomsburg Branch. The Line extends between the PPLS nuclear powered electric generating plant at milepost 170.00 and a point of connection with North Shore Railroad Company (NSRR) at milepost 176.97 at Berwick in Luzerne County, Pa.

PPLS acquired the Line from PennDOT on July 12, 2005, and belatedly seeks approval for the purchase. PPLS's acquisition of the Line came to light in *North Shore R.R.—Acquis. & Operation Exemption—PPL Susquehanna, LLC* (*North Shore*), FD 35377, where NSRR, on May 17, 2010, filed a verified notice of exemption to acquire a rail operating easement over the Line. The Board held NSRR's notice in abeyance and instead issued an order on April 26, 2011, directing PPLS to respond to questions about its acquisition of the Line from PennDOT. PPLS, in a response filed on May 26, 2011, stated that its failure to seek Board approval for its acquisition of the Line was an oversight and expressed the intent to take corrective action. It filed the instant notice on November 21, 2011.

PPLS states that it intends to grant an easement to NSRR, a Class III rail carrier, to provide common carrier service over the Line.[1] That issue will be addressed in *North Shore.*

PPLS certifies that the projected annual revenues as a result of the transaction will not exceed $5 million and will not result in the creation of a Class II or Class I rail carrier.

The exemption will become effective on December 21, 2011 (30 days after the exemption was filed).

If the verified notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed no later than December 14, 2011 (at least 7 days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35545, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on John M. Cutler, Jr. and Andrew P. Goldstein, Suite 700, 1825 K Street NW., Washington, DC 20006.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov*.

Dated: December 2, 2011.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2011–31413 Filed 12–6–11; 8:45 am]

BILLING CODE 4915–01–P

[1] PPLS states that the easement it is granting to NSRR will become effective 31 days after the filing date of this notice of exemption or on the date NSRR is authorized to operate over the Line, whichever date is later.

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Part II

Department of Commerce

Economic Development Administration

13 CFR Parts 300, 301, 302, et al.

Economic Development Administration Regulatory Revision; Proposed Rule

DEPARTMENT OF COMMERCE

Economic Development Administration

13 CFR Parts 300, 301, 302, 303, 304, 305, 306, 307, 308, 310, 311, and 314

[Docket No.: 110726429–1418–01]

RIN 0610–AA66

Economic Development Administration Regulatory Revision

AGENCY: Economic Development Administration, U.S. Department of Commerce.

ACTION: Notice of proposed rulemaking; request for public comment.

SUMMARY: Through this notice of proposed rulemaking (''*NPRM*''), the Economic Development Administration (''*EDA*''), U.S. Department of Commerce (''*DOC*''), proposes and requests comments on updates to the agency's regulations implementing the Public Works and Economic Development Act of 1965, as amended (''*PWEDA*''). On February 1, 2011, EDA published a notice requesting comments on improving the regulations. A 70-day public comment period followed from February 1, 2011 through April 11, 2011, during which EDA received approximately 170 comments. In addition, EDA conducted an internal review of its regulations. This NPRM addresses and incorporates public comments and agency staff suggestions to present an updated set of proposed regulations that reflects the agency's current practices and policies in administering its economic development assistance programs. For convenience, the full text of EDA's regulations as amended is available on EDA's Web site at *http://www.eda.gov/.*

DATES: Written comments on this NPRM must be received by EDA's Office of Chief Counsel no later than 5 p.m. Eastern Time on February 6, 2012.

ADDRESSES: Comments on the NPRM may be submitted through any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Agency Web Site: http://www.eda.gov/.* EDA has created an online feature for submitting comments. Follow the instructions at *http://www.eda.gov/.*
- *Mail:* Economic Development Administration, Office of Chief Counsel, Suite D–100, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230. Please indicate ''Comments on EDA's regulations'' and Docket No. 110726429–1418–01 on the envelope.

FOR FURTHER INFORMATION CONTACT: Jamie Lipsey, Attorney Advisor, Office of Chief Counsel, Economic Development Administration, U.S. Department of Commerce, Room D–100, 1401 Constitution Avenue NW., Washingtonm, DC 20230; telephone: (202) 482–4687.

SUPPLEMENTARY INFORMATION:

Background

EDA leads the Federal economic development agenda by making strategic grants-based investments. EDA's regulations, codified at 13 CFR chapter III, provide the framework through which the agency administers its economic development assistance programs. EDA's programs are built on two key pillars: innovation and regional collaboration. Innovation—the process by which individuals and organizations generate new ideas and put them into practice—is the foundation of American economic growth and national competitiveness. Innovation is the key element to creating new and better jobs and a resilient economy. Regional collaboration also is essential; and Regions that work together to leverage resources and build upon their unique comparative assets are better poised for economic success. This strategic framework builds on EDA's successful history of helping rural and urban communities leverage their unique assets by providing ''bottom up'' investments in infrastructure, planning, and technical assistance that promote regional collaboration, innovation, and regional innovation clusters. EDA's investments are designed to spur innovation and investment at the local level, by providing the tools and the flexibility to build the effective public-private partnerships required for long-term success.

EDA currently is updating the agency's regulations to ensure they reflect and incentivize innovation and collaboration and is committed to ensuring that public feedback helps shape the revised regulations. On February 1, 2011, pursuant to Executive Order 13563 ''Improving Regulation and Regulatory Review'', EDA published a notice in the **Federal Register** (76 FR 5501) requesting public comments on how the agency's regulations can better facilitate more effective economic development assistance programs that advance an innovative economy. Under the February 1, 2011 notice, comments were due no later than March 9, 2011; however, EDA published a second notice (76 FR 12616) on March 8, 2011 to extend the comment deadline until April 11, 2011, allowing for a total comment period of 70 days. EDA received approximately 170 public comments from approximately 71 commenters. In addition, EDA conducted an internal review of its regulations and received approximately 55 suggestions from agency staff.

EDA now publishes this NPRM to incorporate and respond to both public and agency staff comments and suggestions and to propose a revised set of regulations that reflects EDA's current practices and policies in administering its economic development assistance programs. For the most part, comments received express opinions on 13 CFR parts 300 through 307 and 314. Capitalized terms used but not otherwise defined in this NPRM have the meanings ascribed to them in EDA's current regulations (*see, e.g.,* §§ 300.3, 303.2, 307.8, 313.2, 314.1, and 315.2). For convenience, the full text of EDA's regulations as amended is available on EDA's Web site at *http://www.eda.gov/.*

Overview of Comments Received and Proposed Changes

EDA's goal is to help communities and Regions transform their economies towards economic prosperity through innovation, entrepreneurship, and public-private partnerships. Since February 1, 2011, EDA has taken a critical and comprehensive look-back at its regulations to reduce burdens by removing outmoded provisions and streamlining and clarifying requirements. EDA requested both public and internal comments on the regulations and has received a number of helpful suggestions that the agency believes make sense and should be put into practice. Therefore, through this NPRM, EDA proposes intelligent and intuitive revisions to provide additional flexibilities to the agency's stakeholders and support current best practices, while protecting taxpayer dollars and the Federal Interest in EDA-assisted property. These changes are designed to provide greater flexibility and local control to EDA's Recipients and to make the regulations easier to navigate and apply.

As a result of the regulatory revision effort, EDA plans to substantially improve its regulations by removing outdated provisions; streamlining burdensome or unnecessary requirements; and including provisions that increase flexibility, encourage creative collaboration and the effective leveraging of resources, and clarify agency requirements. Regulatory

provisions EDA proposes to remove include:

• Outmoded and overly prescriptive membership requirements related to Comprehensive Economic Development Strategy (''*CEDS*'') Strategy Committees and District Organization governing bodies to help ensure EDA's requirements adapt effectively to the unique qualities of all communities and Regions. *See* proposed revisions to §§ 303.6(b)(1) and 304.2(c)(2).

• The requirement that a disaster-related application must be submitted within 18 months of the relevant disaster declaration to receive a 100 percent grant rate. Applications still must be submitted in an efficient, timely manner, but EDA proposes to remove the regulatory deadline to provide additional flexibility in appropriate situations. *See* proposed revisions to Table 2 in § 301.4(b)(5).

• The unnecessary requirement that an RLF Recipient request EDA to subordinate its interest when seeking EDA's approval to sell or securitize an RLF portfolio. *See* proposed revisions to § 307.19.

Ways the regulations have been streamlined include:

• Modernizing the CEDS requirements from a laundry-list of items to four essential planning elements. EDA will provide further content information to stakeholders through the publication of updated CEDS guidelines, which will be grounded in best practices and developed in collaboration with our economic development and research partners. We expect these changes to enhance local control and allow EDA's planning partners to focus on strategies, performance, and outputs. *See* proposed revisions to § 303.7(b).

• Streamlining and clarifying EDA's Property release requirements. *See* proposed revisions to § 314.10.

Flexibility has been infused throughout the regulations in a number of ways, including:

• Providing that EDA may provide a grant rate of up to 80 percent to incentivize projects that encourage broad, innovative Regional planning. *See* proposed revisions to Table 2 in § 301.4(b)(5).

• Removing unnecessary restrictions on the RLF program to enhance operations in uncertain economic conditions. *See* proposed revisions to §§ 307.17(b)(6) and 307.18(a)(1).

• Setting out EDA's flexibilities with respect to subordinating the agency's interest in Project Property and updating EDA's Property regulations to help Recipients better take advantage of financing tools widely available in today's market—including New Markets Tax Credit (''*NMTC*'') arrangements. These provisions provide flexibilities while protecting the Federal Interest. *See* proposed revisions to § 314.6.

• Setting out EDA's authority to accept an instrument other than a recorded statement to protect the Federal Interest under certain circumstances. *See* proposed revisions to § 314.8.

We have included and enhanced provisions to *facilitate coordination* and the *leveraging of Federal investments* through:

• The updated evaluation criteria, which incentivize the leveraging of resources and collaboration among all levels of government and the public and private sectors. *See* proposed revisions to § 301.8.

• The description of Infrastructure at § 301.11, which provides that EDA, through appropriate Federal Funding Opportunity (''*FFO*'') announcements, will advance interagency collaboration by funding Projects that demonstrate the leveraging of Federal, State, and other resources.

• Providing that EDA may provide a grant rate of up to 80 percent to incentivize Projects that demonstrate effective leveraging of other Federal Agency resources. *See* proposed revisions to Table 2 in § 301.4(b)(5).

• Providing that RLF Recipients may use any Federal loan to meet private leveraging requirements. *See* proposed revisions to § 307.15(d).

This NPRM also proposes a number of *clarifications*, including:

• A definition of *Regional Innovation Clusters* or *RICs* to define this important economic development strategy. See proposed revisions to § 300.3.

• Examples of innovation- and entrepreneurship-related infrastructure under the proposed description of ''Infrastructure'' at § 301.11.

• A description of EDA's improved grant review and selection process. *See* proposed revisions to § 301.7.

• Updates to the data requirements that Eligible Applicants follow to demonstrate economic distress to better reflect the types and content of available data sources. *See* proposed revisions to § 301.3(a)(4).

• A revised accountability provision, which clarifies EDA's performance expectations and reporting requirements. *See* proposed revisions to § 302.16.

• Adding subparts to EDA's regulations at part 303 to clarify the distinctions between EDA's Planning investments and reorganizing the RLF regulations under part 307 so that all RLF requirements are easy to find under ''Subpart B—Revolving Loan Fund Program.''

• Clarifying EDA's Property regulations and adding helpful headings to help stakeholders navigate them. *See* proposed revisions to §§ 314.3, 314.6, and 314.7.

Although this is not strictly a regulatory issue, EDA currently is examining ways to streamline and rationalize its application requirements. EDA expects that its new application requirements will help applicants focus on the competitiveness of their proposed strategies and reduce the cost of applying for EDA assistance, while maintaining accountability for taxpayer dollars.

The following is a thematic summary of most comments received in response to the February 1, 2011 request for comments. A more detailed analysis is provided below under ''Part-by-Part Analysis of Comments Received and Proposed Changes.''

Regional Innovation Clusters and Innovation and Entrepreneurship-Related Infrastructure

EDA received five comments suggesting that EDA provide a definition for the phrase ''regional innovation cluster,'' which is an economic development technique designed to spark job creation and help communities and Regions become more competitive in the global economy. This NPRM adds a definition of ''*Regional Innovation Clusters* or *RICs*'' in EDA's set of regulatory definitions at § 300.3. In addition, EDA has emphasized the importance of using projects and techniques that advance effective innovation ecosystems in Regions throughout the U.S. and help communities support promising entrepreneurs and small businesses. EDA proposes a new regulation at § 301.11 to provide some examples of innovation- and entrepreneurship-related infrastructure Projects. Further, this NPRM proposes to specify reserved part 311 as a holding place for any regulations that may be necessary to implement the America COMPETES Reauthorization Act of 2010 (Pub. L. 111–358). Please see the sections below titled ''Part 300—General Information'' and ''Part 301—Eligibility, Investment Rate and Application Requirements'' for more detailed information.

EDA's Distress Criteria and Match Requirements

EDA received several comments suggesting that EDA reform its Investment Rate framework. EDA understands that communities and Regions face challenging economic

conditions; however, it is the agency's experience that the current Investment Rate determination structure encourages communities to collaborate and prioritize their needs and appropriately marshals resources to distressed Regions. By ensuring that communities have ''skin in the game,'' EDA's Investment Rate framework reinforces the need for local buy-in and participation, which improves economic development outcomes. In addition, the current structure provides EDA with needed flexibility to appropriately increase the EDA share based on Special Need and distress considerations. Therefore, EDA does not propose adjusting its Investment Rate framework through this NPRM. However, this NPRM does provide for an Investment Rate of up to 80 percent to encourage Projects that involve broad Regional planning and coordination and for Projects that effectively leverage other Federal resources. In addition, this NPRM contains a number of provisions designed to smooth connections between EDA and other Federal Agencies to ensure that stakeholders can effectively leverage Federal resources; including specifying that any Federal loan may meet an RLF's private leveraging requirements. Please see the sections below titled ''Part 301—Eligibility, Investment Rate and Application Requirements'' and ''Part 307—Economic Adjustment Assistance Investments'' for more information.

Comprehensive Economic Development Strategies, Economic Development Districts, and EDA's Planning Program

EDA received a number of comments on the regulations governing its Planning program, the requirements of CEDS, and Economic Development Districts (''*EDDs*''). Several comments suggest that EDA provide additional flexibilities with respect to the composition of CEDS Strategy Committees and District Organizations' governing bodies. EDA agrees and proposes revisions to §§ 303.6(b)(1) and 304.2(c)(2) to shift the focus from membership requirements to performance and outcomes, by maintaining the requirement that Strategy Committees and District Organization governing bodies represent the main economic interests of the Region, but no longer require a majority or membership threshold from any type of economic stakeholder. EDA proposes new language to clarify that these organizations must demonstrate the capacity to effectively undertake planning processes and implement strategies, as applicable. EDA expects that these changes will provide communities and Regions the flexibility to establish planning organizations that reflect and work most effectively for their unique make-up and priorities. In accord with best practices, EDA expects that the private sector will be strongly represented on both Strategy Committees and District Organization governing bodies.

Several comments suggest that EDA simplify and streamline the content requirements of CEDS. EDA agrees with the commenters and proposes changes to § 303.7(b) to remove the ''laundry list'' elements of CEDS and replace them with four essential planning elements. EDA will publish CEDS guidelines that incorporate best practice recommendations of EDA's planning and research partners.

Commenters suggest increased coordination with District Organizations in a variety of ways. Some commenters suggest that EDA ensure that all implementation projects are tied to the CEDS, while others request that EDA require coordination between Eligible Applicants and the relevant District Organization. EDA values its relationship with its stakeholders, but does not make these changes because of the requirements of PWEDA. Under sections 201(b)(3) and 209(b)(2) of PWEDA (42 U.S.C. 3141 and 3149, respectively), all grants awarded under EDA's Public Works and Economic Adjustment Assistance programs must be consistent with a relevant CEDS. PWEDA does not impose this requirement upon its other programs. EDA strongly encourages collaboration and coordination amongst District Organizations and other stakeholders, but EDA is not authorized to impose such requirements. Please see the sections below titled ''Part 303—Planning Investments and Comprehensive Economic Development Strategies'' and ''Part 304—Economic Development Districts'' for more information.

Revolving Loan Fund Program

EDA received numerous comments on the agency's revolving loan fund (''*RLF*'') program, several of which recommend that EDA set a time limit for releasing the Federal Interest in RLF grants. EDA understands that some RLF awards have been operating for a considerable length of time, some for as many as three decades, but EDA currently is not authorized to release its interest in RLF awards. EDA continues to work to achieve the necessary authorities. In addition, commenters opine that the RLF program reporting requirements are too burdensome. The semi-annual reporting requirement for the RLF program is in place to address an audit report by the DOC's Office of Inspector General (''*OIG*''), which recommended that EDA undertake more rigorous oversight of the RLF program to ensure the financial integrity and sustainability of the program. Because the reporting requirements are designed to address past program issues and ensure the viability and transparency of the program, EDA declines to make wholesale changes, but intends to continue to improve the Recipient reporting system to make it more user-friendly. In addition, six comments suggest the establishment of an RLF task force to address program issues and improve communications between EDA and program stakeholders. EDA currently is in the process of establishing an internal RLF task force and expects it to begin meeting in the very near future. Please see the section below titled ''Part 307—Economic Adjustment Assistance Investments'' for more information.

Property Management Updates

EDA received several comments that offered ways to make the agency's Property management regulations more flexible and adaptive to today's economy. For example, some commenters suggest that EDA should subordinate its interest when a Project warrants, require a lien only on the value of the Federal Interest, and make necessary changes to facilitate the agency's participation in Projects involving NMTC arrangements and other types of financing. EDA agrees, and proposes clarifying changes to its encumbrances regulation at § 314.6 to set out EDA's subordination flexibilities. EDA also amends its recorded statement requirement at § 314.8 to allow EDA to accept alternative instruments to protect the Federal Interest in certain situations. Please see the section below titled ''Part 314—Property'' for more information.

Non-Regulatory Comments

EDA received a number of comments related to agency policy and process rather than EDA's regulations. For instance, several comments opined on the agency's mission and direction, two of which request that EDA continue to fund traditional infrastructure. One commenter specifically notes that EDA should fund infrastructure to help smaller communities connect more effectively to telecommunications networks and electric grids. On the other hand, another comment suggests that EDA allocate more funding to ''programs and services that create jobs and less on infrastructure.'' Whether the scope of work of an EDA Investment

includes basic infrastructure, such as road upgrades, or business incubation technical assistance, EDA's goals remains the same: advancing the community's or Region's economic development strategy and building the capacity to create and retain jobs. EDA funds a variety of Projects to provide a broad portfolio of assistance through which Eligible Applicants can strategically meet their needs. Another comment encourages EDA to ''consider the funding of operations for business incubator projects for the start-up phase.'' EDA generally avoids funding operations for Projects that provide business incubation, acceleration, and similar services because the agency expects Projects to be self-sustaining. To this end, proposed application requirements for Projects to construct a business, technology, or other type of incubator or accelerator, as set out in § 301.10(d) of this NPRM, are designed to help EDA ensure that these Investments will continue creating jobs once the Project period expires. However, EDA may consider an application that proposes certain eligible business incubation activities performed by an Eligible Recipient.

We received one comment noting a disconnect between EDA's encouragement of ''public-private partnerships'' and the agency's regulatory framework that ''makes it hard to fund a project where a private entity expects to earn a profit.'' EDA acknowledges that private sector profit is essential to sustained economic growth and job creation; however, profit for a particular entity cannot be an objective under the terms of an EDA award. EDA's goal is not to replace private sector investment, but to spark economic development Projects that would not happen otherwise by leveraging private investment more efficiently. EDA believes the public and private sectors must work together to achieve vibrant Regional economies and encourages appropriate partnerships through its evaluation criteria, which are proposed in this NPRM at § 301.8. However, such partnerships must meet EDA's conflicts-of-interest requirements as set out at § 302.17. See the discussion under ''Part 302—General Terms and Conditions for Investment Assistance'' for more information.

EDA also received two comments stating that EDA's ''[f]ield representatives in the states are absolutely necessary.'' EDA agrees, and the agency's Economic Development Representatives (''*EDRs*'') serve every State.

EDA received several comments on its award approval process. One commenter suggests that the agency ''[s]treamline submittal and reporting procedures for smaller grants ($100,000 or less).'' EDA understands the commenter's concern; however, EDA is responsible for ensuring all requirements are met and for tracking performance on all of its awards, and so must require certain submittals and reports to ensure Federal funds are used efficiently and effectively. However, as noted above, EDA is reviewing its application requirements to reduce burdens and ensure efficiency for all Eligible Applicants. Two commenters suggest that ''the amount of time it takes to get an EDA grant approved'' is excessive. EDA recently undertook a comprehensive effort to improve the agency's award selection processes to shorten the amount of time between application and final award approval, while maintaining EDA's excellent customer service. The new award selection process that went into effect on October 14, 2010, greatly enhances transparency and competitiveness and significantly reduces the time it takes for EDA to evaluate an application. EDA now considers applications in quarterly funding cycles. Applications still are accepted on an ongoing basis, but instead of funding Projects on a piecemeal basis, EDA now competitively evaluates all applications received during a particular funding cycle. As a result, Eligible Applicants that submit a complete application by a funding cycle deadline are notified of EDA's selection decision within 20 business days of the deadline. *Please see* EDA's Web site at *http://www.eda.gov/PDF/Process%20Improvement%20Nov%204,%202010%20Webinar.pdf* for more information on EDA's new award selection process.

EDA received one comment stating that the new award approval process ''worked'' to make EDA's ''programs more user friendly and efficient.'' However, EDA received another comment requesting that EDA ''return to the rolling submission of grant requests.'' The commenter suggests that the new process ''fails communities'' that seek to attract new businesses and prospects because such prospects are ''unwilling to wait until the next submittal deadline to decide if a community can provide adequate water pressure or sewer capacity.'' EDA's new process is designed to speed up the approval process and provide Eligible Applicants with feedback earlier. Under the new process, EDA still accepts applications on a rolling basis and generally provides feedback on an application within 15 business days of application receipt. Although EDA makes awards on a quarterly basis, those awards are made much more efficiently. EDA believes that the new process provides Eligible Applicants and their stakeholders increased certainty, but welcomes additional comments.

The commenter also suggests that the new process ''favors mega-projects that would succeed without EDA's assistance.'' While the new process is designed to be competitive, EDA is committed to helping distressed communities flourish, and is not interested in assisting Projects that would succeed in any case. In fact, one criterion on which EDA evaluates every application is the extent to which it assists economically distressed and underserved communities. Two commenters state that ''EDA should not depend solely on a strict standard application and point grading system.'' While EDA's staff works hard with communities as they develop their applications, evaluating submitted applications in a standard manner is the only way to achieve objective, data-driven results. Two commenters suggest that ''[r]estricting projects to those that are shovel ready [is] likely to eliminate promising projects in need of some extra funding to become a reality.'' EDA is committed to providing its limited resources to distressed communities so they can spark job creation and positive economic change as efficiently as possible. Waiting on projects that are not yet ready for implementation would be a disservice to communities across the U.S. EDA works closely with communities as they develop projects that are ready for consideration.

EDA received five comments requesting that EDA provide ''conditional grants of funding using written documentation that lists the conditions and timeframe for meeting requirements * * *.'' Through the new award selection process, EDA attempts to strike a balance between cost efficiency and certainty for Eligible Applicants. Under the new process, an Eligible Applicant that submits an application sufficiently in advance of a funding cycle deadline receives an initial project analysis on the application's fit with EDA's priorities using the evaluation criteria set out in the relevant FFO and completeness, which lets the Eligible Applicant know what additional materials must be submitted before a funding cycle deadline. EDA cannot make a conditional award before a complete application is received because it is very difficult to competitively evaluate such applications. EDA strongly encourages Eligible Applicants to work with EDA

staff as early as possible to help ensure successful outcomes. In addition, as noted above, EDA is reviewing its application requirements to streamline them and ensure they are efficient and cost-effective for communities.

EDA received one comment suggesting that the ''very rigid legal interpretation of scope of work compliance * * * be relaxed'' as ''frequently innovation efficiencies emerge after project work has begun, but these efficiencies, and the related potential for over delivering the project are not allowed because they were not specifically identified in the original project scope of work.'' EDA understands that new efficiencies and synergies may emerge as a Project moves forward, and EDA staff work closely with Recipients to ensure that useful changes to a Project's scope of work can be implemented. However, EDA must be careful to maintain the competitiveness and transparency of its grant process and ensure that any proposed changes do not affect the nature and justification of the Project as originally proposed.

EDA received one comment requesting that EDA no longer use *www.grants.gov* for application submissions. Application submission through *www.grants.gov* is a requirement across the Federal government and is designed to reduce paperwork, while making the application process simpler and more efficient. Numerous improvements have been made to *www.grants.gov* over the past several years, which have greatly improved system performance.

One commenter suggests that ''EDA consider establishing a state-by-state grant formula.'' EDA is uniquely effective because the agency can encourage Regional collaboration across State borders and work directly with communities in implementing economic development plans. EDA works closely with its State partners, and State coordination is required under EDA's ''Inter-governmental review of projects'' regulation (§ 302.9). Therefore, EDA has not revised its regulations based on this comment.

EDA received several comments on post-award issues. One commenter suggests that EDA measure jobs created using a count of ''pay checks to people * * * instead of the constant debate of what a job is and is not.'' EDA will consider the comment in developing performance measures; however often EDA is constrained by government-wide guidance and requirements with respect to performance measures, including how to count jobs. The agency received five comments requesting that it no longer collect information for individual background screenings using Form CD–346 (*Applicant for Funding Assistance*). EDA is required to perform this due diligence step in accordance with DOC policy, which recently was changed to require Form CD–346 from additional types of Eligible Applicants. EDA apologizes for any inconvenience, but is not authorized to change the requirement.

We received one comment suggesting that EDA had imposed ''arbitrary caps on [facilities and administrative] F&A reimbursement'' creating ''a[n] unsustainable financial burden for research institutions.'' The commenter particularly cites EDA's FY 2010 i6 Challenge competition, which resulted in six Economic Adjustment Assistance Investments under part 307. EDA is uncertain of the precise circumstances behind the comment, but in general, if facilities and administrative costs (also referred to as indirect costs) are included in a project budget, EDA may accept the Eligible Applicant's approved ''Facilities and Administrative Cost Rate Agreement.'' Nonetheless, EDA is responsible for taxpayer dollars and ensuring that Projects generate effective economic impacts. Every EDA Project represents an important opportunity to create jobs and improve the quality of life in Regions across the U.S; therefore, EDA looks carefully at Project budgets to maximize the use of funds for direct program costs and EDA staff may work with Recipients to negotiate effective budgets. Also, note that under the University Center program, § 306.6(d) requires that 80 percent of EDA funding be allocated to direct costs of Program delivery.

One commenter suggests that ''it is important [for stakeholders] to have more dialogue with senior officials within the EDA so they can hear from the field, in addition to the internal management teams.'' The commenter goes on to tell of an experience with ''a very well structured round table with the Assistant Secretary'' that was coordinated by EDA's Philadelphia regional office, and comments that ''more of these need to occur.'' EDA believes that stakeholder input and feedback is invaluable. Forums that facilitate dialogue between EDA's senior management and economic development practitioners in the field, including face-to-face meetings, teleconferences, and webinars, are a high priority and EDA coordinates as many as possible. Over the past year, each region held a conference to share innovative ideas and best practices. We hope to continue to offer these conferences as a venue to bring together practitioners, EDA staff and leadership, and experts to continue the important dialogue about how to continue to improve our nation's economy. Senior management from both Headquarters and the regional offices frequently are out in the field gathering information and requesting feedback and ideas. We welcome additional suggestions for useful dialogue opportunities.

Part-by-Part Analysis of Comments Received and Proposed Changes

Specifically, this NPRM proposes the following revisions to EDA's regulations:

Part 300—General Information

Part 300 of the regulations states EDA's mission and highlights the policies and practices that EDA employs in order to attract private capital investments and new and better jobs to those Regions experiencing substantial and persistent economic distress. EDA seeks to help Regions become more competitive in an innovative economy. To facilitate these goals, this NPRM introduces several new terms and revises existing terms to assist readers in better understanding EDA's requirements and ensure clarity, consistency, and technical precision.

EDA proposes revising § 300.1, which introduces EDA and sets out the agency's mission, by inserting the term ''new and better jobs'' in place of the phrase ''higher-skill, higher-wage jobs.'' The current use of the phrase ''higher-skill, higher-wage jobs'' may cause confusion and suggest that EDA is only interested in ''high tech'' jobs or jobs that require particular skill sets. The phrase ''new and better'' is qualitative enough to adapt to all communities. EDA also revises § 300.2, which provides information on EDA's Headquarters and regional offices, to replace the address ''14th Street and Constitution Avenue NW.'' with the more precise address ''1401 Constitution Avenue NW.'' in § 300.2(a). This NPRM revises the first sentence of § 300.2(b) to replace the phrase ''Web site'' with the word ''Web site'' for consistency with EDA's current convention, the word ''notice'' with ''applicable announcement'' to provide greater clarity on the type of funding announcement that EDA issues, and the word ''published'' with ''issued'' to better describe how EDA makes such announcements public. In addition, we propose removing the word ''annually,'' as EDA may issue several funding announcements throughout the year.

This NPRM proposes several clarifying revisions to the ''Definitions'' section of EDA's regulations at § 300.3.

First, EDA proposes revising the definitions of ''*Cooperative Agreement*'' and ''*Grant*'' in § 300.3 to specify that EDA may administer a cooperative agreement or a grant under a statute other than PWEDA. In both definitions, EDA removes the phrase ''under PWEDA'' and replaces the phrase ''the activities contemplated in an agreement between the parties'' with the phrase ''a purpose or activity authorized under PWEDA or another statute'' to provide greater clarity and improve sentence structure.

EDA proposes a minor change to the definition of ''*Eligible Recipient*'' to delete an unnecessary reference to ''of part 306.'' We also propose revising the definition of ''*Federal Funding Opportunity*'' or ''*FFO,*'' by replacing the phrase ''the notice EDA publishes annually'' with the phrase ''an announcement EDA publishes during the fiscal year,'' as EDA may issue several funding announcement throughout the fiscal year. In addition, for clarity, EDA proposes revising the first sentence of the definition by replacing the phrase ''Web site'' with ''Web site'' and the word ''describes'' with ''provides;'' adding the word ''funding'' before the word ''amounts;'' replacing the phrase ''particular application procedures'' with the phrase ''application and programmatic requirements;'' and replacing the phrase ''special circumstances and other relevant information concerning EDA's Investment programs for the year'' with the phrase ''special circumstances, and other information concerning a specific competitive solicitation for EDA's economic development assistance programs.'' EDA also corrects a grammatical error in the second sentence of the definition by replacing the phrase ''EDA may also'' with ''EDA also may.''

EDA proposes minor punctuation and capitalization corrections to the definition of ''*Federally Declared Disaster*'' to remove the hyphens between ''Federally'' and ''Declared'' and ''Presidentially'' and ''Declared'' and to capitalize ''Federally.'' We also propose revising the definition of ''*Indian Tribe*'' to replace the phrase ''any Indian tribe, band, nation, pueblo, or other organized group or community, including * * *'' with the phrase ''an entity on the list of recognized tribes published pursuant to the Federally Recognized Indian Tribe List Act of 1994 (Pub. L. 103–454) (25 U.S.C. 479a *et seq.*), as amended, and* * * '' This revision does not affect EDA's relationship with Indian Tribes in any way, but provides greater clarity and ensures the regulation comports with the definitions of other Federal Agencies, including the U.S. Department of the Interior. In addition, we propose removing an unnecessary reference to ''an EDA'' from the definition of ''*Investment*'' or ''*Investment Assistance.*'' We also propose replacing ''costs'' with the singular ''cost'' in the definition of ''*Investment Rate.*''

With respect to the definition of ''*Local Share*'' or ''*Matching Share,*'' we received one comment requesting that EDA ''allow for Federal funds that are designated to local state agencies, to be considered as eligible matching funds for EDA funding.'' EDA is working to address this issue by ensuring that Federal Agency resources can be leveraged efficiently and effectively, but is not authorized to allow all Federal funds provided to States to be used as Matching Share because of the requirements of appropriations law. All Federal funds are appropriated for particular purposes, as mandated by Congress and set out in the relevant authorizing statute, appropriation, or other Congressional statement of intent. For another Federal Agency's funds to be used to match an EDA award, there must be such a statement of Congressional intent. In some cases Congress has indicated that other Federal funds may be used to meet EDA's match requirement. For instance, currently one of the uses to which Community Development Block Grant (''*CDBG*'') funds provided by the U.S. Department of Housing and Urban Development ''*HUD*'' may be put is ''payment of the non-Federal share required in connection with a Federal grant-in-aid program'' undertaken as part of HUD's Community Development program. *See* 42 U.S.C. 5305(a)(9). In addition, section 205 of PWEDA (42 U.S.C. 3145) authorizes EDA to supplement a grant awarded under another designated Federal program. EDA must determine that Federal funds may be used as match for another Federal grant each time funds from another Federal Agency are requested to be all or a portion of the Matching Share, including when the Federal funds are made available to a State.

In addition, we received three comments regarding costs that may be considered as Local Share or Matching Share. Two suggest that EDA consider certain pre-award costs ''to verify eligibility for EDA funds'' as a portion of the Matching Share and the third comment sets out the commenter's own experience in which the agency did not allowed a particular Recipient to use purchased property as Matching Share. All costs under an award are determined in accordance with relevant Federal cost principles, as set out in the following Office of Management and Budget (''*OMB*'') Circulars: Circular No. A–122 titled ''Cost Principles for Nonprofit Organizations'' (2 CFR part 230); Circular No. A–21 titled ''Cost Principles for Education Institutions'' (2 CFR part 220); and Circular No. A–87 titled ''Cost Principles for State, Local and Indian Tribal Governments'' (2 CFR part 225). EDA, in its sole discretion, may accept certain eligible costs, including pre-award costs and Recipient-provided property, as Matching Share or reimburse them consistent with the EDA-approved Investment Rate. For pre-award costs related to contracts for goods and services to be used as Matching Share, such contracts must have been procured in accordance with Federal competitive procurement requirements as set out at 15 CFR 14.43 or 24.36, as applicable. EDA is uncertain of the precise circumstances behind the comment with respect to property used as Matching Share, but we encourage all Eligible Applicants to work with EDA staff early in the application process to ensure costs are allowable. We propose non-substantive revisions to the definition of ''*Local Share*'' or ''*Matching Share*'' to replace plural references with singular ones for better sentence structure. Accordingly, we replace ''Recipients'' with ''a Recipient,'' ''third parties'' with ''third party,'' and ''other Federal agencies'' with ''another Federal agency.''

In the definition of ''*Presidentially Declared Disaster,*'' we correct a punctuation error by removing the hyphen between ''Presidentially'' and ''Declared.'' With respect to the definition of ''*PWEDA,*'' we propose removing the unnecessary phrase ''including the comprehensive amendments made by the Economic Development Reauthorization Act of 2004 (Pub. L. 108–373, 118 Stat. 1756).''

EDA proposes removing the definition of ''*Private Sector Representative*'' to reflect proposed changes to the membership requirements applicable to CEDS Strategy Committees and District Organization governing bodies. Under current § 303.6(a), a CEDS Strategy Committee must include Private Sector Representatives as a majority of its membership and under § 304.2(c)(2), the governing body of a District Organization must include at least one Private Sector Representative. Under this NPRM, EDA proposes removing CEDS Strategy Committee and District Organization governing body membership threshold requirements; and proposes instead to focus on

program processes and outputs. Because the defined term ''*Private Sector Representative*'' is used largely in the context of these membership threshold requirements, EDA proposes to remove the definition. *See also* the proposed changes to parts 303 and 304.

EDA corrects a grammatical error in the third sentence of the definition of ''*Region*'' or ''*Regional*'' by replacing the phrase ''may also'' with ''also may.''

In response to five comments the agency received that support a definition of regional innovation cluster, this NPRM includes a definition of ''*Regional Innovation Clusters*'' or ''*RICs*'' after the definition of ''*Regional Commission*'' in § 300.3. One comment requests EDA to ensure that the definition does not exclude communities that may lack the resources to form a RIC from partnering with communities that do have that capacity. Another comment notes that EDA should ''make sure [the] reader understands the vertical integration of the cluster and [that] it is not just a conglomerate of like [North American Industry Classification System] NAICS [codes].'' Other comments express concern regarding the implications of RICs, including two that question how RICs will work as a strategy for isolated communities ''where the nearest town could be 90 to 167 miles away'' and in communities that ''are not accessible by roads and lack many essential infrastructure and program needs.'' In addition, two comments warn that ''[r]egionalism and collaboration are two words espoused at most conferences, however, there is a real need to look at these concepts and adjust as needed for particular projects'' and that ''while 'regionalism' is the buzz word * * * revitalization and progress must begin locally before it ever reaches a regional stage.'' One commenter goes on to note, ''government funds should not be awarded unless there are identifiable [benchmarks] to incorporate these concepts.'' Another comment states that ''EDA should be willing to fund existing programs that have successful track records just as much as new programs with promising projections.''

EDA thanks the commenters for their thoughtful responses and will endeavor to ensure the proposed definition of RICs addresses these concerns. EDA is striving to create a highly flexible and inclusive RIC framework that works for all types of Regions. EDA recognizes that RIC participants can and should have strategic partnerships outside of the RIC's geographic Region and the definition emphasizes that a RIC can cross jurisdictional boundaries. EDA's RIC-based programs are designed to increase the capacity of distressed communities to establish a RIC and take advantage of the resources of existing RICs. Also, EDA has tried to craft the definition to emphasize vertical integration while remaining flexible by defining RICs as ''networks of similar, synergistic, or complementary entities'' that ''have active channels for business transactions and communication.'' EDA believes RICs can be integral to successful economic development strategies for many communities and continues to develop performance measures and goals to help assess the impact of RICs and build a portfolio of best practices. Also, RICs are just one strategy amongst EDA's array of policy and program options that can be tailored to meet communities' needs. Through the RIC framework, EDA will work closely to articulate a strategy that incorporates the attributes and challenges of all types of communities, from densely populated to very rural. We invite additional constructive comments on ways to improve the definition.

Last, EDA proposes revising the definition of ''*Trade Act*'' to include a reference to the statutory citation for the Trade Adjustment Assistance for Communities program. Therefore, in the definition of Trade Act, the phrase ''chapters 3 and 5'' is revised to read as ''chapters 3, 4, and 5.'' Finally, EDA adds the phrase ''for purposes of EDA,'' to clarify that the definition of ''*Trade Act*'' is specific to EDA and its programs.

Part 301—Eligibility, Investment Rate and Application Requirements

Part 301 sets forth eligibility criteria, the maximum allowable Investment Rates, and application requirements common to all PWEDA-enumerated programs (excluding Community Trade Adjustment Assistance at part 313 and Trade Adjustment Assistance for Firms (''*TAAF*'') at part 315). In general, subpart A of part 301 presents an overview of EDA's eligibility requirements; subpart B addresses applicant eligibility; subpart C addresses Regional economic distress level requirements; subpart D sets forth maximum allowable Investment Rates and Matching Share requirements; and subpart E addresses application requirements, as well as the evaluation criteria used by EDA in selecting Projects. EDA revises the table of contents of part 301 to include a reference to new § 301.11—Infrastructure, which is described below.

We propose clarifying changes to § 301.1 to simplify the provision and ensure it better reflects EDA's application process. We remove the phrase ''an applicant and the Project proposed by the applicant must satisfy each of'' so that the provision's introductory text simply and clearly reads ''In order to receive EDA Investment Assistance, the following requirements must be met.'' In addition, to better reflect EDA's application selection process, we propose relocating the phrase ''EDA must select the Eligible Applicant's Project'' from § 301.1(d) to new § 301.1(f) and rephrase it slightly to read ''EDA must select the Eligible Applicant's proposed Project.''

EDA received one comment on the agency's economic distress level requirements, which are set out at § 301.3. The commenter expresses concern that one of the economic distress criteria to demonstrate eligibility for EDA's Public Works and Economic Adjustment Assistance programs may disproportionately exclude rural communities where ''smaller job loss numbers become huge in today's economy.'' The commenter urges ''EDA to consider lowering the dislocation job requirement.'' The regulation at § 301.3 tracks the requirements of section 301 of PWEDA (42 U.S.C. 3161), which requires that a Project be located in a Region that meets one or more of the following economic distress criteria in order to be eligible for EDA assistance:

- An unemployment rate that is, for the most recent 24-month period for which data are available, one percentage point greater than the national unemployment rate;
- Per capita income that is, for the most recent period for which data are available, 80 percent or less of the national average per capita income; or
- A ''Special Need,'' as determined by EDA.

EDA does not have the authority to adjust these requirements, but recognizes the devastation that loss of a significant number of jobs has on a smaller community. If a Region does not meet the statistical economic distress criteria set out by PWEDA, EDA may be authorized to provide assistance through its Special Need criteria as defined at § 300.3, which provide the flexibility to address a variety of sudden and severe economic dislocations.

In response to an internal comment from EDA staff, EDA proposes changes to § 301.3(a)(4) to reduce confusion regarding data sources for demonstrating economic distress. The proposed text recognizes that the U.S. Census Bureau's American Community Survey (''*ACS*''), which is EDA's default data source for determining distress

levels, does not include 24-month unemployment data. For clarity, EDA proposes to insert the heading *Data requirements to demonstrate economic distress levels* to § 301.3(a)(4). For distress levels based on per capita income, the regulation provides that EDA still will base its determination on ACS data, and EDA proposes making the first sentence of § 301.3(a)(4)(i) specific to per capita income by removing the reference to ''the unemployment rate or * * *'' EDA also relocates the clause that currently concludes the first sentence of § 301.3(a)4)(i), which sets out the requirement that data correspond to the geographic area upon which the Eligible Applicant is basing eligibility, to be the final sentence of the provision. EDA appropriately rephrases the sentence to remove the unnecessary word ''either'' so that the sentence begins ''The required data must be for the Region * * *'' The remainder of the sentence remains unchanged. EDA proposes a second sentence specific to distress levels based upon the unemployment rate that reads ''For economic distress levels based upon the unemployment rate, EDA will base its determination upon the most recent data published by the Bureau of Labor Statistics (''*BLS*''), within the U.S. Department of Labor.'' EDA proposes revising the sentence of the provision that currently begins ''Where a recent ACS is not available,'' by replacing that introductory phrase with a clarifying introductory clause that reads ''For eligibility based upon either per capita income requirements or the unemployment rate, when the ACS or BLS data, as applicable, are not the most recent Federal data available.'' The remainder of the sentence remains unchanged.

In addition to the changes to § 301.3(a)(4), EDA makes a non-substantive change to § 301.3(a)(1) to remove the parentheses from around the phrase ''or more.'' For clarity and better sentence structure in § 301.3(a)(2), EDA replaces the phrase ''economic distress criteria of paragraph (a)(1) of this section'' with ''economic distress criteria described in paragraph (a)(1) of this section'' and the phrase ''is also'' with ''also is.'' This NPRM also proposes removing repetitive numerical references by replacing ''twenty-four (24) month'' with ''24-month'' and ''one (1)'' with ''one'' in § 301.3(a)(1)(i); replacing ''eighty (80)'' with ''80'' in § 301.3(a)(1)(ii); and replacing ''one (1)'' with ''one'' in § 301.3(c)(1).

EDA received 17 comments regarding the agency's Investment Rate requirements, which are set out at § 301.4 and provide the framework for the proportion of total Project costs EDA may provide. In general, § 301.4 provides that an Eligible Applicant may be eligible for a 50 percent grant rate. Applicants experiencing relatively higher levels of distress or that are subject to a Special Need may be eligible for a higher grant rate, up to 80 percent. *See* § 300.3 for the definition of ''*Special Need*.'' Several comments express concern regarding the 50 percent Investment Rate and suggest additional flexibilities to establish higher rates, particularly for EDA's Planning awards and Projects in distressed communities. In addition, one internal comment suggests that EDA establish standard Investment Rates for certain Recipients of Planning awards; specifically 75 percent for District Organizations and 100 percent for Indian Tribes.

The general Investment Rate requirements in § 301.4(b)(1) implement section 204 of PWEDA (42 U.S.C. 3144), which requires a 50 percent baseline share plus an additional amount up to 80 percent ''based on the relative needs of the area.'' EDA is not authorized to set particular Investment Rates for Planning awards, but the agency is authorized to provide higher maximum Investment Rates for all types of awards based on a Region's distress level, as set out in Table 1 of § 301.4(b)(1)(ii). In addition, in accordance with Table 2 in § 301.4(b)(5), EDA may establish an Investment Rate of up to 100 percent for special Projects, including Projects of Indian Tribes.

Two commenters suggest that EDA restore ''EDA's local match rate requirements to the pre-2005 levels'' and two commenters support EDA's inclusion of ''the revised Federal-local cost share provisions included in S. 2778 by the U.S. Senate Committee on Environment and Public Works during the 111th Congress.'' EDA understands that communities and Regions face challenging economic conditions; however, it is the agency's experience that the current Investment Rate determination structure encourages communities to collaborate and prioritize their needs and appropriately marshals resources to distressed Regions. By ensuring that communities have ''skin in the game,'' EDA's Investment Rate framework reinforces the need for local buy-in and participation, which improves economic development outcomes. In addition, the current structure provides EDA with needed flexibility to appropriately increase the EDA share based on Special Need and distress considerations. Therefore, EDA does not propose adjusting its Investment Rate framework through this NPRM. However, this NPRM does provide additional flexibilities for higher Investment Rates, specifically, up to 80 percent to encourage Projects that involve broad Regional planning and coordination, and Projects that effectively leverage other Federal resources. Also, this NPRM contains a number of provisions designed to smooth connections between EDA and other Federal Agencies to ensure that stakeholders can effectively leverage Federal resources; including specifying that any Federal loan may meet an RLF's private leveraging requirements.

In response to an internal comment, EDA proposes syntax changes to § 301.4(b)(1), which sets out the general requirements with regards to Investment Rates, to clarify that EDA's grant rates generally must be determined in accordance with Table 1 of § 301.4(b)(1)(ii). EDA proposes splitting the initial sentence of the provision into two clearer sentences. In the first sentence of the provision, EDA replaces the phrase ''shall, after the application of Table 1'' with the phrase ''shall be determined in accordance with Table 1.'' EDA proposes ending the sentence at the word ''subsection.'' To begin the second sentence of the provision, EDA proposes adding the phrase ''The maximum EDA investment rate shall'' before the clause that begins with the phrase ''not exceed the sum of.'' In addition, EDA removes use of the variables (x) and (y) in the second sentence for clarity. These revisions do not change EDA's current practice and only clarify the regulation to reflect the requirements of PWEDA. In addition, EDA proposes removing the second sentence of § 301.4(b)(3)(iii), to allow the Assistant Secretary to delegate authority to grant a waiver of the requirement that for Planning Investments under part 303, the Investment Rate shall be the maximum allowable under Table 1 of § 301.4(b)(1)(ii). In addition, in § 301.4(c), EDA replaces the phrase ''Federal Funding Opportunity notices'' with ''Federal Funding Opportunity announcements'' for increased clarity.

Six comments suggest that EDA use its grant rates ''to re-establish Federal incentives for regional collaboration of local governments and other related entities through the national network of Economic Development Districts.'' Regional collaboration in planning and implementing economic development projects is a key indicator of success, and EDA agrees that such efforts should be incentivized. Therefore, EDA revises Table 2 of § 301.4(b)(5) to authorize an Investment Rate of up to 80 percent for

Projects that involve broad Regional planning and coordination with other entities outside the Eligible Applicant's political jurisdiction or area of authority, under special circumstances as determined by EDA. In general, to demonstrate broad Regional planning and coordination, Eligible Applicants must demonstrate costs necessary for such efforts that would not ordinarily have been incurred in the course of their usual planning and Project efforts; for example, new maps and analyses because of the expanded Regional coverage. Also, EDA proposes revising Table 2 to incentivize Projects that effectively leverage other Federal Agency resources with a maximum grant rate of up to 80 percent. Note that EDA also incentivizes broad Regional collaboration through its evaluation criteria as set out at § 301.8.

Two comments recommend that EDA waive match for FEMA-declared disasters. EDA agrees that maximum flexibility is necessary in disaster situations, and therefore also amends Table 2 of § 301.4(b)(5) to clarify that EDA may provide up to a 100 percent grant rate when ''EDA receives appropriations under section 703 of PWEDA (42 U.S.C. 3233),'' which authorizes disaster economic recovery activities. EDA proposes a second revision to remove a deadline that applies to disaster applications. Under the current regulation, to be eligible for a 100 percent grant rate, an application for a Project to address a Presidentially Declared Disaster must be submitted within 18 months of the disaster declaration. EDA believes that the 18 month requirement may be unduly restrictive, and revises the provision to provide that EDA may provide a maximum Investment Rate of 100 percent for ''Projects to address and implement post-disaster economic recovery efforts in Presidentially Declared Disaster areas in a timely manner.'' EDA expects that communities will respond to disasters expeditiously, and the phrase ''in a timely manner'' gives EDA the flexibility to set time limits appropriate to a disaster scenario.

This NPRM proposes removing repetitive numerical references throughout § 301.4 by replacing ''Fifty (50)'' with ''50'' and ''thirty (30)'' with ''30'' in § 301.4(b)(1); ''one (1)'' with ''one'' in § 301.4(b)(1)(ii); all instances of ''twenty-four (24) month'' with ''24-month'' and ''1 percentage point '' with ''one percentage point'' in Table 1 in (b)(1)(ii); ''eighty (80)'' with ''80'' in § 301.4(b)(2); ''fifty (50)'' with ''50'' in § 301.4(b)(3)(i); ''eighty (80)'' with ''80'' in § 301.4(b)(3)(ii), and ''one hundred (100)'' with ''100'' in § 301.4(b)(4).

We propose clarifying revisions to § 301.6, which sets out the requirements for EDA to provide assistance to supplement another Federal grant, to correct capitalization errors in the section heading so that it reads ''Supplementary Investment Assistance'' instead of ''Supplementary investment assistance.'' We also revise the beginning of the first sentence of § 301.6(a) to read ''Pursuant to a request made by an Eligible Applicant, EDA Investment Assistance may supplement a grant'' instead of ''Pursuant to a request by an Eligible Applicant, EDA Investment Assistance may supplement grants'' and replace the phrase ''any Federal grant program'' with ''a Federal grant program'' in the second sentence. We also revise the beginning of the first sentence of § 301.6(b) to read ''For a Project that meets the economic distress criteria provided in § 301.3(a)'' instead of ''For Projects located in Regions meeting the criteria of § 301.3(a)'' and remove the unnecessary reference to ''EDA'' immediately before the phrase ''Investment Assistance.'' For clarity, in the second sentence of § 301.6(b), we replace the phrase ''the combination of EDA Investment and other Federal funds'' with the phrase ''the EDA Investment and other Federal funds together'' and insert the word ''that'' after provided.

This NPRM revises and reformats § 301.7(a) for clarity and to reflect EDA's improved grant-making process under the agency's Public Works and Economic Adjustment Assistance programs, which is designed to provide greater transparency and faster feedback to Eligible Applicants. EDA continues to accept applications on a continuing basis, but in general competitively evaluates all applications received in quarterly funding cycles. Note that in cases of extremely urgent distress, EDA may evaluate and select an award outside of the usual funding cycles. Also, applications under EDA's Planning, Local Technical Assistance, University Center, and Research and Evaluation programs are not subject to the funding cycle deadlines. Therefore, EDA proposes revising the first sentence of the provision by removing the second use of the phrase ''Investment Assistance'' immediately preceding ''application,'' as it is unnecessary. EDA clarifies the second sentence of § 301.7(a) to specify that EDA's application, Form ED–900, is available electronically from *www.grants.gov* instead of on EDA's Web site. In addition, we revise the third sentence of the provision to add the introductory phrase ''In general;'' remove the words ''competitive and'' immediately before ''continuing;'' and replace the concluding phrase ''to respond to market forces in Regional economies'' with the clause ''and competitively evaluates all applications received in quarterly funding cycles throughout the fiscal year.'' For better sentence structure and to reduce confusion, we propose revising the fourth sentence of the provision so that it reads ''Subject to the availability of funds, the timing in which EDA receives complete and competitive applications affects EDA's ability to participate in a given Project,'' instead of ''The timing with which competitive investment opportunities arise, as determined by the criteria set forth in § 301.8, paired with the availability of funds in a given fiscal year, will affect EDA's ability to participate in any given Project.'' In the fifth sentence of the provision, EDA replaces the phrase ''using the criteria set forth in § 301.8'' with the phrase ''in accord with the criteria set forth in the applicable FFO and in § 301.8'' to clarify that a published FFO may contain specific evaluation criteria. In addition, in § 301.7(a)(1), EDA replaces the phrase ''upon corrections'' with ''after corrections are made'' for better sentence structure.

EDA revises § 301.8 to set out EDA's updated evaluation criteria. As set out in § 301.8(a) through (f), EDA will evaluate applications on the extent to which they:

- Ensure collaborative Regional innovation;
- Leverage public-private partnerships;
- Advance national strategic priorities;
- Enhance global competitiveness;
- Encourage environmentally sustainable development; and
- Support economically distressed and underserved communities.

EDA also proposes minor changes within the introductory text to § 301.8 to replace the phrase ''EDA statutory and regulatory requirements'' with ''EDA's statutory and regulatory requirements'' in the first sentence of the provision; replace ''applicant'' with ''Eligible Applicant'' in the second sentence; and add the introductory clause ''In addition to criteria set out in the applicable FFO'' and replace ''one (1)'' with ''one'' in the third sentence.

EDA received eight comments regarding the evaluation criteria. One comment requests ''that EDA establish preferential selection criteria recognizing communities that are impacted by Defense Department actions such as base realignment and

closure (BRAC), specifically base closure and mission growth.'' EDA does not enumerate this as an evaluation criterion because Projects involving communities impacted by military base closures or realignments, as well as defense contractor reductions-in-force and U.S. Department of Energy defense-related funding reductions, are considered under EDA's Special Need criterion for eligibility. *See also* the definition of ''*Special Need*'' as set out in § 300.3 and the distress requirements of § 301.3(a). The evaluation criteria are geared towards selecting applications that best demonstrate the ability to help the impacted community grow the local economy effectively, create new and better jobs, and coherently engage local partners.

A second comment suggests that EDA's evaluation criteria ''should favor awards to regions with developing clusters that need help rather than rewarding established clusters that will continue to grow on their own.'' EDA's proposed evaluation criteria incentivize RICs, and the agency's programs are designed to assist distressed communities; therefore, EDA anticipates helping Regions nurture developing clusters. Depending on the unique circumstances facing a Region, leveraging an established cluster may be the most effective strategy to aid a distressed Region. Another commenter requests that EDA not so heavily favor distressed communities in order to allow healthier communities to access its grant assistance. EDA's mission is to help distressed communities become competitive, productive, and strong; and Congress mandates that appropriated funds meet those goals. EDA encourages healthy communities to mentor and share best practices with distressed communities to help develop robust Regional economies across the U.S. In addition, EDA's Research and National Technical Assistance programs provide tools and resources that all types of communities are encouraged to access. *See http://www.eda.gov/Research/Research.xml* for more information.

Two comments suggest that EDA support sustainable development through ''grant guidelines that reward communities for sustainable development strategies such as locating new development on previously developed land or close to existing activity centers and near transportation choices'' and ensure that the agency's rules and regulations do not contribute to development sprawl. EDA encourages such Projects through the evaluation criterion (set out at § 301.8(e)) that highlights environmentally sustainable development, and an application that includes elements of place-based development may meet EDA's ''sustainable development'' evaluation criterion. EDA strongly encourages Projects that enhance the environment and advance economic development goals and welcomes comments that offer specific ways the agency can incentivize sustainable development practices.

Another commenter suggests that ''EDA consider evaluating * * * projects * * * on the extent to which they engage the full spectrum of key participants,'' and illustrates the point by citing research on the creation of innovation networks. EDA realizes that having the right stakeholders at the table is crucial to a coordinated, efficient economic development program, and through its evaluation criteria set out at § 301.8, EDA encourages collaborative Regional innovation and public-private partnerships. In addition, through the agency's initiatives to encourage commercialization and technology transfer, including the i6 Challenge competitions, EDA encourages partnerships that engage the full spectrum of necessary stakeholders, from research and development to marketing and commercialization.

Two comments suggest that EDA should not focus on Projects with indicia of success (i.e., high matching levels, clear leadership, etc.) to avoid ''funding projects that do not need government assistance.'' One of the commenters notes that ''EDA should continue to make sure that projects have sound business plans for sustainability, but rural projects should not be held to the same economic thresholds for economic benefit because they do not have the population base and economy to support rural projects as urban projects do.'' EDA is accountable for Federal funds, and to ensure that they go the furthest and provide the most benefit, EDA does assess the feasibility and job creation potential of Projects. However, EDA is sensitive to the unique economic condition of individual communities and Regions. While EDA ensures that Recipients are accountable for individual Project goals, EDA does not require any particular output or benefit threshold, and seeks to incentivize results that work for and are proportionate to each community. *See also* EDA's revised accountability provision at § 302.16.

EDA received one overarching comment requesting that the agency adopt and announce specific award and match amounts, eligible areas, and project types. PWEDA and the agency's implementing regulations provide an adaptable framework within which EDA helps communities assess their present economic environment, envision their future goals and develop economic development plans accordingly, and deploy resources appropriate to effect those plans. EDA's assistance also allows Regions to adapt to changing economic landscapes and needs. Adopting specific requirements would stymie EDA from meeting the current needs of distressed Regions and helping to implement the most effective economic development strategies. Therefore, EDA declines to make this change.

This NPRM proposes to amend § 301.9 to remove the phrase ''for further consideration'' in paragraph (a), which relates to a concept specific to EDA's application selection process that was in place prior to October 14, 2010. In addition, EDA proposes minor changes to replace the phrase ''based on'' with ''in accord with'' in § 301.9(a)(2) and rephrase § 301.9(b) to read ''EDA will endeavor to notify applicants as soon as practicable regarding whether their applications are selected for funding'' instead of ''EDA will endeavor to notify applicants regarding whether their applications are selected as soon as practicable.''

EDA proposes removing the word ''construction'' from the first sentence of § 301.10(c). The use of ''construction'' is confusing as CEDS are required for all Projects under parts 305 and 307, including non-construction implementation Projects under part 307. Note that a CEDS is not a requirement for Strategy Grant Projects and a Project located in a Special Impact Area, as specified under § 301.10(c)(1) and (2). In addition, we propose minor changes to capitalize ''Federal'' in § 301.10(b) to adhere to the capitalization convention of the regulations, replace the word ''of'' with the phrase ''stated in'' in the third sentence of § 301.10(c), and replace ''Projects'' with ''A Project'' in § 301.10(c)(2). In response to an internal comment from EDA staff, EDA proposes amending § 301.10 by adding new paragraph (d) to clarify the application requirements for the construction of business, technology, or other types of incubators or accelerators. Because these types of construction Investments are designed to catalyze growth in innovative sectors, EDA proposes requiring a feasibility study to evaluate the need for the Project and an operational plan based on industry best practices to ensure the Project's longevity. EDA will provide additional information on these requirements in an applicable FFO. The information provided by such documents is crucial in helping EDA ensure that Federal

funds are put to their best use. The third sentence of new § 301.10(d) also provides that EDA may require a Recipient to demonstrate that a feasibility study has been conducted by an impartial third party, as determined by EDA.

This NPRM also adds a new section at § 301.11 to clarify that EDA funds a broad spectrum of construction and non-construction infrastructure to meet a community's strategic goals, from basic assets to innovation- and entrepreneurship-related infrastructure. Each EDA Investment is designed to meet a community where it is and help it reach its highest economic development potential. Paragraph (a) of the proposed provision provides some examples of innovation- and entrepreneurship-related infrastructure, including business incubation, business acceleration, venture development organizations, proof of concept centers, and technology transfer. Before this NPRM, these terms had not been delineated within the framework of EDA's regulations. Paragraph (b) of the proposed provision provides that EDA will seek to fund Projects that effectively leverage Federal resources and restates EDA's statutory restriction on providing funds to any for-profit entity. Proposed § 301.11 is intended to help clarify these terms and is not intended to be restrictive or exclusive.

Part 302—General Terms and Conditions for Investment Assistance

Part 302 sets forth the general terms and conditions for EDA Investment Assistance, including environmental reviews of Projects; relocation assistance and land acquisition requirements; inter-governmental review of Projects; and Recipients' reporting, recordkeeping, post-approval, and civil rights requirements.

EDA proposes a minor change to the third sentence of § 302.1 to clarify that environmental information may be obtained from the individual serving as the Environmental Officer in the appropriate regional office. EDA also capitalizes ''Project'' in the second sentence, and replaces the word ''can'' with ''may'' and removes ''as'' immediately before ''listed'' in the third sentence. We propose small changes to § 302.3 to replace the word ''any'' with ''an'' immediately preceding the phrase ''EDA-administered program'' in the first sentence of the provision and to remove the unnecessary phrase ''but is not limited to'' in the second sentence. We also propose removing the unnecessary phrases ''but not limited to'' from §§ 302.6 and 302.8. In addition, the agency proposes non-substantive changes to § 302.9(a), which sets out the requirements for inter-governmental reviews of Projects, to replace ''fifteen (15)'' with ''15'' in the first sentence of the provision and ''Eligible Applicants'' with ''the Eligible Applicant'' and ''their'' with ''its'' in the second sentence of the provision. In addition, EDA proposes to make the regulation easier to read by separately listing the documentation required when a Recipient either does or does not receive comments from an Authority as subsections (1) and (2) under paragraph (a). In § 302.9(b), EDA makes a grammatical correction by replacing the phrase ''must also'' with ''also must.'' EDA also proposes a minor change by replacing the phrase ''Web site'' with ''website'' in § 302.11.

This NPRM also proposes updating § 302.10, which implements section 606 of PWEDA (42 U.S.C. 3216) and sets out requirements regarding entities that expedite applications to EDA and restrictions on the employment of certain EDA employees by Eligible Applicants. Section 606(2) of PWEDA (42 U.S.C. 3216) sets out a post-employment restriction that requires ''businesses'' to refrain from offering employment to or employing certain EDA employees for a period of two years after an award of Investment Assistance. The purpose of the post-employment restriction is to prevent situations in which an Eligible Applicant uses or appears to use its employment practices to influence EDA and DOC employees with award decision-making authority. EDA recently made a policy decision to provide greater flexibility in the application of the post-employment restriction, specifically addressing Eligible Applicants where there is a greater chance of such undue influence. In general, such Eligible Applicants are smaller organizations or organizations that lack standard hiring procedures. Therefore, in the context of the post-employment restriction, EDA has determined that ''businesses'' means Eligible Applicants that are: (1) Non-profit organizations; (2) District Organizations of an EDA-designated EDD; and (3) for-profit organizations. In addition, EDA retains the flexibility to require another type of Eligible Applicant to execute an agreement to abide by the above-described post-employment restriction on a case-by-case basis; for example when an institution of higher education implements the EDA scope of work or activities related to the EDA scope of work through a separate non-profit organization.

EDA proposes revising § 302.10 to reflect its updated policies. Currently, both the expediter requirements and post-employment restriction are combined in § 302.10. EDA proposes to restructure the regulation so that § 302.10(a) incorporates the expediter requirements, which remain substantively unchanged, and § 302.10(b) incorporates the updated post-employment restriction. Accordingly, EDA revise the heading of § 302.10 to read ''Attorneys' and consultants' fees, employment of expediters, and post-employment restriction'' instead of ''Attorneys' and consultants' fees; employment of expediters and administrative employees,'' adds the heading *Employment of expediters* to revised § 302.10(a), and the heading *Post-employment restriction* to revised § 302.10(b). EDA makes minor clarifying corrections, replacing two instances of the word ''applications'' with ''an application'' or ''the application,'' as applicable, in the second sentence of proposed § 302.10(a) and removing two repetitive numerical references from proposed § 302.10(b), replacing ''two-year (2)'' with ''two-year'' and ''one-year (1)'' with ''one-year.''

EDA received two comments requesting that EDA relax or waive the wage rate requirements of the Davis-Bacon Act (40 U.S.C. 3142 *et seq.*), which apply to contractors and subcontractors performing on Federally funded or assisted contracts in excess of $2,000 for the construction, alteration, or repair (including painting and decorating) of public buildings or public works. The Davis-Bacon Act requires contractors and subcontractors to pay any laborers and mechanics employed under the contract (or subcontract) no less than the locally prevailing wages and fringe benefits for corresponding work on similar projects in the area. Section 602 of PWEDA (42 U.S.C. 3212) provides that Davis-Bacon applies to all ''projects assisted by the Secretary under this Act.'' Therefore, EDA cannot waive the wage rate requirements. Accordingly, the regulation at § 302.13 implements the Davis-Bacon requirement. EDA provides guidance and works closely with Recipients to ensure that the Davis-Bacon requirements and responsibilities are clear under the terms of an award of financial assistance.

This NPRM makes a clarifying revision to the heading of § 302.15 by inserting the word ''made'' immediately after the word ''certifications.'' This NPRM revises § 302.16 to set out EDA's accountability and performance expectations, along with its reporting

requirements. Accordingly, EDA revises the heading of the provision to read ''Accountability'' instead of ''Reports by Recipients.'' EDA also adds new paragraph (d) to clarify that EDA expects Recipients to use good faith efforts to meet Project goals and set out the consequences for failure to undertake such efforts. This provision is not punitive and is not intended to discourage accurate reporting; EDA understands that at times, circumstances beyond a Recipient's control will prevent the fulfillment of Project goals. Its purpose is to underscore the importance that a Recipient undertake the Project scope of work in good faith and with integrity. EDA works closely with its partners to make sure they have the tools and resources necessary to achieve the best economic outcomes possible. Also, EDA adds paragraph headings to § 302.16 to help the reader navigate the provision; specifically adding the header *General* to paragraph (a); *Data on Project effectiveness* to paragraph (b); *Reporting Project service benefits* to paragraph (c); and *Consequences for failure to undertake good faith efforts* to new paragraph (d). We propose removing a repetitive numerical reference in paragraph (a) by replacing ''ten (10)'' with ''ten.'' In the first sentence of paragraph (b) of the provision, EDA proposes adding the phrase ''and meeting Project goals'' immediately following the phrase ''including alleviation of economic distress'' with the parenthetical, inserting ''as amended'' following the reference to the Government Performance and Results Act of 1993 (''*GPRA*''), and adding a citation for the GPRA, specifically, Public Law 103–62.

EDA received three comments on the agency's conflicts-of-interest requirements, which are set out at § 302.17. Under EDA's policy, Eligible Applicants must avoid the appearance of or actual conflicts-of-interest, which generally exist when an Interested Party of a Recipient participates in a matter that has a direct and predictable effect on the Interested Party's personal or financial interests. EDA defines ''*Interested Party*'' as ''any officer, employee or member of the board of directors or other governing board of the Recipient, including any other parties that advise, approve, recommend or otherwise participate in the business decisions of the Recipient, such as agents, advisors, consultants, attorneys, accountants or shareholders. An Interested Party also includes the Interested Party's Immediate Family and other persons directly connected to the Interested Party by law or through a business arrangement.'' *See* § 300.3. The comments suggest that EDA reevaluate and relax the conflicts-of-interest requirements. One commenter details how EDA's conflicts-of-interest policy impacted a Project and was particularly concerned with the ''vague'' standard of an apparent conflict-of-interest and how the requirement impacts the ability of small communities to attract ''well-informed and motivated residents to run for locally elected offices.''

EDA's requirements comport with the requirements of other Federal Agencies, including DOC's requirements set out at 15 CFR 24.36(b) or 14.42, as applicable, and are designed to maintain public trust in the efficiency and effectiveness of the agency's grant assistance. EDA does not intend for its conflicts-of-interest policy to burden or penalize communities or to halt innovative economic development projects, but does believe that the policy is extremely important to the integrity and transparency of EDA's programs. EDA staff work closely with Eligible Applicants to identify conflicts-of-interest issues early on and develop solutions that will keep Projects on track. This NPRM does not propose substantive changes to § 302.17, but EDA welcomes constructive comments on ways to balance the agency's fiduciary and transparency responsibilities with the goal of implementing economic development projects. Note that this NPRM does make minor grammatical corrections by replacing ''may also'' with ''also may'' in the third sentence of § 302.17(a), replacing ''shall also'' with ''also shall'' in § 302.17 (b)(2), and removing ''also'' from § 302.17(c)(2). We replace ''two (2)'' with ''two'' in § 302.17(c)(3).

EDA received one comment that the agency's post-approval requirements regulation (§ 302.18) is confusing in that it does not specifically apply to all EDA awards. This NPRM proposes revising the regulation by removing paragraph (b), which applies only to EDA's Economic Adjustment Assistance Investments, in its entirety. We maintain paragraph (a) in substance, but remove the unnecessary lettered designation and revise the provision to clarify that post-approval requirements apply to all EDA awards. EDA also replaces the phrase ''special terms'' with ''special award conditions'' to comport with EDA's usual terminology.

EDA received an internal comment suggesting that EDA specify in the regulations that the requirements under the Americans with Disabilities Act (''*ADA*'') (42 U.S.C. 12101 *et seq.*) apply to EDA Projects. The civil rights requirements applicable to Recipients and Other Parties are set out at § 302.20. Section 302.20 specifies that discrimination is prohibited by a Recipient or Other Party with respect to a Project receiving Investment Assistance under PWEDA or by an entity receiving Adjustment Assistance under the Trade Act, in accordance with a list of enumerated authorities. While EDA agrees that it should be clear that the ADA applies to EDA Projects, we note that the enumerated list set out at § 302.20 includes section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794), which prohibits discrimination on the basis of disabilities. In addition, the requirements of the ADA are applicable to all EDA Recipients by virtue of the DOC's Financial Assistance Standard Terms and Conditions, which apply to all non-construction awards, and EDA's Standard Terms and Conditions for Construction Projects, which apply to all construction awards. Because discrimination on the basis of disability already is prohibited with respect to EDA Projects, we decline to make the change. EDA makes non-substantive changes in § 302.20(b)(1) by replacing ''fifteen (15)'' with ''15,'' making a minor grammatical correction by replacing ''is also'' with ''also is,'' and replacing the final usage of the term ''Investment Assistance'' immediately following the phrase ''EDA's final disbursement of'' with ''award'' for simplicity.

Part 303—Planning Investments and Comprehensive Economic Development Strategies

Part 303 sets forth regulations governing EDA's Planning program, through which the agency provides assistance to help Eligible Applicants create strategies or plans to stimulate and guide the economic development efforts of a community or Region. EDA has three distinct types of Planning Investments: (1) Partnership Planning; (2) State Planning; and (3) short-term Planning. Through EDA's Partnership Planning Investments, the agency facilitates the development, implementation, revision, or replacement of CEDS. EDA provides Partnership Planning awards to Planning Organizations (e.g., District Organizations) serving EDA-designated EDDs (as defined in § 300.3) throughout the U.S. The EDDs are recognized by the State(s) in which they reside as multi-jurisdictional councils of governments, regional commissions, or planning and development centers. Further information on EDDs may be found on EDA's Web site at *http://www.eda.gov/*

PDF/EDD%20List_030410.pdf. The Partnership Planning awards enable Planning Organizations to manage and coordinate the development and implementation of CEDS to address the unique needs of their respective Regions. The CEDS are central to EDA's economic development initiatives, and a proposed Project must be consistent with a relevant CEDS before EDA makes a competitive award under the Public Works or Economic Adjustment Assistance programs under parts 305 or 307. Finally, part 303 sets forth the requirements for State and short-term Planning Investments, which can help distressed Regions strategize to create and retain new and better jobs and respond quickly and effectively to sudden economic dislocations.

In response to a suggestion from EDA staff, this NPRM proposes adding subparts to part 303 to better organize and clarify the distinctions between EDA's Planning Investments. General requirements that apply to all Planning Investments are set out at §§ 303.1 thorough 303.5 and included under new ''Subpart A—General.'' Requirements specific to Partnership Planning Investments are set out at §§ 303.6 and 303.7 under new ''Subpart B—Partnership Planning Assistance.'' Similarly, requirements specific to State plans and short-term Planning Investments, §§ 303.8 and 303.9, respectively, are included under new ''Subpart C—State and Short-Term Planning Assistance.''

This NPRM proposes revising the heading of § 303.1 from ''Purpose and scope'' to ''Overview of EDA's Planning Program'' to clarify the content of the provision. In the final sentence of the introductory text to § 303.1, EDA proposes to replace the phrase ''Private Sector Representatives'' with ''the private sector.'' As noted above under ''Part 300—General Information'' this NPRM proposes to remove ''*Private Sector Representative*'' as a defined term; however, EDA expects that the private sector will remain actively involved in Regions' planning processes. We also propose adding ''non-profit organization'' and ''educational institutions'' to the list of entities that EDA expects will be active participants in the planning process. EDA also proposes minor changes to § 303.1 to move the phrase ''short-term Planning Investments'' after ''State plans'' to comport with the order of the regulations, and to replace the phrase ''higher-skill, higher-wage jobs'' with ''new and better jobs.'' EDA capitalizes ''Regional'' in the second sentence for consistency in the use of defined terms. In § 303.3, EDA proposes minor textual changes to paragraph (a)(5) by replacing the phrase ''higher-skill, higher wage'' with ''new and better'' and to paragraph (c) by replacing ''shall also'' with ''also shall.'' In § 303.4(a), EDA proposes replacing the sentence ''Planning Investments shall function in conjunction with any other available Federal, State or local planning assistance to ensure adequate and effective planning and economical use of funds'' with ''Planning Investments shall be coordinated with and effectively leverage any other available Federal, State, or local planning assistance and private sector investments'' for better sentence structure and to emphasize the importance of public-private partnerships. EDA also removes a redundant numerical reference from § 303.4(c), replacing ''thirty-six (36) month'' with ''36-month.''

As noted above, this NPRM proposes incorporating all Partnership Planning provisions under new ''Subpart B—Partnership Planning Assistance'' for increased clarity. Because the Partnership Planning Investments and CEDS process are closely linked, EDA proposes restructuring § 303.6, which currently sets out the process requirements for developing a CEDS, to incorporate a description of Partnership Planning along with the CEDS process requirements. Accordingly, this NPRM revises the heading of § 303.6 to read ''Partnership Planning and the EDA-funded CEDS process'' to better specify the intent of the provision. EDA proposes a description of Partnership Planning Investments at new § 303.6(a), which this NPRM titles *Partnership Planning overview,* and incorporates CEDS Strategy Committee and process requirements, which are currently set out under § 303.6(a) through (e), under § 303.6(b), which this NPRM titles *CEDS process.* EDA also appropriately renumbers proposed § 303.6(b). EDA proposes subparagraph headings within § 303.6(b) to serve as guideposts to help the reader more easily navigate the provision. Accordingly, headings to proposed § 303.6(b)(1) through (b)(5) are added to read as follows: *CEDS Strategy Committee, Public notice and comment, Reports and updates, Inadequate CEDS,* and *Regional Commission notification,* respectively.

EDA received five public comments suggesting that the agency provide increased flexibility with regard to the membership requirements of CEDS Strategy Committees, the requirements of which currently are set out at § 303.6(a) and that this NPRM proposes relocating to § 303.6(b)(1) as stated above. Currently, a CEDS Strategy Committee must represent the main economic interests of the Region, and must include Private Sector Representatives as a majority of its membership. For the CEDS process and the resulting strategy to be effective, the Strategy Committee must reflect all key stakeholders from across the Region. However, EDA wishes to provide flexibility for all types of communities and Regions, and therefore, under this NPRM, EDA proposes to maintain the requirement that a Strategy Committee represent the main economic interests of the Region, including the private sector, public officials, community leaders, private individuals, representatives of workforce development boards, institutions of higher education, and minority and labor groups, but no longer requires a majority or membership threshold from any type of economic stakeholder. In addition, EDA proposes to add the clause ''and others who can contribute to and benefit from improved economic development in the Region'' to revised § 303.6(b)(1) to address any stakeholders that EDA's list may miss. Although EDA proposes to remove the membership threshold, the capability of each Strategy Committee to undertake a Regional planning process remains of principal importance. Accordingly, EDA adds the sentence ''In addition, the Strategy Committee must demonstrate the capacity to undertake a collaborative and effective planning process.'' EDA will provide guidance to implement this requirement. EDA expects that every Strategy Committee will include strong private sector representation unless such representation is proscribed by State law.

One public comment and an internal comment from EDA staff suggest that EDA reform its regulations to ''emphasize broader and ongoing multi-stakeholder input in the planning process.'' The current public review and comment requirement, as set out at § 303.6(b)(2), requires simply that CEDS be made available to the public for comment for at least 30 days before submission to EDA. EDA believes that public input is crucial to a Regional planning process and agrees that the requirement should contain further details. EDA proposes revising the regulation to combine existing § 303.6(b)(1) and (b)(2) into revised § 303.6(b)(2), which sets out revised public comment requirements. Under the revised requirements, before submission of a CEDS to EDA, the Planning Organization must provide the public and appropriate governments and interest groups with adequate notice and opportunity to comment on

the CEDS. For maximum flexibility, EDA maintains the requirement that the comment period be for at least 30 days, but goes on to specify that the Planning Organization must make the CEDS available appropriately, electronically and otherwise, throughout the comment period. The Planning Organization also must make the CEDS available in hardcopy upon request. Finally, the provision states that EDA may require the Planning Organization to provide any comments received on the CEDS and demonstrate how the comments were resolved. The proposed regulation is designed to be flexible enough to work for all communities, while providing ample guidance to gather public input.

The remainder of the CEDS process requirements remain substantively the same, and are incorporated under § 303.6(b)(3)–(5). This NPRM also removes a repetitive numerical reference, replacing ''five (5)'' with ''five'' in proposed § 303.6(b)(3)(ii).

EDA proposes textual changes to the introductory text of § 303.7(b), which frames the process and participation expectations of CEDS and introduces the content requirements. EDA revises the heading of § 303.7(b) to read ''*Strategy requirements''* instead of ''*Technical requirements''* to emphasize that CEDS are strategy documents and replaces the word ''continuing'' with the phrase ''comprehensive and continuous'' in the first sentence of § 303.7(b)(1). EDA proposes a second sentence to EDA highlight that CEDS must be consistent with section 302 of PWEDA (42 U.S.C. 3162), which sets out the requirements for CEDS, and that CEDS must promote Regional economic resiliency and be unique and responsive to the relevant Region.

EDA received several comments, both public and internal, on the content requirements of CEDS, which currently are set out at § 303.7(b)(1)–(10). One commenter recommends that EDA ''support regional and local planning and economic visioning efforts that take into account local and regional assets.'' Another commenter suggests that EDA ensure the Planning program encourages ''strategic doing'' by ''funding strategic planning activities that begin with an initial survey of regional assets, stakeholders, and opportunities and provide a framework for activities for ongoing networking and feedback.'' EDA's Planning program and the requirements of CEDS accomplish those goals by creating an ongoing planning process that begins by evaluating current Regional baselines, setting a vision for competitiveness and innovation, and establishing a strategy tailored to reach the Region's goals.

Several comments suggest that the current CEDS content requirements are counterproductive in that they create ''a situation in which the CEDS must be used as a place to dump data and becomes a lengthy narrative * * * of limited value to businesses and economic development practitioners'' and that ''plan writers spend most of their time trying to check off its boxes rather than focus on a plan that is truly relevant to the unique circumstances and assets of any given region.'' The commenters suggest various ways to streamline CEDS, including four that suggest adopting the National Association of Development Organizations' (''*NADO''*) Peer Standards of Excellence. One of the comments suggests that the amount of background materials required in CEDS should be reduced to ''[a]llow EDDs to focus CEDS on specific strategies (put the S back in CEDS), rather than a comprehensive narrative of the region.'' EDA received several comments that focus on the ''project list'' aspect of CEDS in current § 303.7(b)(5), which requires that CEDS include ''[a] section listing all suggested Projects and the projected numbers of jobs to be created as a result thereof.'' Two comments request that EDA eliminate this requirement, suggesting that it encourages the making of project laundry lists instead of catalyzing strategic thinking. Four comments suggest that any required CEDS project list should be meaningful in the EDA selection process, and one comment recommends that any project not included in a CEDS should not be considered for funding by EDA. One comment states that ''[o]nly in rare and unusual circumstances should projects not prioritized in the CEDS be supported without a full CEDS amendment including public review of project priorities.''

EDA agrees with its stakeholders that the list of CEDS requirements may be counterproductive for many Regions and therefore proposes significantly streamlining § 303.7(b) from ten detailed specifications to four essential planning elements set out at § 303.7(b)(1)(i) through (iv): (1) A summary of economic development conditions of the Region; (2) an in-depth analysis of economic and community strengths, weaknesses, opportunities, and threats (commonly known as a ''*SWOT''* analysis); (3) strategies and an implementation plan to build upon the Region's strengths and opportunities and resolve the weaknesses and threats facing the Region, which should not be inconsistent with applicable State and local economic development or workforce development strategies; and (4) performance measures used to evaluate the Planning Organization's successful development and implementation of the CEDS. Lists of specific projects, including prioritized lists, will not be required in the CEDS, but may be used by the Planning Organization to illustrate the implementation of the CEDS. EDA neither encourages nor discourages such project lists in order to provide Planning Organizations the maximum flexibility to create strategies most suited to their Region.

EDA recognizes that economic development planning is a dynamic field and best practices are constantly evolving. Therefore, EDA will publish and periodically update specific CEDS content guidelines, which will be based on best practices developed in collaboration with the agency's cutting edge planning and economic development partners as well as on leading edge research. For example, EDA expects that the relevant guidelines will include NADO's Peer Standards of Excellence, which are strategic principles that ensure accountability and performance, while allowing for Regional flexibility and creativity. Transformative CEDS take the form of effective, agile strategies, not static lists of requirements and projects. The development and maintenance of a CEDS requires Planning Organizations to undertake an iterative process of gathering data and community input and adapting the strategy to the facts on the ground. EDA expects that these changes will ensure that CEDS remain relevant economic development strategies by allowing Planning Organizations to focus on inclusive planning processes and positive economic development results.

With respect to the comment suggesting that EDA implementation projects must be tied to the CEDS of EDDs, EDA already requires that Projects under the agency's Public Works and Economic Adjustment Assistance programs be consistent with a relevant CEDS, per the requirements of sections 201 and 209 of PWEDA (42 U.S.C. 3141 and 3149, respectively).

Other comments suggest discrete changes, including requiring an analysis of RICs in the CEDS document and modernizing ''CEDS data sets * * * to include relevant 21st Century global knowledge economy indicators and measures at the regional level.'' EDA thanks the commenters and expects that these comments will be addressed through the CEDS guidelines that EDA

publishes incorporating the best practices of its economic development and research partners.

EDA received two public comments and an internal comment regarding the agency's consideration of a CEDS developed independent of EDA assistance, as set out at § 303.7(c). EDA-funded CEDS must adhere to the requirements of § 303.7(b), but the agency may accept a non-EDA funded strategy as a CEDS at the agency's discretion. Both public and internal comments suggest that consistent requirements should apply to both EDA-funded and non-EDA funded CEDS. EDA is currently reviewing the issue, and expects to address the requirements of non-EDA funded CEDS in published CEDS guidelines.

As noted above, State and short-term Planning requirements are incorporated under new ''Subpart C—State and Short-Term Planning Assistance.'' In addition, this NPRM proposes minor changes to the first sentence of § 303.9(a), replacing the phrase ''may also'' with ''also may,'' for better sentence structure, and to § 303.9(b) to remove the unnecessary phrase ''but are not limited to.''

In addition, EDA received two comments stating that ''[d]ocumentation on how to prepare CEDS Updates, Government Performance and Results Act reports, and CEDS Annual Performance reports is ambiguous or unclear and results in a disparity among reports of EDDs.'' Clearer guidance on what EDA expects in these documents is an identified need. Accordingly, EDA currently is evaluating its Planning program and expects to issue updated guidance in the near future.

Part 304—Economic Development Districts

Part 304 on Economic Development Districts, which also may be referred to as a ''*District*'' or an ''*EDD*'' in § 300.3, sets forth the Regional eligibility requirements that must be satisfied in order for EDA to consider a District Organization's request to designate a Region as an EDD, including submission of an EDA-approved CEDS, and the District Organization's formation and organizational requirements. This part also contains provisions relating to termination and performance evaluations of District Organizations.

EDA corrects a punctuation error in § 304.1(c) by adding a colon (':'') at the end of the phrase ''Has an EDA-approved CEDS that.'' In addition, we remove a redundant numerical reference by replacing ''one (1)'' with ''one'' in § 304.1(a) and, for better sentence structure, replace ''must also'' with ''also must'' in § 304.2(c)(1) and ''shall also'' with ''also shall'' in § 304.2(c)(4)(i).

Section 304.2(c)(2) sets out the requirements for governing bodies (sometimes known as ''policy boards'') of District Organizations. Currently, the governing body of a District Organization must be broadly representative of the principal economic interests of the Region and, unless prohibited by State or local law, must include:

- At least one Private Sector Representative;
- At least one or more Executive Directors of Chambers of Commerce, or representatives of institutions of post-secondary education, workforce development groups, or labor groups, all of which must comprise in the aggregate a minimum of 35 percent of the District Organization's governing body; and
- A simple majority of its membership who are elected officials and/or employees of a general purpose unit of State, local, or Indian tribal government who have been appointed to represent the government.

EDA received four public comments suggesting that the regulations should provide ''[i]ncreased flexibility for governance structure and local control of EDD policy boards.'' EDA agrees that District Organizations should be focused on implementing a dynamic and effective planning process for the Region instead of meeting and maintaining membership thresholds. Therefore, we propose revisions to § 304.2(c)(2) to remove the current membership thresholds, but maintain the requirement that governing bodies demonstrate that they are broadly representative of the principal economic interests of the Region, including the private sector, public officials, community leaders, representatives of workforce development boards, institutions of higher education, minority and labor groups, and private individuals. Although EDA proposes to remove the membership thresholds, the capability of each governing body to implement the relevant CEDS remains of principal importance. Accordingly, EDA adds the sentence ''In addition, the governing body must demonstrate the capacity to implement the EDA-approved CEDS.'' EDA will provide guidance to implement this requirement. EDA expects that every District Organization governing body will include strong private sector representation unless such representation is proscribed by State law.

EDA makes conforming changes to § 304.2(c)(2) to remove the provisions that allow the Assistant Secretary to waive the Private Sector Representative requirement upon a Region's showing of its inability to locate such a representative and the prohibition on the Assistant Secretary's delegation of this waiver authority.

Also with respect to District Organization governing body membership requirements, one commenter suggests that EDA ''expand its list of representatives able to be members of an EDD Board to include Executive Directors of Economic Development Corporations in addition to Chambers of Commerce directors.'' One internal comment suggests that EDA specify that the simple majority requirement can be met by special purpose as well as general purpose units of government and a second internal comment suggests that EDA reduce the 35 percent requirement to 25 percent to better fit with local board composition requirements. EDA agrees, but as EDA has revised the membership requirements of District Organization governing bodies to remove membership thresholds, these changes are no longer necessary.

In response to an internal comment, EDA revises § 304.2(c)(4) to require that governing bodies of District Organizations meet at least twice a year, instead of only once a year. EDA hopes that requiring at least two meetings a year will increase public participation in District Organization operations and help to provide increased insight into the importance of these organizations.

EDA corrects a typographical error in § 304.4(a)(3), replacing the phrase ''on this chapter'' with ''of this chapter.'' In addition, this NPRM removes redundant numerical references by replacing ''sixty (60)'' with ''60'' in § 304.3(b), two instances of ''three (3)'' with ''three'' in § 304.4(a), and ''one (1)'' with ''one'' in § 304.4(b).

EDA received six comments suggesting that the agency require greater coordination between Eligible Applicants and District Organizations. Commenters provide a variety of coordination recommendations; two suggest that EDA not fund projects that are not included in a CEDS, three suggest that EDA ''require coordination with Districts for projects submitted by those outside the District but proposing activities that affect a District's communities,'' and one suggests requiring a letter of consistency from the relevant District Organization for all projects. EDA strongly values its partnerships with District Organizations of EDDs. However, EDA does not make these changes because of the requirements of PWEDA. Under sections

201(b)(3) and 209(b) of PWEDA (42 U.S.C. 3141 and 3149, respectively), all grants awarded under EDA's Public Works and Economic Adjustment Assistance programs must be consistent with a relevant CEDS. PWEDA does not impose this requirement upon its other programs.

EDA received two comments that recommend restoring the 10 percent bonus for Eligible Applicants that demonstrate active participation with the relevant District Organization. The Economic Development Administration Reauthorization Act of 2004 (Pub. L. 108–373) removed former section 403 of PWEDA, which authorized up to a 10 percent ''bonus'' for certain Projects as an incentive for coordination with District Organizations. Because such use of appropriated funds is not authorized under PWEDA, EDA is unable to reinstate the bonus.

EDA also received two comments suggesting that the agency provide additional financial resources to District Organization planners and staff and provide ''access to regularly scheduled professional development opportunities to [ensure] that their skill sets are at peak performance'' and that they are the ''best economic development professionals in a region.'' One commenter suggests that EDA's University Center program be ''encouraged to provide * * * professional development for District Organizations to improve and enhance their professional capacity.'' EDA endeavors to fulfill the budget requirements and needs of all of its District Organizations across the U.S. The agency strongly encourages District Organization planners and staff to seek out and take advantage of professional development opportunities; and the agency strives to be a part of this by providing regional conferences and webinars throughout the year and by providing practitioner tools. *See http://www.eda.gov/Research/Research.xml.*

In addition, EDA agrees that collaborations across programs are essential to leveraging constrained resources and continually seeks ways to ensure its programs coordinate effectively. For example, in EDA's FY 2011 University Center program competition, EDA specified that the agency encourages University Center Projects that ''present a clear plan for collaborating with and assisting other EDA investment partners, recipients, and stakeholders, including EDA-funded Economic Development Districts'' and Projects that ''offer a full range of economic development research and technical assistance services to EDA regional partners (e.g., District Organizations * * *).'' *See* section I.B. of EDA's FY 2011 University Center FFO dated March 31, 2011.

Finally, one comment suggests that District Organizations provide ''grant-writing support'' to rural regions and that EDA provide ''additional resources to support this function'' and an internal comment suggests that EDA ''identify ways to compensate or provide financial incentives for District Organizations that help design and process successful EDA applications.'' As noted above, EDA supports such collaborations and strives to provide the resources to make them happen.

Part 305—Public Works and Economic Development Investments

Part 305 provides information about EDA's Public Works and Economic Development Investments. Section 305.1 explains the purpose and scope of these Investments. Section 305.2 specifies the scope of activities eligible for consideration under a Public Works Investment and sets forth a list of determinations that EDA must reach in order to award a Public Works Investment. Specific application requirements are set forth in § 305.3, and § 305.4 provides the requirements for Public Works Investments awarded solely for design and engineering work.

EDA proposes a minor change to § 305.1 to replace the phrase ''higher-skill, higher-wage job opportunities'' with ''new and better job opportunities'' in the last sentence of the provision. EDA also replaces the phrase ''the creation of new, or the retention of existing'' with the phrase ''to create new or retain existing'' in the second sentence of the provision for better sentence structure. Section 305.2(c) sets out the requirement that not more than 15 percent of EDA's appropriations made available for Public Works Investments be used in any one State. We received an internal comment suggesting that EDA revise § 305.2(c) by replacing the phrase ''Not more than fifteen (15) percent of the annual appropriations made available to EDA to fund Public Works Investments'' with the phrase ''Not more than fifteen (15) percent of EDA's *total* annual appropriations to fund Public Works Investments.'' The comment raises the question of whether EDA's regular annual appropriations include special or supplemental appropriations that may be used for Public Works Investments. We have examined the law on this topic and, since an agency's annual appropriations include both regular annual and any special or supplemental appropriations, the requested change does not add anything to the phrase and therefore we decline to make it. However, EDA proposes non-substantive revisions to § 305.2(c) to remove repetitive numerical references, replacing ''fifteen (15)'' with ''15'' and ''one (1)'' with ''one.''

Section 305.5 sets out the requirements for a request and EDA's determination that a District Organization may administer a Project on behalf of another Recipient. Section 305.5(b) provides that EDA may approve such a request either by approving the application in which the request is made or through a separate specific written approval. We received an internal comment suggesting that the reference to the separate specific written approval be removed; however, we decline to make the change as we believe the regulation is clear and that the additional language gives EDA's regional offices needed flexibility. In addition, we received two internal comments suggesting that the regulation be clarified with respect to whether competition is required when a District Organization administers a Project. PWEDA envisions a special role for District Organizations of EDDs as Regional economic development planners and leaders, and we believe the current regulations reflects that role. Therefore, we decline to make the change.

EDA received one public comment and an internal staff comment with respect to the alternate construction procurement methods set out at § 305.6(a). The commenters recommend that ''construction management at risk'' not be allowed as an alternate construction procurement method because such contracts are contrary to the Government-wide competitive procurement requirements (*see* DOC's regulations at 15 CFR 14.43 and 24.36, as applicable). We have considered the commenters' concern; but determined that EDA's regulation is consistent with DOC's requirements, which prescribe the procurement requirements applicable to Federal grant assistance, and decline to make the requested change. However, in response to another internal comment from EDA staff, we propose revising the first sentence of § 305.6(a) to clarify that use of an alternate procurement method is subject to EDA's approval by adding the phrase ''shall seek EDA's prior written approval to'' immediately following ''Recipients.'' EDA believes that this approval step will help ensure that Recipients follow correct procedures and that the maximum amount of Project costs are allowable under applicable regulations and Federal cost principles. Also, to provide additional clarity on the content

of the justification a Recipient must provide to use an alternate procurement method, we propose the clause '', including a brief analysis of the appropriateness and benefits of using the method to successfully execute the Project and the Recipient's experience in using the method'' to § 305.6(a)(1). For better sentence structure, EDA replaces the introductory phrase ''These methods include but are not limited to'' with ''These alternate methods may include'' in the second sentence of § 305.6(a). In addition, in § 305.6(b), EDA proposes replacing the phrase ''procurement standards'' with ''procedures and standards'' for consistency with the content of the DOC regulations at 15 CFR parts 14 and 24.

EDA proposes revisions to § 305.8 to improve sentence construction by replacing ''may also'' with ''also may'' in the second sentence of § 305.8(a) and replacing ''and/or'' with ''or'' and ''is also'' with ''also is'' in § 305.8(c). In response to an internal comment from EDA staff, we propose to add a regulatory provision regarding procedures with respect to bid overrun, the omission of which appears to simply have been an oversight. Accordingly, we propose revising the heading of § 305.10, which currently only addresses construction contract bid underrun procedures, to read ''Bid underrun and overrun.'' We incorporate the existing provision regarding procedures in case of bid underrun under new paragraph (a), titled *Underrun.* We add a new paragraph (b) titled *Overrun* to set out EDA's procedures in case of an overrun at construction contract bid opening. In general, the proposed provision provides that in case of an overrun at the construction contract bid opening, the Recipient may take deductive alternatives if provided for in the bid documents, reject all bids and re-advertise, or augment the Matching Share. If the Recipient demonstrates to EDA's satisfaction that the above options are not feasible and the Project cannot be completed otherwise, the Recipient may submit a written request to EDA for additional funding, which will be at EDA's sole discretion and considered in accord with EDA's competitive process requirements. The new provision on bid overrun does not add to or change current requirements; it simply clarifies EDA's existing practice.

EDA received an internal comment suggesting that EDA specify that underrun amounts be transferred to the contingencies line item. EDA agrees that the current provision regarding bid underrun does not reflect EDA's procedures and revises proposed § 305.10(a) to provide that the Recipient must contact EDA immediately to determine correct procedures by replacing the phrase ''the Recipient will notify EDA to determine whether Investment funds should be deobligated from the Project'' with the phrase ''the Recipient shall notify EDA immediately to determine relevant procedures.''

EDA received one comment requesting that EDA streamline its contract approval procedures, suggesting that the agency adopt a pre-approval system or ''some dollar limit or some other threshold'' that triggers EDA's review. Section 305.11 requires EDA to ''determine that the award of all contracts necessary for design and construction of the Project facilities is in compliance with the terms and conditions of the Investment award in order for the costs to be eligible for EDA reimbursement.'' EDA's contract review is intended to help Recipients navigate various Federal requirements, including DOC's regulations (*see* 15 CFR parts 14 and 24, as applicable) and relevant OMB cost principles (*see* 2 CFR parts 220, 225, and 230, as applicable), and help EDA determine whether it can reimburse specific Project costs. EDA's review is not intended to be burdensome and staff makes every effort to expedite the process. As the regulation is in the interest of both the agency and Recipients, EDA does not propose a substantive change.

Part 306—Training, Research and Technical Assistance

Part 306 sets out the requirements for EDA's Local and National Technical Assistance and Research Investments. Both Local and National Technical Assistance Investments help Recipients fill the knowledge and information gaps that may prevent leaders in the public and non-profit sectors in economically distressed Regions from making optimal decisions on local economic development issues. Through the Research program, EDA invests in research and technical assistance-related Projects to promote competitiveness and innovation in distressed rural and urban Regions.

EDA received two comments on part 306. One comment states that ''[c]oordinated regional research networks can provide local political, economic development and business leaders with an understanding of the regional economic context in which they operate, set policy, attract investment and attract and retain jobs,'' and suggests that ''[r]esearch dollars ought to be invested in building coordinated broad-based regional efforts that provide for better dissemination and application of research findings to improve the life of Midwest residents and the competitiveness of Midwest employers.'' EDA has invested extensively in RIC research and capacity building, including the *Know Your Region* project, which provides resources to help practitioners across the nation implement effective Regional economic development strategies. Please see the *Know Your Region* Web site at *http://www.knowyourregion.org/about* for more information. *See* EDA's Web site at *http://www.eda.gov/AboutEDA/RIC/* for more information on EDA's RIC efforts.

The second comment recommends that Technical Assistance program awards ''be reserved for the EDDs to conduct feasibility studies, management and operation plans, and CEDS coordination to [ensure] that any investment targeted [at] RICs [includes] measures that will address the five core evaluation criteria of EDA and create value-added outcomes for the region.'' An EDD is one of the Eligible Recipients listed in section 3 of PWEDA (42 U.S.C. 3122). EDA is not authorized to reserve Technical Assistance program funds for any particular group of Eligible Recipients. Therefore, we decline to make a change to the regulations; however, EDA continues to support District Organizations of EDDs in their efforts to advance new and established RICs.

We make several non-substantive changes to part 306, including rephrasing § 306.1(a) to read ''Local and National Technical Assistance Investments may be awarded to'' instead of ''Local and National Technical Assistance Investments may.'' In addition, we propose italicizing the parenthetical ''(''*University Centers''*)'' in the final sentence of § 306.4. This NPRM also removes repetitive numerical references from part 306 by replacing the phrase ''twelve (12) to eighteen (18)'' with ''12 to 18'' in § 306.3(a); ''eighty (80)'' with ''80'' in § 306.6(d); two instances of ''three (3)'' with ''three'' in § 306.7(a)(1); and ''one (1)'' with ''one'' in § 306.7(c). EDA proposes no other revisions to part 306.

Part 307—Economic Adjustment Assistance Investments

Part 307 sets out the requirements for awards under EDA's Economic Adjustment Assistance program, which can provide a wide-range of technical assistance, planning, and infrastructure assistance in Regions experiencing adverse economic changes that may occur suddenly or over time, including strategy development, infrastructure

construction, and revolving loan fund (''*RLF*'') capitalization. Subpart A of part 307 details the general requirements for Economic Adjustment Assistance awards, and subpart B sets out requirements specific to the RLF program.

Through this NPRM, EDA proposes reorganizing part 307 to help clarify award requirements and incorporate all RLF program requirements under subpart B, which EDA proposes renaming the ''Revolving Loan Fund Program.'' Currently, certain RLF application and post-approval requirements are set out under subpart A of part 307, which may make them difficult to locate. For example, RLF-specific application review requirements are set out at § 307.4(c)(2) and RLF post-approval requirements are set out under § 307.6(d), both of which currently are under subpart A. To eliminate confusion, this NPRM incorporates the RLF application review and post-approval requirements under new § 307.7 titled ''Revolving Loan Fund award requirements'' in subpart B. In addition, EDA proposes non-substantive changes by removing the unnecessary phrase ''but not limited to'' from the first sentence of § 307.1 and removing the hyphen from the phrase ''Federally Declared Disasters'' in § 307.1(b).

In EDA's interim final rule (''*IFR*'') published in the **Federal Register** on October 22, 2008 (73 FR 62858), EDA made revisions to clarify that it no longer allows RLF Recipients to use RLF Capital to guarantee loans. As stated in the 2008 IFR, while the authority for RLF Recipients to guarantee loans with RLF Capital has been used extremely infrequently throughout the four-decade history of the RLF program, EDA determined that loan guaranties are too risky and of limited utility, since, unlike Federal guaranties that are backed by the full faith and credit of the United States, RLF loan guaranties are backed only by the assets in the RLF. Therefore, in response to an internal comment from EDA staff, this NPRM proposes a minor revision to § 307.3(b)(2) to remove a reference to ''loan guaranties'' that was inadvertently missed in the last revision to the regulations.

Through the RLF program, EDA assists Regions affected by a variety of types of distress, including Regions that are Presidentially Declared Disaster areas, by supplying businesses and entrepreneurs with the gap financing necessary to start or expand their businesses. Currently, EDA's regulation at § 307.4(c)(2) specifies that EDA will review applications to capitalize or recapitalize an RLF to assess the need for a new or expanded public financing tool to enhance other business assistance programs and services targeting economic sectors and locations described in the CEDS. However, the provision fails to reference how EDA will assess RLF applications to address Presidentially Declared Disaster areas. Therefore, EDA proposes revisions to the text of new § 307.7(a)(1)(ii) to specify that EDA will review disaster-related RLF applications to assess the need to provide appropriate support for post-disaster economic recovery efforts in Presidentially Declared Disaster areas. In order to consolidate award requirements in a single section, this NPRM proposes relocating the remainder of text in connection with Economic Adjustment Assistance post-approval requirements, which currently are set out at § 307.6(a) through (c), to § 307.4(b) and (c) of subpart A, titled *Strategy Grants* and *Implementation Grants,* respectively. We also revise § 307.4(d) to refer the reader to § 307.7 for RLF award requirements and relocate the sentence specifying that funding priority considerations for Economic Adjustment Assistance may be set forth in an FFO from § 307.4(d) to § 307.4(a) and revise it to add a reference to RLF Grants. Note that these revisions do not change the requirements applicable to Economic Adjustment Assistance awards; they simply make part 307 easier to navigate. EDA also proposes conforming changes to the table of contents of part 307 to appropriately renumber the regulations affected by reorganizing part 307.

We received an internal comment suggesting that EDA replace the term ''CEDS'' with ''strategy'' throughout part 307. We decline to make the change because sections 209 and 302 of PWEDA (42 U.S.C. 3149 and 3162, respectively) refer to the requirement of a ''comprehensive economic development strategy,'' and we believe the current language is helpful in that it encourages the creation of CEDS, yet allows for alternatives when necessary.

EDA received an internal comment from EDA staff requesting that the ''Application requirements'' provision as set out at § 307.5 provide greater specificity in what is required in an application for Economic Adjustment Assistance. Section 307.5 provides guidance that follows the requirements of PWEDA and other regulations. Because of the flexibility inherent in the regulation and other tools available to provide specificity in application requirements, including FFOs, we decline to make the requested change. However, we welcome further constructive comments on needed adjustments.

We received another internal comment suggesting changes to § 307.4(c)(i), which states that EDA will review Economic Adjustment Assistance implementation applications to ensure the applicable CEDS meets the requirements of § 303.7. The suggested change appears to suggest that CEDS are not required for non-construction implementation grants. However, CEDS are required for all Economic Adjustment Assistance implementation grants, whether they are construction or non-construction, and therefore we decline to make the change.

EDA received an internal comment suggesting that § 307.6 should be revised and that subsections (a) and (c) should be removed as Economic Adjustment Assistance post-approval requirements are set out in current § 302.18. EDA believes that the cross-references in current § 307.6 provide useful information for the various types of Economic Adjustment Assistance Projects. In addition, this NPRM proposes changes to current § 302.18 to remove the specific reference to Economic Adjustment Assistance post-approval requirements, making the cross-references even more salient. However, as noted above, through this NPRM, we propose relocating the provisions of § 307.6 to relevant portions of part 307. Accordingly, the text of current § 307.6(a) is relocated to § 307.4(b); the text of current § 307.6(b) is relocated to § 307.4(c)(2); the text of current § 307.6(c) is relocated to § 307.4(c)(3); and the text of § 307.6(d) is relocated to redesignated § 307.7(b).

We propose revising the heading of ''Subpart B—Special Requirements for Revolving Loan Funds and Use of Grant Funds'' to read ''Subpart B—Revolving Loan Fund Program'' for simplicity and to comport with the convention of the subpart setting out requirements for the University Center program in part 306. This NPRM proposes redesignating current § 307.7 as § 307.6 and incorporating redesignated § 307.6 under Subpart B. EDA also makes a minor change to the first sentence of redesignated § 307.6 to improve sentence structure, replacing ''may also'' with ''also may.'' As noted above, EDA also proposes new § 307.7 to set out RLF award requirements under Subpart B.

In response to an internal comment, EDA also proposes amending § 307.9(a)(2) to clarify the existing requirement that the RLF Recipient is responsible for complying with applicable environmental laws as set out at § 307.10, which means the Recipient must adopt compliance

procedures and ensure that borrowers adhere to relevant environmental laws and regulations. In addition, in the second sentence of § 307.9(c)(2), EDA adds the word ''consolidation'' between the word ''merger'' and the phrase ''or change in the EDA-approved lending area under § 307.18'' to comport with the proposed revisions to § 307.18(b) to more precisely use the terms ''consolidation'' and ''merger.'' Note that these revisions do not add to or change existing requirements. EDA proposes minor, non-substantive changes to § 307.9(b)(2)(ii) by replacing ''EDA policies and requirements'' with ''EDA's policies and requirements'' and § 307.9(b)(3) by replacing ''shall also'' with ''also shall'' in the second sentence, § 307.9(c)(1) by replacing ''five (5)'' with ''five,'' § 307.10(a) by removing the unnecessary phrase ''but not limited to'' in the second sentence and replacing ''must also'' with ''also must'' in the third sentence, § 307.10(b) by adding the clarifying word ''Accordingly,'' to the beginning of the second sentence, § 307.11(b) and (e) by replacing three instances of ''thirty (30)'' with ''30,'' and to § 307.11(f)(2) by replacing ''twenty (20)'' with ''20.'' In addition, EDA corrects capitalization errors by revising the paragraph heading of § 307.11(d) to read *Interest-bearing account* instead of *Interest-bearing Account* and replacing ''federal'' with ''Federal'' in § 307.12(b). EDA also removes an unnecessary parenthetical reference to ''(an ''EDA funds account'')'' in § 307.11(d), as that phrase is not used elsewhere in the regulations. In addition, EDA removes additional repetitive numerical references by replacing two instances of ''six-month (6)'' with ''six-month'' in § 307.12(a)(1) and (a)(2) and one instance of ''three-year (3)'' with ''three-year'' and two instances of ''three (3) years'' with ''three years'' in § 307.13(a), (b)(2), and (b)(3).

Nine comments express concern with EDA's RLF reporting requirements, which are set out at § 307.14. Most comments suggest that RLF reporting is overly burdensome and request that EDA ''pursue some more flexible options to minimize the reporting burdens for RLF intermediaries with a proven track record.'' EDA has made numerous improvements to the RLF program in response to the OIG's report titled *Aggressive EDA Leadership and Oversight Needed to Correct Persistent Problems in the RLF Program* (March 2007), including establishing a framework for ensuring compliance with RLF reporting requirements. In response to the OIG's recommendations, RLF Recipients must report to EDA on a semi-annual basis in order to maintain the proper operational and financial integrity of RLF awards established with assistance from EDA. In April 2010, EDA successfully launched the Revolving Loan Fund Management System (''*RLFMS*''), which is the agency's central electronic management system for the program. The RLFMS greatly enhances EDA's ability to manage the RLF program in a consistent, cohesive manner, and provides a medium for record-keeping and clear communication between agency staff and RLF Recipients. Semi-annual reports must be submitted electronically through RLFMS, which has significantly reduced paperwork and made reporting more efficient.

In addition, EDA has taken steps to make the RLF reporting form more effective and user-friendly. In June 2008, EDA issued the revised RLF semi-annual reporting form (Form ED-209) to replace the former semi-annual and annual reporting forms. Form ED-209 collects more useful information and has additional data fields to allow EDA to exercise more rigorous oversight of the RLF program. In the agency's IFR published in the **Federal Register** on October 22, 2008 (73 FR 62858), EDA noted that the new Form ED-209 will reduce the average paperwork burden for each RLF report from 12 hours to 2.9 hours. This significant decrease results from the elimination of duplicative fields and EDA's successful launch of RLFMS on April 1, 2010.

EDA received an internal comment from EDA staff suggesting that the agency no longer require submission of the RLF Income and Expense Statement (Form ED-209I), which is required of any RLF Recipient that uses either 50 percent or more (or more than $100,000) of RLF Income for administrative costs in a six-month Reporting Period. *See* § 307.14(c). EDA surveyed agency staff members, and some reported that Form ED-209I is helpful as it does provide useful information and serves as an incentive for RLF Recipients to avoid high administrative costs. Therefore EDA declines to remove the requirement wholesale, but understands that in certain cases, particularly for RLFs that are smaller and may have relatively less RLF Income, proportionately higher administrative costs may be unavoidable. Therefore, EDA provides additional language to § 307.14(c) to provide that EDA may waive the requirement to submit Form ED-209I for small RLFs as determined by EDA. EDA expects to make such a determination on a case-by-case basis and will provide guidance on requesting a waiver. Because EDA recently changed the RLF reporting requirements to address management and oversight issues and to ensure the administrative integrity and sustainability of the RLF program, this NPRM does not make any further substantive changes to § 307.14. This NPRM does propose removing repetitive numerical references from § 307.14(c), replacing ''fifty (50)'' with ''50'' and ''six-month (6)'' with ''six-month.''

In response to an EDA staff comment, EDA proposes a revision to § 307.15(b)(1), which sets out the requirement that an accountant certify to the adequacy of an RLF Recipient's accounting system before EDA can disburse funds. The current regulation requires that the certification be made by ''an independent accountant familiar with the RLF Recipient's accounting system.'' This provision has raised concerns in past programmatic audits, and therefore, this NPRM proposes new language to require that the certification be made by ''a qualified independent accountant who preferably has audited the RLF Recipient in accordance with OMB Circular A–133 requirements.'' EDA received another internal comment suggesting that the phrase ''board of directors'' should be changed to ''Loan Administration Board'' in § 307.15(b)(2)(iii) to comport with previous regulations, FFOs, and EDA-approved RLF Plans. We decline to make this change because the term ''board of directors'' as used in the regulations is a generic term used to refer to the body of elected or appointed members who jointly oversee the activities of the RLF. In practice, the body sometimes has a different name, such as board of trustees, board of governors, board of managers, or executive board.

An internal comment suggests revising § 307.15(d) to clarify that private investment is not limited to a 12-month period before loan approval. We note that the January 27, 2010 final rule (75 FR 4259 at 4261) added the phrase ''within twelve (12) months of approval of an RLF loan'' to § 307.15(d)(1) to clarify that RLF operators may count as private leveraging any funds invested from private sources within 12 months before or after the RLF loan is made, rather than just 12 months before the loan is made. We believe that this previous revision addresses any private leveraging undertaken short of the 12-month limit. Please also see the full discussion on the provision in the January 27, 2010 final rule.

In response to another internal comment, EDA proposes revising § 307.15(d)(1)(iii) to provide that any

Federally guaranteed loan may leverage an RLF portfolio by inserting the phrase ''a Federal loan, including'' in between ''the guaranteed portions of'' and ''the U.S. Small Business Administration's.'' This change provides Recipients with greater flexibility in meeting the RLF leveraging requirement with Federal resources. Currently, certain Small Business Administration (''*SBA''*) loans are the only Federal loans that may meet the leveraging requirement. In addition, we propose to reference U.S. Department of Agriculture loans as an example of a type of Federal loan that can be used as leverage, as many RLF stakeholders may have experience with such loans. EDA expects that these revisions will provide needed flexibility for RLF Recipients to meet RLF leveraging requirements in challenging economic conditions and will further incentivize the leveraging of Federal investments.

EDA also removes redundant numerical references by replacing ''sixty (60)'' with ''60'' in § 307.15(b)(1), two instances of ''four (4)'' with ''four'' in § 307.15(c)(1), ''fourteen (14) with ''14'' and ''ten (10)'' with ''ten'' in § 307.15(c)(2), ''twelve (12)'' with ''12'' in § 307.15 (d)(1), and ''ninety (90)'' with ''90'' in § 307.15(d)(1)(iii).

EDA received an internal comment requesting the deletion of § 307.16(c)(1)(i), which sets out an exception to EDA's capitalization utilization standard of 75 percent of RLF Capital in the case of an RLF Recipient that anticipates making large loans relative to the size of its RLF Capital base. The commenter notes that the exception provision is incorrectly worded and should be removed ''because it gives tacit approval to make loans in excess of 25 percent of the capital base to a single borrower.'' Upon consideration, EDA agrees to remove the provision, as it is incorrectly phrased as an ''exception.'' The relevant RLF Plan sets out the minimum and maximum amounts that the RLF Recipient may loan, and the Recipient must request EDA's approval (with appropriate justification) for any deviation from the prescribed procedures and amounts contained in the Plan. Therefore, the provision in § 307.16(c)(1)(i) is a deviation from the rule, rather than an exception. In all cases, the Recipient must (a) adhere to prudent and appropriate underwriting standards and practices, and (b) seek EDA's approval for any variation below the capital utilization standard set of 75 percent. Accordingly, EDA will consider the qualitative aspects of a requested deviation. The capitalization utilization standard of 75 percent is EDA's required floor. Therefore, this NPRM proposes to remove § 307.16(c)(1)(i) and replace the phrase ''The following exceptions apply:'' in paragraph (c)(1) with the introductory phrase ''except that'' and the text of current § 307.16(c)(1)(ii). As the removal of § 307.16(c)(1)(i) makes a list unnecessary, EDA incorporates the contents of existing (c)(1)(ii) under (c)(1).

In response to an internal comment, EDA proposes a clarifying amendment in § 307.16(d)(1)(i) to replace the phrase ''business plan'' with the correct defined term ''RLF Plan'' and corrects a grammatical error by removing the unnecessary second use of the word ''and'' in the subparagraph. EDA also proposes removing redundant numerical references by replacing ''three (3)'' with ''three'' in the second sentence of § 307.16(a)(1), ''forty-five (45)'' with ''45'' in § 307.16(a)(2)(i), ''seventy-five (75)'' with ''75'' in § 307.16(c)(1), and ''two (2)'' with ''two'' in the first sentence of § 307.16(c)(2)(i). This NPRM also revises § 307.16(d)(1) to remove the unnecessary parenthetical phrase ''(as defined in § 314.5 of this chapter),'' as that phrase already appears in § 307.16(c)(2)(i).

Generally, RLF Capital cannot be used to refinance existing debt. However, under § 307.17(b)(6)(ii), EDA may allow the RLF Recipient to use RLF Capital to purchase the rights of a prior lien holder during a foreclosure action, if such action is necessary to prevent significant loss on an RLF loan. Currently, to make such use of RLF Capital, the RLF Recipient must demonstrate that there is a high probability that the sale of assets will result in compensation sufficient to cover the RLF's costs, plus a reasonable portion of the outstanding loan within 18 months of the refinancing. In response to a comment from EDA staff, this NPRM proposes a small change to § 307.17(b)(6)(ii) to provide greater flexibility in uncertain economic conditions by changing the 18-month time limit to ''a reasonable time, as determined by EDA.'' This NPRM also proposes to remove a repetitive numerical reference from § 307.17(c), replacing ''three (3)'' with ''three'' in the first sentence.

Also in response to an internal comment from EDA staff, this NPRM proposes revisions to § 307.18(a) to allow EDA to approve the addition of a new lending area (at the request of an RLF Recipient) before the full amount of the RLF Grant is disbursed to the Recipient. This change will provide EDA with needed flexibilities to respond to changing economic conditions and to quickly provide assistance in distressed areas. To effect this amendment, we remove § 307.18(a)(1)(i), which requires that ''EDA shall have disbursed the full amount of its Investment Assistance to the RLF Recipient'' before new lending areas may be added, and renumber the remainder of the subparagraph accordingly, redesignating subsections § 307.18(a)(1)(ii) through (vii) as § 307.17(a)(1)(i) through (vi).

Also, as all RLF loans must be in accordance with the relevant RLF Plan, we propose a clarifying change to remove the phrase ''to implement and assist economic activity'' from the first sentence of § 307.18(a)(1). EDA proposes minor changes to correct a capitalization error in the heading of § 307.18(a)(1), revising it to read *Addition of lending areas* instead of *Addition of Lending Areas;* remove the unnecessary phrase ''an additional'' from the second sentence of § 307.18(a)(1); replace the term ''fulfill'' with ''meet'' and the phrase ''Economic Adjustment Investments'' with ''Economic Adjustment Assistance Investments'' in redesignated § 307.18(a)(1)(i); and, at the suggestion of EDA staff, replace the term ''RLF Grant award agreement'' in redesignated § 307.18(a)(1)(v) with the term ''financial assistance award'' for increased clarity and consistency.

EDA received four comments suggesting that ''EDA should use its existing authority to allow for shared management, marketing, and administration of RLFs for underperforming loan funds.'' EDA believes these comments suggest allowing an RLF Recipient to contract with a third party to carry out certain tasks such as shared management, marketing, and administration of RLFs, or obtaining EDA's approval to merge an underperforming RLF award with another award to form a single RLF award. EDA currently may authorize both of these actions. If the RLF Recipient contracts with a third party to undertake these tasks, the contract must be procured in accordance with Federal competitive procurement requirements as set out at 15 CFR 14.43 or 24.36, as applicable. In addition, under § 307.18(b)(2), EDA may approve the merger of two or more RLF awards into a single RLF award. This authority can and has been used to address underperforming RLF awards. In addition, in response to an EDA staff comment, this NPRM proposes textual revisions to § 307.18(b) to more precisely use the terms ''consolidation'' and ''merger.'' For purposes of the RLF program, a ''consolidation'' under § 307.18(b)(1) occurs when a single RLF Recipient that has multiple RLF awards requests, and EDA approves, the

consolidation of the multiple awards into a single RLF. In contrast, a ''merger'' under § 307.18(b)(2) occurs when two or more RLF Recipients request, and EDA approves, the merger of their respective RLF awards to form a single RLF award. Accordingly, EDA revises the heading of § 307.18 to read ''Addition of lending areas; consolidation and merger of RLFs'' instead of ''Addition of lending areas; merger of RLFs'' and the heading of § 307.18(b) to read *Consolidation and merger of RLFs* instead of *Merger of RLFs.* In addition, EDA replaces ''merger'' with ''consolidation'' in § 307.18(b)(1)(ii) and (b)(1)(iii) and ''consolidate'' with ''merge'' in § 307.18(b)(2). These revisions do not change existing requirements; they merely clarify terminology. Finally, we propose removing repetitive numerical references, replacing ''one (1)'' with ''one'' and ''two (2)'' with ''two'' in both § 307.18(b)(1) and (b)(2).

Section 307.19 sets out the requirements for an RLF Recipient to sell or securitize RLF loans, which may be an important and efficient way of infusing an RLF with new RLF Capital. Under § 307.19, EDA may approve a Sale or Securitization of all or a portion of an RLF loan portfolio, provided that: (a) The RLF Recipient uses all proceeds from any Sale or Securitization to make additional RLF loans; (b) the RLF Recipient requests that EDA subordinate the agency's interest in all or a portion of the RLF loan portfolio to be sold or securitized; and (c) any Sale or Securitization in which an RLF Recipient may participate complies with the Securities Act of 1933, the Securities Exchange Act of 1934, and any rule or regulation made public by the Securities and Exchange Commission. EDA received an internal comment suggesting the deletion of § 307.19(b), which sets out the subordination request requirement. The comment notes that subordination of the agency's interest could ''greatly affect the value of the portfolio, having an adverse consequence on the sale'' of all or a portion of the RLF Recipient's RLF loan portfolio. In considering the comment and the provision, EDA notes that the agency's interest is in the proportional dollar amount of the RLF Capital base. EDA has no interest per se upon the conclusion of a Sale or Securitization, at which point its interest is limited to the cash proceeds received upon the Sale or Securitization, which the Recipient must use to make additional loans. Worded differently, EDA's interest in the RLF loan portfolio, in relation to the RLF Capital base, is alive only up to the point of a Sale or Securitization. If, after seeking EDA's approval, the Recipient sells a portion of its loan portfolio, there is no ''interest'' for EDA to subordinate. In all cases, EDA, considering the Recipient's request, will evaluate the provisions or conditions to the proposed Sale or Securitization vis-à-vis dictated conformance to standards and market practices. Accordingly, this NPRM eliminates paragraph (b) in § 307.19 and re-alphabetizes paragraphs (c) and (d) as (b) and (c), respectively. The commenter also suggests that EDA delete the reference to Securitizations in an effort to streamline the regulations. Although RLF portfolio Securitizations may not happen frequently, EDA declines to make this revision because the agency wishes to maintain maximum flexibility in an RLF Recipient's ability to raise additional RLF Capital.

Two internal comments suggest that EDA remove the references to specific situations that may result in partial liquidation or disallowance of a portion of an RLF Grant as set out at § 307.20(a)(1) through (5) and suspension or termination of an RLF Grant for cause as set out in § 307.21(a)(1)(i) through (x). EDA declines to make these changes as the agency believes it is important to specify circumstances that merit partial liquidation, disallowance, suspension, and termination and because the language addressing circumstances that may warrant termination for cause were added to the regulations through the October 22, 2008 IFR at the recommendation of the OIG (73 FR 62858). However, EDA proposes removing the unnecessary phrases ''but are not limited to'' from the final sentence of § 307.20(a) and ''but not limited to'' from § 307.21(a)(1). We also remove redundant numerical references in § 307.20, replacing ''one hundred and twenty (120)'' with ''120'' in § 307.20(a)(1), ''twelve (12)'' with ''12'' in § 307.20(a)(2), and ''one (1)'' with ''one'' in § 307.20(c)(3). EDA also proposes small changes by italicizing the acronym ''*SEFA*'' and capitalizing the first instance of ''Federal'' in § 307.21(a)(1)(viii).

EDA received nine comments requesting that EDA ''fully defederalize RLFs within the constraints of the current law.'' One commenter notes the success of specific RLF Grants in meeting program goals of job creation and investment leveraging and goes on to state ''[t]he continued requirement by EDA regarding reporting and guidelines seems ludicrous given the excellent performance record.'' EDA appreciates that some stakeholders may be frustrated with Federal requirements on RLF Grants that have been operating for several years, some for as many as three decades. EDA realizes the value of these grants and wishes to reduce burdens on the successful RLFs operating across the country; however, EDA currently is not authorized to release its Federal Interest in RLF awards. EDA's authority to release its interest after 20 years (section 601(d) of PWEDA, 42 U.S.C. 3211) applies to Real Property and tangible Personal Property only, and does not apply to RLF awards, which exist in theoretic perpetuity so long as borrowers repay loans and the RLF Recipient continues to makes new loans. Although EDA currently does not have authority to release its interest in RLF awards, EDA is engaged in an ongoing effort to revise its authorities to provide greater flexibility for RLF Recipients.

EDA received two comments stating that the requirements of ''Davis-Bacon should not apply to borrowers of RLF dollars'' because such loans are ''not grant proceeds, and the company [or relevant borrower] must repay these loans with non-tax dollars.'' The wage rate requirements under the Davis-Bacon Act (40 U.S.C. 3142 *et seq.*) apply to contractors and subcontractors performing on Federally funded or assisted contracts in excess of $2,000 for the construction, alteration, or repair (including painting and decorating) of public buildings or public works. Under the Davis-Bacon Act, contractors and subcontractors must pay any laborers and mechanics employed under the contract (or subcontract) no less than the locally prevailing wages and fringe benefits for corresponding work on similar projects in the area. Section 602 of PWEDA (42 U.S.C. 3212) makes the Davis-Bacon wage requirements mandatory in all ''projects assisted by the Secretary under [PWEDA].'' *See also* § 302.13. Therefore, Recipients and any RLF borrower, contractor, or subcontractor must comply with Davis-Bacon prevailing wage rate requirements where RLF funds under an EDA award are used for construction work.

EDA received six comments suggesting EDA establish ''an RLF Advisory Committee of RLF practitioners to assist in the development of a more streamlined and user-friendly RLF reporting system and process.'' EDA has identified the need to create an internal RLF task force to improve communications and resolve program issues, and currently is in the process of establishing one. EDA expects that the task force will consist of Headquarters staff and RLF

administrators from each of the agency's six regional offices.

Part 308—Performance Incentives

Part 308 sets out EDA's performance incentives for Recipients. When a Project is constructed under projected cost, EDA may allow the Recipient to use the excess funds to either increase the Investment Rate of the Project to the maximum percentage allowable under § 301.4 for which the Project was eligible at the time of the Investment award, or further improve the Project consistent with its purpose. The terms for performance awards under EDA's Public Works and Economic Adjustment Assistance programs are set out in § 308.2 and the terms for performance awards under EDA's Planning program are set out under § 308.3.

EDA did not receive any comments on part 308, but capitalizes ''Federal'' in § 308.3(a)(3) to adhere to the capitalization convention of the regulations and removes repetitive numerical references throughout the part by replacing use of ''ten (10)'' with ''ten'' in § 308.2(a), ''one (1)'' with ''one'' in § 308.2(b) and § 308.3(a)(2), ''three (3)'' with ''three'' in § 308.2(c), two references to ''one-hundred (100)'' with ''100'' in § 308.2(d) and § 308.3(b), and ''five (5)'' with ''five'' in § 308.3(a).

Part 309—Redistributions of Investment Assistance

Part 309 sets out EDA's policies regarding redistributing grant funds in the form of subgrants, loans, or other appropriate assistance. Information with respect to redistributions of Investment funds for Planning, Public Works, and Training, Research, and Technical Assistance Investments is presented in § 309.1. Specifically, § 309.1(a) provides that a Recipient under any program governed by parts 303, 305, and 306 may directly expend the Investment Assistance, or, with prior EDA approval, redistribute such funds in the form of a subgrant to another Eligible Recipient that qualifies for EDA Investment Assistance under the same program part as the Recipient. All subgrants must be subject to the same terms and conditions applicable to the Recipient under the original Investment award. Subsection 309.1(b) stipulates that Investment Assistance received under parts 303 or 305 may not be redistributed to a for-profit entity.

Section 309.2 addresses redistributions under part 307 for Economic Adjustment Assistance Investments. This section reads similarly to § 309.1. However, a Recipient under part 307 may redistribute Investment funds to another Eligible Recipient in the form of a grant or to a non-profit and private for-profit entity in the form of a loan or other appropriate assistance under subpart B of part 307. EDA did not receive any comments on and does not propose any revisions to part 309.

Part 310—Special Impact Areas

Part 310 implements section 214 of PWEDA (42 U.S.C. 3154), which authorizes the Assistant Secretary to waive the CEDS requirements of section 302 of PWEDA (42 U.S.C. 3162) for a Project that will fulfill a ''pressing need'' of the Region or prominently address or alleviate Regional underemployment or unemployment. Section 310.1 outlines the process for designating a Region as a Special Impact Area and § 310.2 defines what may be considered a pressing need. EDA did not receive any comments on part 310.

This NPRM proposes revising §§ 310.1 and 310.2(b) and (c) to replace ''Recipient'' with ''Applicant,'' in order to clarify that designations under part 310 occur at the application stage. In addition, this NPRM proposes minor, non-substantive changes to § 310(a)(6) to replace ''Federally-Declared Disaster area'' with ''Federally Declared Disaster area'' and § 310.2(b) to replace the percentage symbol (''%'') with the word ''percent'' for consistency with the rest of the regulations and to remove a repetitive numerical reference, replacing ''twenty-four (24) month'' with ''24-month.''

Part 311—America COMPETES

EDA proposes revising the heading of reserved part 311 to read ''America COMPETES'' in preparation for any regulations necessary to implement the ''America Competes Reauthorization Act of 2010'' (''*COMPETES*'') (Pub. L. 111–358, January 4, 2011). EDA currently does not propose regulations to implement COMPETES.

Part 312—[Reserved]

Part 313—Community Trade Adjustment Assistance

Part 313 sets forth regulations to implement the Trade Adjustment Assistance for Communities program authorized under chapter 4 of title II of the Trade Act of 1974, as amended (19 U.S.C. 2371 *et seq.*) EDA did not receive any comments on and does not propose any revisions to part 313.

Part 314—Property

Part 314 sets forth the rules governing Property acquired or improved, in whole or in part, with EDA Investment Assistance. Through the February 1, 2011 **Federal Register** notice, EDA sought comments on how the Property regulations could be improved to provide needed flexibilities to encourage innovative economic development projects, while still protecting taxpayer dollars and the Federal Interest. EDA received a number of helpful comments in this regard specifically recommending that EDA provide flexibility both to the Recipient to deal with grant-assisted Real Property and to enhance EDA's ability to work with new forms of financing to support job creation in distressed communities. This NPRM sets forth proposed amendments to help reach these goals, along with additional revisions designed to streamline EDA's requirements.

EDA proposes to amend the table of contents to part 314 to eliminate subparts A through D. EDA proposes this format change because the entire part contains only ten sections and dividing the ten sections into four subparts hinders comprehension. Because of the elimination of the subparts, EDA revises the section heading for § 314.8 to read ''Recorded Statement for Real Property'' instead of simply ''Recorded Statement'' as additional context is needed to clarify that § 314.8 sets out recorded statement requirements for Real Property. Similarly, as § 314.9 concerns the requirements for recordation of Personal Property interests, the section heading is revised to read ''Recorded Statement for Personal Property.'' These changes are designed to help the reader more easily navigate part 314 and are not substantive.

EDA proposes a non-substantive revision to remove the unnecessary phrase ''but not limited to'' from the definition of ''*Real Property*'' in § 314.1. We received an internal comment on § 314.2, which sets out the legal tenants of EDA's Federal Interest in Project Property, suggesting that EDA should consider ''parity consideration (as opposed to subordination)'' to ''be fair to other funders.'' EDA's regulations do not preclude this option; however, to make this clearer, EDA proposes clarifications to its encumbrances regulation (§ 314.6) to specify the agency's authority to accept a shared first lien position. *See* proposed § 314.6(b)(1) below titled *Shared first lien position.*

Section 314.3, titled *Authorized Use of Property,* provides the circumstances under which Recipients may use Property acquired or improved, in whole or in part, with Investment Assistance. An internal comment noted that EDA's regulations did not refer to the terms and conditions of the award

as the reference point for determining the purpose of a given Project. Therefore, EDA proposes dividing § 314.3(a) into two clearer sentences and replacing the phrase ''only for the authorized purpose of the Project'' with the phrase ''only for authorized Project purposes as set out in the terms and conditions of the Investment Assistance.'' The prohibition on disposing of or encumbering Project Property without EDA's prior written authorization is now the second sentence in the provision. Also, in response to an internal comment from an EDA employee, this NPRM adds the clause ''during the Estimated Useful Life of the Project'' to both § 314.3(a) and (b) to clarify that EDA's use restrictions apply only during the Estimated Useful Life of Project Property.

We received another internal comment suggesting that the regulations setting out the authorized and unauthorized uses of Project Property (§§ 314.3 and 314.4, respectively) should be ''relaxed so as not to deter or discourage developers from the opportunity to make a fair recovery on their investments when they sell or lease the non-public rights-of-way.'' EDA believes §§ 314.3 and 314.4 appropriately articulate the authorized and unauthorized uses of Property funded or improved by EDA assistance. EDA is proposing clarifications to its title regulation as set out at 314.7(c), which may provide needed clarification and certainty to help address this comment. In addition, we propose minor changes to add a reference to EDA's proposed accountability provision (§ 302.16) to § 314.4(c) and remove the unnecessary phrases ''but not limited to'' from §§ 314.3(c) and 314.4(c). In addition, EDA proposes removing two repetitive numerical references from § 314.5(b), replacing ''fifty (50) percent'' with ''50 percent.''

EDA received five comments suggesting various flexibilities with respect to the agency's Property encumbrance requirements set out at § 314.6. By way of background, as trustee of appropriated taxpayer dollars, EDA safeguards the public's interest in award assets by taking and retaining a security interest (the Federal Interest) in Property purchased or improved with grant funds. In general, Property must remain unencumbered and the Recipient must hold title to the Property for its Estimated Useful Life. In some instances, the regulations at § 314.6 have proved particularly challenging for public-private partnerships. Two of the comments suggest that EDA should be amenable to subordinating the Federal Interest if the Project will not move forward without such action and the Recipient has a strong financial standing in the community and a proven history of meeting its obligations. In such circumstances, the Recipient's agreement to return the grant funds in the event of default should be sufficient. EDA understands the comment and by-and-large agrees. EDA in fact added flexibility to this section in the IFR published on October 22, 2008 (73 FR 62858) to take into consideration the difference in risks posed by Recipients that are governmental bodies and Recipients that are non-profit organizations. The 2008 IFR also clarified that a key factor in determining whether to subordinate the Federal Interest is whether the Recipient requesting the subordination poses a relatively lower risk because it has demonstrated stability over time. *See* paragraph (b)(3)(iv) of § 314.6, which includes one of the requirements for EDA to accept an encumbrance, namely that EDA determine that there is a reasonable expectation that the Recipient will not default on its obligations. One of the comments also recommends that when a Project is designed to help a community adjust to the departure of a significant employer, it is critically important that EDA act expeditiously and allow alternate mechanisms when a lender is unwilling to subordinate its interest to EDA. The agency agrees that timeliness is important and is adding flexibility depending on whether the request for EDA to subordinate is made prior to, contemporaneous with, or after the EDA Grant award. In addition, see the discussion set out below regarding new flexibility in § 314.8 regarding forms of security as alternatives to mortgages, such as execution of a letter of credit or escrow agreement in EDA's favor.

Similarly, a third comment suggests that EDA should consider compromising its lien position in certain cases because a bank sometimes cannot afford to take less than a first lien position when there simply is not sufficient equity coverage. In such circumstances, it is important for EDA to agree to a second position in order to engender more economic development opportunities. As noted above, EDA agrees and has added additional flexibility to § 314.6 (*see* discussion below). The fourth comment suggests that EDA require a first position lien only on the portion of the Project financed by EDA, allowing the Recipient to encumber the remainder of the equity in Project Property to obtain additional capital. This comment appears to suggest that EDA should consider subordinating its interest in real estate after issuance of the Grant to allow the Recipient to obtain additional financing, which could then enable the Recipient to finance more job-creating projects. EDA's ability to revise the regulations to accommodate this comment is constrained by legal considerations. To the extent the terms and conditions of the award do not contemplate consideration of subordination subsequent to the Grant award, which is EDA's current practice, the agency would need to demonstrate the financial benefit to the Federal government in agreeing to subordinate its interest. Federal law prohibits EDA from agreeing to cede the Federal Interest in Property without receiving fair compensation in return unless specifically authorized by statute. The Supreme Court established this principle in *Royal Indemnity Co.* v. *United States,* 313 U.S. 289, 294 (1941), in what is sometimes referred to as the ''quid pro quo'' doctrine. The *Royal Indemnity* Court held that the:

> [p]ower to release or otherwise dispose of the rights and property of the United States is lodged in the Congress by the Constitution. Art. IV, § 3, Cl. 2. Subordinate officers of the United States are without that power, save only as it has been conferred upon them by Act of Congress or is to be implied from other powers so granted.

This ruling established that no Federal government agent can give up something of value without receiving equal value in return absent express authority to do so. Hence, in order to give EDA authority to release its interest at the request of a Recipient, EDA either needs to receive fair value in return or obtain additional discretion from Congress under PWEDA to release the Federal Interest in such circumstances. Nonetheless, in appropriate circumstances, such as when the appraised value of the Property substantially exceeds the amount of EDA's Investment, there would appear to be little risk for EDA to accept a subordinate position, provided the value of the Property continues to cover the risk of default. The agency will consider adding flexibility in the terms and conditions of the Investment Assistance to enable EDA to consider requests for subordination once a Grant award has been made. In such cases, EDA would not be ceding a vested government property interest, but simply exercising discretion built in at the time of the award.

The fifth comment suggests that EDA should reform its financing framework to help Projects take advantage of New Markets Tax Credit (''*NMTC*'') programs. Because NMTC arrangements generally

are in place over a seven-year period, Projects involving the tax credits raise novel issues about whether EDA will subordinate its interest at a time subsequent to the initial award decision. EDA's regulations currently do not contemplate the possibility that EDA would presently agree to agree in the future to subordinate its interest. In a time of severe budgetary constraints at all three levels of government (Federal, State, and local), EDA agrees that it must explore additional ways to leverage current levels of assistance.

In light of these comments, EDA amends § 314.6 to provide additional flexibility in subsection (b), which sets out exceptions to the general rule that Property must be free of encumbrances. For clarity, EDA is reordering subsection (b) to set out appropriate requirements that apply based on the point in time when a Recipient requests EDA to agree to subordinate the Federal Interest; namely, whether the Recipient already has mortgaged the Project Property before EDA's award decision, or is making the request for subordination simultaneously with EDA's award decision or after the award decision already has been made. EDA relocates existing paragraph (b)(1) and redesignates it as (b)(3) as provided below. EDA also proposes adding new paragraph (b)(1), titled *Shared first lien position,* to set out EDA's authority to enter into an inter-creditor agreement under which EDA and another lien holder share a first lien position. In light of the requirements applicable to requests for subordination, whenever possible, EDA ordinarily will prefer to subordinate its first lien position to a shared first-lien position with a lender pursuant to an inter-creditor agreement. EDA revises the paragraph heading of current paragraph (b)(2), which concerns encumbrances in connection with water, sewer, and other utility projects, to read *Utility encumbrances.*

As noted above, EDA clarifies its requirements for subordinating the Federal Interest based on when the subordination is requested under proposed paragraphs (b)(3) through (b)(5). Current paragraph (b)(1) is re-designated as paragraph (b)(3) and is amended to add the heading *Pre-existing encumbrances* and to delete the phrase ''Recipient-owned Property that is subject to an encumbrance'' and substitute the phrase ''Encumbrances already in place'' for increased clarity and ease of comprehension.

Under current § 314.6(b)(3), EDA can consider requests to subordinate its interest, provided that: (1) There is good cause; (2) all proceeds from the other financing will be used only for the Project or related activities; (3) the grantor or lender will not provide funds without the security of a lien on the Property; and (4) there is a reasonable expectation that the Recipient will not default on its obligations. As drafted, this paragraph is unclear whether it requires an Eligible Applicant to request subordination prior to the Grant award decision or whether it also applies after EDA has awarded funds to the Recipient, or both. To provide clarity, EDA adds a new paragraph (b)(4) with the heading *Encumbrances proposed proximate to Project approval,* which sets out requirements applicable to requests for subordination made contemporaneously with the Grant award decision. New paragraph (b)(4) provides that upon an Applicant's request, EDA may subordinate its interest in conjunction with the Grant decision when EDA determines that: (1) There is good cause and legal authority to waive the general requirement; (2) all the proceeds will be used to enhance Project Property or for related activities or other activities consistent with the purpose of EDA's programs; (3) the grantor or lender will not provide funds without the security of a lien; (4) the terms and conditions of the encumbrance are satisfactory to EDA; and (5) the risk of the encumbrance is acceptable based on a number of factors, including the approximate value of the Project Property at the time the encumbrance is requested and the financial strength of the Recipient. The list of determinations that EDA must make to subordinate its interest are similar to the existing list as set out at current § 314.6(b)(3); however, EDA has added the requirement that the terms and conditions are satisfactory to the agency. In addition, EDA proposes to revise the text of paragraph (b)(4)(i) to add the clause ''and legal authority'' to indicate that EDA may waive the restriction against encumbrances if it finds there is both ''good cause'' to waive the restriction and legal authority to waive. EDA is making this change because of the need to review such requests in light of the ''quid pro quo'' principle noted above. In paragraph (b)(4)(ii), EDA is broadening its authority to facilitate the availability of the equity in Project Property provided the request is consistent with the mission of the agency. Accordingly, EDA adds the phrase ''or other activities that EDA determines are authorized under PWEDA'' to ensure that to the extent equity is used to support other economic development projects, such projects are consistent with EDA's programs. In addition, EDA adds a new requirement designated as paragraph (b)(4)(v)(C) to require the submission of an appraisal so that EDA can weigh the risk to the Federal Interest if the agency agrees to subordinate at a time that may be several years after the original award decision.

In addition, EDA designates each of the requirements under paragraph (b)(4)(v) with the letters ''A'' through ''D,'' to improve the organization of the provision. The introductory text to paragraph (b)(4) also specifies that the kind of ''debt'' that may be the subject of a subordination request includes ''time or maturity-limited debt that finances the Project Property.'' EDA includes this phrase to better accommodate NMTC and other financing mechanisms, which may require EDA to agree to subordinate its interest at a future date when needed to support the financial structure of the tax credits, which often require refinancing at the conclusion of the credit allowance period (*see* the NMTC program Web page on the U.S. Department of the Treasury's Web site at *http://www.cdfifund.gov/what_we_do/programs_id.asp?programID=5*).

The text of current paragraph (b)(3) is re-designated as (b)(5). This NPRM proposes to revise re-designated paragraph (b)(5) to provide additional flexibility to waive the prohibition on encumbrances subsequent to the grant award. This new flexibility is intended to address the comment regarding the possible use by a Recipient of the equity in grant-assisted Property to sponsor additional economic development. As amended, this paragraph will enable a Recipient to request EDA agree to subordinate its interest when the appraised value of the Real Property provides ample collateral for the EDA award even if EDA takes a second lien position. This NPRM adds the heading *Encumbrances proposed after Project approval* to new § 314.6(b)(5) and amends the introductory text to read, ''Encumbrances proposed to be incurred after Project approval where all of the following are met:'' Similar to the requirements set out at revised paragraph (b)(4), revised paragraph (b)(5) provides that EDA may subordinate its interest after grant award when EDA determines that: (1) There is good cause and legal authority to waive the general requirement; (2) all the proceeds will be used to enhance Project Property or for related activities or other activities consistent with the purpose of EDA's programs; (3) the grantor or lender will not provide funds without the security of a lien; (4) the terms and conditions of the encumbrance are satisfactory to EDA;

and (5) the risk of the encumbrance is acceptable based on a number of factors, including the approximate value of the Project Property at the time the encumbrance is requested, and the financial strength of the Recipient.

Several internal comments noted that EDA's title regulation at § 314.7 ''is dense and the source of much confusion.'' One commenter suggests that the provision ''should be more specific about how the Recipient and private property owners are to comply [with certain portions of the provision].'' EDA agrees and proposes a number of changes to streamline the requirements and make them more readily understandable, including providing paragraph and subparagraph headings to act as guideposts as the reader navigates the regulation. To this effect, EDA proposes to revise the heading of § 314.7(a) to read *General title requirement* instead of simply *General* and to add a heading to § 314.7(b)(1) to read *Disclosure of encumbrances.* Within § 314.7(c), EDA also adds subparagraph headings as guideposts for explaining the exceptions to the general title requirement. Accordingly, the following headings are added to § 314.7(c)(1) through (c)(5): *Real Property acquisition, Leasehold interests, Railroad right-of-way construction, Public highway construction,* and *Construction of Recipient-owned facilities to serve Recipient or privately owned Real Property,* respectively. EDA expects that these headings will help the reader locate information more efficiently and make the regulation easier to understand. We also propose removing the unnecessary phrase ''but not limited to'' from § 314.7(b)(1).

With one exception noted below, EDA does not propose substantive changes to the exceptions to the agency's general title requirement; however, EDA proposes adding the substance of § 314.7(c)(6) to § 314.7(c)(5) and then removing § 314.7(c)(6). EDA proposes this revision because subsections (c)(5) and (6) address analogous situations where the EDA-approved purpose of a Project is to construct facilities that benefit Real Property owned by the Recipient (§ 314.7(c)(5)) or privately owned Real Property (§ 314.7(c)(6)), where the benefited Real Property ultimately will be sold or leased to private parties in order to spur economic development. The requirements of the two provisions are similar, and, as set out in revised § 314.7(c)(5)(i), in both cases the Recipient or private Owner must demonstrate that the Recipient or Owner holds title prior to disbursement of EDA funds; the Recipient must provide assurances that the Project and the development of the Real Property to be served by the Project will be completed in accordance with the terms of the Investment Assistance; during the Estimated Useful Life, the sale or lease of the Project or of Real Property to be served by the Project must be for Adequate Consideration and the terms and conditions of the Project must continue to be fulfilled; and the Recipient must agree that any failure to complete the Project or the development of the Real Property to be served by the Project constitutes a failure on behalf of the Recipient. This NPRM also makes conforming changes to paragraph (c)(5)(i) of § 314.7 to clarify that these provisions apply to both Recipients and private Owners.

The one substantive change to § 314.7 affects an identical provision currently set out in sub-paragraph (i)(D) of § 314.7(c)(5) and 314.7(c)(6). In response to a suggestion by EDA staff, this NPRM proposes removing the provision in § 314.7(c)(5)(i)(D), which provides that 10 years after an award is made, EDA may waive the requirement that a sale of Project Property during the Estimated Useful Life be for Adequate Consideration and that the purpose of the award continue to be fulfilled. This provision is inconsistent with EDA's policy on Estimated Useful Life and causes confusion in situations involving the sale of Property. When EDA added the provision in the IFR published on August 11, 2005 (70 FR 47002), EDA invited the public to comment on whether the new provision would be useful. At the time, EDA received no comments on the provision and since the provision was added, EDA has never had occasion to use it. Accordingly, EDA proposes removing the phrase in § 314.7(c)(5)(i)(D) that reads ''; provided, however, that EDA may waive this provision for any sale or lease occurring after the ten (10) year anniversary of the award date of the Investment Assistance.'' In addition, EDA removes the unnecessary phrase ''but not limited to'' from § 314.7(c)(5)(i) and one repetitive numerical reference from § 314.7(c)(5)(i)(E), replacing ''five (5) year'' with ''five-year.''

The current regulation at § 314.7(c)(5) refers to both the authorized scope of work and the Property that is to be benefitted by the scope of work as the ''Project.'' In certain circumstances, the failure to distinguish between the ''Project'' supported by the EDA grant, such as water and sewer infrastructure leading to an industrial park, and the real estate underlying that industrial park which is connected by that infrastructure, makes it difficult to comprehend exactly what the regulation requires. This broader interpretation of what constitutes the ''Project'' is inconsistent with the definition of ''Project'' in § 300.3, which defines the term to mean the ''proposed or authorized activity (or activities) the purpose of which fulfills EDA's mission and program requirements as set forth in PWEDA and this chapter and which may be funded in whole or in part by EDA Investment Assistance.'' This NPRM proposes revisions to § 314.7(c)(5) to distinguish between these two different concepts by clarifying that the Recipient is responsible for completing the Project, which indicates the activities to be completed under the EDA-approved scope of work and supported by the grant, and in appropriate situations, also is responsible for ensuring that the development of land and improvements on the Real Property to be served by or that provides the economic justification for the Project is completed in accordance with the terms and conditions of the Investment Assistance. The revisions refer to Real Property to be benefitted by the Project as ''the development of land and improvements on the Real Property to be served by or that provides the economic justification for the Project.'' The revisions insert this clause with appropriate phrasing into § 314.7(c)(5)(i)(C), (D), and (E).

This NPRM proposes adding a useful heading that reads *Additional conditions on sale or lease* to § 314.7(c)(5)(i), which sets out the existing requirement that EDA may condition the sale or lease of Recipient or Privately owned Real Property improved or benefitted by a Project on the satisfaction of additional EDA requirements by the Recipient, Owner, purchaser, or lessee, as appropriate. This NPRM also proposes removing the unnecessary phrase ''but not limited to'' from § 314.7(c)(5)(ii). In addition, under current § 314.7(c)(6)(i)(B), when an authorized use of the Project is to construct facilities to benefit privately owned Real Property, the Recipient and Owner must agree to use the Real Property improved or benefitted by the EDA Investment Assistance only for authorized uses of the Project and consistent with the terms and conditions of the Investment Assistance. EDA proposes to relocate this requirement to new § 314.7(c)(5)(iii), titled with a descriptive heading that reads *Agreement between Recipient and Owner.* For clarity, EDA also proposes relocating the statement currently set out at § 314.7(c)(5)(i)(F) and (c)(6)(i)(F)

that EDA may deem that a violation of § 314.7(c)(5) constitutes an Unauthorized Use of Project Property as new § 314.7(c)(5)(iv).

EDA received one comment suggesting that the agency not require a Recipient to hold title in all cases, allowing ''long term or low cost leases for important community projects.'' EDA recognizes that it is not always realistic for the Recipient to hold title, and the agency's exception to the title requirement set out at § 314.7(c)(2), titled *Leasehold interests,* allows EDA to determine that a long-term leasehold interest for at least as long as the Estimated Useful Life of Project Real Property may meet the title requirement in certain circumstances.

In light of the elimination of the subpart B designation, EDA amends the heading of § 314.8 by adding the phrase ''for Real Property'' after the word ''statement'' to clarify that this section sets out recordation requirements specifically for Real Property. In addition, EDA proposes adding new paragraph (d) to provide that EDA may choose to accept an alternate instrument to protect EDA's interest in Project Property, such as an escrow agreement or a letter of credit. EDA seeks comments from economic development practitioners on whether this language will help facilitate innovative Projects.

In light of the removal of the subpart C heading for Personal Property, the phrase ''Recorded statement'' in the heading of § 314.9 is replaced with the phrase ''Recorded statement for Personal Property'' to clarify that the requirements of the regulation apply only to Personal Property. In response to an internal comment, EDA proposes to amend the first sentence in § 314.9 to better explain the form of the security interest EDA requires with respect to Personal Property. Accordingly, the phrase ''security interest'' is replaced with the phrase ''Uniform Commercial Code Financing Statement (Form UCC–1, as provided by State law)'' in the first sentence of the provision. In addition, EDA proposes removing the unnecessary phrase ''but not limited to'' following the word ''including'' in the first sentence of the provision.

EDA received two public comments regarding the length of EDA's interest in Project Property. One commenter suggests that EDA's ''20 year lien position on real estate deals'' is too long in today's economy and another commenter suggests that EDA ''choose estimated useful lives for facility projects that would increase the potential for effective and profitable economic development over the short and long term * * * based on factual circumstances, replacement policies, or industry practices.'' The commenter recommends that Recipients ''would be responsible for delineating the reasons for a shorter useful life based on certain material criteria established by the EDA.'' EDA has carefully reviewed its authorities and regulations and determined that it has the flexibility to set an Estimated Useful Life for its Investments based on the expected level of effort to create jobs. As the Federal Interest normally is coterminous with the useful life of Project Property, EDA's interest generally will be extinguished at the expiration of a Project's useful life. The Economic Development Administration and Appalachian Regional Development Reform Act of 1998 (Pub. L. 105–393) added section 601(d) to PWEDA (42 U.S.C. 3211) to allow EDA to release its interest in Real or Personal Property after 20 years. This amendment was designed to provide EDA with additional flexibilities to release its interest in Project Property, particularly as some Projects implicated 40-year Estimated Useful Lives, not to mandate a minimum 20-year useful life for all Project Property. EDA's current general practice is to establish an Estimated Useful Life of 20 years for new construction and 15 years for rehabilitation, although EDA may establish an Estimated Useful Life of more or less than those timeframes when appropriate depending on the circumstances of a particular Investment.

While EDA understands the comment, EDA's regulations currently do not prescribe the appropriate length of the Estimated Useful Life of Project Property, which EDA establishes on a case-by-case basis by means of a special award condition. As this matter is better handled on a case-by-case basis, EDA does not need to address the matter by regulation.

In addition, EDA received an internal comment suggesting that EDA revise § 314.10, which sets out the procedures for releasing EDA's Property interest, ''by providing some relief of the 20-year period under certain circumstances, such as providing relief if the project met or exceeded its projected performance after 9 years (which is the last year EDA reports on project performance for purposes of the Government Performance Results Act) or reducing the value of the residual Federal Interest over time.'' Section 314.10(a) currently provides that at the request of a Recipient and before the expiration of the Estimated Useful Life of a Project, EDA may release its interest in Project Property 20 years after the Investment Assistance was awarded. As noted above, EDA has the authority to set an Estimated Useful Life commensurate with job creation and economic development expectations of a particular Project. Once EDA establishes the Estimated Useful Life and secures the Federal Interest for its duration, EDA obtains the benefit of that security for the entire Estimated Useful Life. EDA is constrained by law from ceding something of value without obtaining equal value in return unless expressly authorized by statute. EDA is able to release its interest after 20 years because section 601(d)(2) of PWEDA provides such specific authority. Accordingly, EDA declines to make the textual change to § 314.10 requested by the commenter.

However, with a view to providing Recipients greater flexibility to deal with Project Property, EDA is proposing revisions to § 314.10 to streamline procedures for the release of the Federal Interest in connection with EDA-assisted Property. This NPRM reorganizes § 314.10 to add new § 314.10(a), which provides additional information regarding EDA's practice in establishing the Estimated Useful Life of Projects. This paragraph notes specifically EDA's historical practice before 1999 in establishing Estimated Useful Lives for periods of 40 years or more. Since 1999, EDA typically establishes useful lives between 15 and 20 years, depending on the nature of the asset. Current paragraph (a) is redesignated as new paragraph (d). EDA proposes to delete current paragraph (b), which announced the release of the Federal Interest with the Local Public Works and Capital Investment program that EDA conducted from 1976 until 1978, in its entirety. Since the regulation that added this provision in February 1999 was a simple announcement of the release, there is no current need to repeat the provision in the proposed rule. EDA replaces the content of paragraph (b) with a new paragraph to set out the general rule that upon written request, EDA may release the Federal Interest in Project Property at the expiration of the Project's Estimated Useful Life, provided that the Recipient has made a good faith effort to fulfill the terms and conditions of the award, as determined by EDA. Accordingly, EDA revises the heading of § 314.10(b) to read *Release of Property after the expiration of the Estimated Useful Life* instead of *Exception.*

This NPRM proposes to remove and relocate certain portions of the content of current paragraph (c) and revises the paragraph to provide that EDA can release its interest before the expiration of the Estimated Useful Life of Project

Property only if it receives compensation for the fair market value of the Federal Interest. Accordingly, EDA revises the heading of § 314.10(c) to read *Release prior to expiration of the Estimated Useful Life* instead of *Unauthorized Use.* This paragraph refers to a similar statement in § 314.4, but repeats it here in order to place all of the provisions relating to release of the Federal Interest in the same regulation. Please see below for a detailed explanation of content revisions to current § 314.10(c). EDA also redesignates current § 314.10(a), which details the process for EDA's release of the Federal Interest before the expiration of the Estimated Useful Life but at least 20 years after date of award, as § 314.10(d). EDA adds a clarifying heading to read *Release of certain Property after 20 years* and the introductory phrase ''In accord with section 601(d)(2) of PWEDA'' to redesignated paragraph (d). Also, EDA adds the clause ''that exceeds 20 years'' immediately following the phrase ''before the expiration of the Estimated Useful Life of a Project'' to further clarify EDA's practice. Additionally, EDA removes one repetitive numerical reference in newly designated § 314.10(d) by replacing ''twenty (20)'' with ''20.''

EDA is removing the content of current paragraph (c)(1)(ii) of § 314.10, which provides that notwithstanding the release of the Federal Interest, Project Property may not be used for inherently religious activities prohibited by applicable Federal law. EDA included this subsection in the regulation in 1999 to address the legal requirements of and *Tilton* v. *Richardson,* (403 U.S. 672 (1971)), which held with respect to a grant program to support the construction of educational facilities and notwithstanding express statutory authority to release the Federal government's interest in grant property 20 years after the date of the award that, if such property had value, it remained subject to the requirements of the Establishment Clause of the First Amendment to the U.S. Constitution (U.S. Const. amend. I). Since *Tilton* was announced, the courts have made a number of important distinctions to Establishment Clause jurisprudence. Importantly, the Office of Legal Counsel (''*OLC*'') at the U.S. Department of Justice issued an opinion in a question regarding the Old North Church, which is the historic property where Robert Newman hung lanterns to alert Paul Revere of oncoming British troops; Revere's warnings to colonial militias led to the battles of Lexington and Concord (2003 WL 21246893 (O.L.C.) (April 30, 2003)). The OLC opinion discusses whether the Government retains the flexibility to assist religious institutions to carry out secular purposes in certain circumstances. In the Old North Church opinion, OLC distinguished the grant program under its review, the U.S. Department of the Interior's Save America's Treasures program, from the educational program under review in *Tilton.* OLC concluded that there was no Constitutional bar to the use of historic preservation grants for the preservation of historic properties that satisfy the generally applicable criteria for funding under the program. The opinion may be found on the OLC Web site at *http://www.justice.gov/olc/OldNorthChurch.htm.*

The transactional analysis at the heart of the opinion suggests that the prohibition currently set out at § 314.10(c)(1)(ii) may not be required and may, to the contrary, serve to disfavor religious institutions from full participation in EDA's economic development assistance programs by treating them as less than equal in their ability to obtain a release of the Federal Interest. Similar to OLC's analysis of the legal effect of providing support for improvements to the historic church of Paul Revere in return for guaranteed public access, EDA does not make Investments to improve properties to ensure their availability as educational resources as was the case with the buildings at the heart of *Tilton.* Rather, the purpose of an EDA Investment is to support the job-creating activities of the Recipient to help counter the economic distress of the Region. It is entirely appropriate that EDA establish a reasonable timeframe in which it expects a Recipient to pursue its efforts to create jobs. As EDA reports on the performance of its programs for purposes of the GPRA at the third, sixth, and ninth anniversaries of the date of the award, it makes sense for EDA to secure its Investment by using the concept of Estimated Useful Life to ensure EDA receives the benefit of its bargain in making the funding decision. As noted above, EDA typically establishes an Estimated Useful Life of between 15 and 20 years, well in excess of the nine-year GPRA reporting timeframe. Inasmuch as EDA programs support the construction of economic development related Projects, such as a job training facility or business incubation center, there would appear to be less potential concern on Establishment Clause grounds.

While EDA is removing the provisions currently set out in § 314.10(c)(1)(ii), the agency need not decide the underlying legal issue as part of this regulation. New paragraph (e) includes an important limitation that a release of the Federal Interest is not automatic, but requires EDA's express approval. In determining whether to agree to release the Federal Interest, this paragraph provides expressly that EDA may not approve a release if the agency lacks legal authority to do so, including governing Establishment Clause law; if the Recipient has not performed in accordance with the terms and conditions of the Investment or has used Project Property in violation of §§ 314.3 or 314.4; or other such factors as EDA deems appropriate. With this reservation of authority, EDA will review its legal authority to release the Federal Interest at the time of the request. In general, EDA will not release the Federal Interest in the case of a Recipient's poor or non-performance under the terms and conditions of the Investment Assistance or the Recipient's violation of the terms and conditions applicable to the Investment Assistance. EDA may refuse to release its interest if EDA determines that the Recipient has failed to carry out the scope of work or a portion thereof under the Investment Assistance (e.g., if the Recipient constructs a building to be used as a training center, but does not obtain necessary State and local permits and approvals so that the building can be used for the purpose authorized under the Investment Assistance). In addition, EDA may refuse to release its interest if EDA determines that the Recipient has used Project Property for an unauthorized use in violation of §§ 314.3 or 314.4. For example, if the Recipient's incidental use of Project Property under § 314.3(f) does interfere with the scope of the Project or violates applicable law, including the requirement that Project Property not be used in violation of nondiscrimination requirements or for inherently religious activities prohibited by applicable Federal law. If EDA determines it is legally constrained from releasing the Federal Interest, all Project requirements will continue to apply until EDA determines that all requirements and expectations of the Investment Assistance have been fulfilled.

However, notwithstanding any release of the Federal Interest under § 314.10, in accordance with DOC's regulations at 15 CFR part 8, compliance with nondiscrimination requirements is a continuing obligation. Therefore, EDA is retaining the content of § 314.10(c)(1)(i).

EDA proposes relocating the provision to new paragraph § 314.10(e)(3).

In addition to comments regarding specific regulatory provisions, EDA received three comments with respect to EDA's overall policies regarding property management. One commenter suggests that EDA consider ''[p]articipating mortgages and joint ventures for buildings. * * * [w]inners could offset losers and result in new opportunities and profit.'' EDA assumes that the commenter is suggesting that EDA enter into participating mortgages with its Recipients. Generally speaking, a participating mortgage is a mortgage loan under which the lender is entitled to share in the rental or resale proceeds from a property owned by the borrower or mortgagor. EDA lacks the authority to make a regulatory change to carry out this suggestion because PWEDA does not authorize profit as part of an EDA award, and all award benefits accrue to the community in terms of job creation and economic diversification. Under current government-wide procedures, however, any income generated under the Project generally is directed to accomplish further Project objectives. *See also* the requirements of ''program income'' at 15 CFR 14.24 or 24.25, as applicable.

EDA received two comments suggesting that EDA create an ''alternate'' mechanism to provide a ''gap financing vehicle which could be a letter of credit or the like that would be sufficient to a bank'' for critical, time-sensitive Projects. While complex Projects that incorporate a variety of financing types may take a longer time to be approved, EDA is committed to acting on applications in an expeditious manner and recently converted its grant processes to a quarterly cycle with award decisions to be made within 20 business days of each funding cycle deadline. EDA's statutory authority, PWEDA, does not permit EDA to make financial assistance available through a letter of credit. Accordingly, EDA is unable to provide an applicant with an irrevocable ''promise to pay'' by issuing such a document in advance of EDA's approval process.

Part 315—Trade Adjustment Assistance for Firms

Part 315 sets forth regulations to implement the TAAF program authorized under chapters 3 and 5 of title II of the Trade Act of 1974, as amended (19 U.S.C. 2341 *et seq.*) EDA did not receive any comments on and does not propose any revisions to part 315.

Classification

Prior notice and opportunity for public comment are not required for rules concerning public property, loans, grants, benefits, and contracts (5 U.S.C. 553(a)(2)). Because prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553, or any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are inapplicable. Therefore, a regulatory flexibility analysis has not been prepared.

Executive Order No. 12866

The Office of Management and Budget (OMB) has determined that this proposed rule is significant for purposes of Executive Order 12866.

Congressional Review Act

This NPRM is not major under the Congressional Review Act (5 U.S.C. 801 *et seq.*)

Executive Order No. 13132

Executive Order 13132 requires agencies 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 Executive Order 13132 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.'' It has been determined that this proposed rule does not contain policies that have federalism implications.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (''*PRA*'') requires that a Federal agency consider the impact of paperwork and other information collection burdens imposed on the public and, under the provisions of PRA section 3507(d), obtain approval from OMB for each collection of information it conducts, sponsors, or requires through regulations. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the PRA unless that collection displays a currently valid OMB Control Number.

The following table provides a complete list of the collections of information (and corresponding OMB Control Numbers) set forth in this proposed rule. These collections of information are necessary for the proper performance and functions of EDA.

Part or section of this proposed rule	Nature of request	Form/title/OMB control number
301.2; 301.10	With an application for Investment Assistance, a non-profit Eligible Applicant must include a resolution passed by an authorized representative of a political subdivision of a State.	ED–900, Application for Investment Assistance (0610–0094)
301.3(a); 301.10; 305.3(a)(1)	An Eligible Applicant must substantiate Regional eligibility and justify the requested EDA Investment Assistance based on, for example, the unemployment rate, per capita income levels, or a Special Need (as determined by EDA) in the Region in which the Project will be located. The Eligible Applicant also must identify and submit to EDA the source of data used to substantiate Regional eligibility (e.g., ACS or BLS data, other Federal data for the Region in which the Project will be located, or data available through the State government).	ED–900, Application for Investment Assistance (0610–0094)
301.4(b)(1)(i); 305.3(a)(1)	An Eligible Applicant must provide information on the severity of the Region's unemployment and its duration, the per capita income levels, and extent of the Region's unemployment or outmigration.	ED–900, Application for Investment Assistance (0610–0094)
301.4(b)(4)	An Eligible Applicant for a Project under part 306 must provide information to show that the Project merits an increase to the Investment Rate because of the Project's infeasibility without such an increase, or because the Project will be of no or only incidental benefit to the Eligible Applicant.	ED–900, Application for Investment Assistance (0610–0094)

Part or section of this proposed rule	Nature of request	Form/title/OMB control number
301.5; 301.10	An Eligible Applicant must provide information to show that Matching Share funds will be available for the Project.	ED–900, Application for Investment Assistance (0610–0094)
301.10(c)	An Eligible Applicant for a Project under parts 305 or 307 must include with its application for Investment Assistance a CEDS acceptable to EDA (pursuant to part 303) or otherwise incorporate by reference a current CEDS that EDA approves for the proposed Project.	ED–900, Application for Investment Assistance (0610–0094)
301.10(d)	An Eligible Applicant for a Project to construct a business, technology, or other type of incubator or accelerator, must include a feasibility study demonstrating the need for the Project and an operational plan based on industry best practices demonstrating the Eligible Applicant's plan for ongoing successful operations.	ED–900, Application for Investment Assistance (0610–0094)
302.7(a)	Recipients must submit requests for amendments to Investment awards in writing to EDA for approval and provide information and documentation as EDA deems necessary.	Award Amendment Request (0610–0102)
302.9(a)	An Eligible Applicant must furnish comments on the Project from the relevant governmental authority in the Region or proof of efforts to obtain comments if none were provided by the governmental authority.	ED–900, Application for Investment Assistance (0610–0094)
302.10(a)	An Eligible Applicant must certify to EDA the names of any persons engaged by or on behalf of the Eligible Applicant for the purpose of expediting Investment Assistance applications made to EDA.	ED–900, Application for Investment Assistance (0610–0094)
302.14(a)	Recipients shall keep records of the amount and disposition of awards of Investment Assistance, the total cost of the Project, the amount and nature of the portion of the Project costs provided by other sources and other records that would facilitate an effective audit.	Audits of States, Local Governments, and Non-Profit Organizations, OMB Circular A–133
302.15	An Eligible Applicant must certify (and submit evidence thereof satisfactory to EDA) that it meets the requirements for receiving Investment Assistance.	ED–900, Application for Investment Assistance (0610–0094)
302.16(b)	Recipients are required to submit reports consisting of data-specific evaluations of the Project's effectiveness.	GPRA Performance Validation Forms (0610–0098)
302.16(c)	EDA may require a Recipient to provide a ''Project service map'' and other information in order to determine which segments of the Region are being assisted with the Investment Assistance.	Project Service Map (0610–0102)
302.20(d)	Recipients and Other Parties must submit written assurances to EDA that they will comply with nondiscrimination laws and regulations.	ED–900, Application for Investment Assistance (0610–0094)
303.9(c)	Eligible Applicants for short-term Planning Investment Assistance must provide performance measures acceptable to EDA, and provide EDA with progress reports during the term of the Planning Investment.	GPRA Performance Validation Forms (0610–0098)
304.1; 304.4(a)	To have a Region certified as an EDD, a District Organization must submit information showing that the Region contains at least one area subject to the relevant economic distress criteria, is able to foster development on a larger scale than in a single area, has an EDA-approved CEDS, and obtains commitments from a majority of the relevant counties and States.	Comprehensive Economic Development Strategies and Planning Investments (0610–0093)
304.2(c)(2); 304.4(b)	The District Organization must demonstrate that its governing body is broadly representative of the principal economic interests of the Region.	ED–900, Application for Investment Assistance (0610–0094); Comprehensive Economic Development Strategies and Planning Investments (0610–0093)
304.2(c)(4)	The District Organization must notify the public of its annual meetings, its decisions, the results of programs, and as reasonably requested, the results of audited statements, annual budgets, and minutes of public meetings.	Comprehensive Economic Development Strategies and Planning Investments (0610–0093)
305.2(b); 305.3(a)(3)	An Eligible Applicant must show that a Public Works Project will promote: the growth of industrial or commercial plants, the creation of long-term employment opportunities primarily for low-income families, and the fulfillment of the Region's pressing needs.	ED–900, Application for Investment Assistance (0610–0094); Construction Investments (0610–0096)
305.4(c)	In order to receive any portion of the Investment Assistance for design and engineering work, an Eligible Applicant must submit and certify information that documents compliance with Investment award requirements of all design and engineering contracts.	ED–900, Application for Investment Assistance (0610–0094); Construction Investments (0610–0096)
305.5	In order to allow a District Organization to administer the Project for another Recipient, the Recipient must make this request and submit information to EDA showing that the Recipient does not have the current staff capacity to administer the Project, the District Organization would be more effective than another local business or organization, the District Organization would not subcontract the work, and the costs of District Organization administration will not exceed allowable costs were the Recipient administering it.	ED–900, Application for Investment Assistance (0610–0094); Construction Investments (0610–0096)

Part or section of this proposed rule	Nature of request	Form/title/OMB control number
305.6	A Recipient shall seek EDA's prior written approval to use an alternate construction procurement method to the traditional design/bid/build. If an alternate method is used, the Recipient must submit to EDA for approval a construction services procurement plan and the Recipient must use a design professional to oversee the process.	ED–900, Application for Investment Assistance (0610–0094); Construction Investments (0610–0096)
305.7	The Recipient may use "in-house forces" for design, construction, inspection, legal services, or other work on the Project if it submits a sufficient justification to EDA.	ED–900, Application for Investment Assistance (0610–0094); Construction Investments (0610–0096)
305.8(a); 305.8(b)	Recipients of EDA construction awards must obtain prior approval for the use of furnished equipment and materials. Requests must show that costs claimed for furnished equipment and materials are competitive with local market costs for similar equipment and materials.	ED–900, Application for Investment Assistance (0610–0094); Construction Investments (0610–0096)
305.9	An EDA construction award Recipient must submit information to EDA regarding why phasing is necessary, a description of the phasing, related costs and schedules, and certification that the Recipient will pay for overruns and that it is capable of paying for incurred costs before the first disbursement.	ED–900, Application for Investment Assistance (0610–0094); Construction Investments (0610–0096)
305.10(a)	If at the construction contract bid opening, the lowest responsive bid is less than total Project cost, the Recipient will notify EDA to determine relevant procedures.	Construction Investments (0610–0096)
305.10(b)	In case of an overrun at construction contract bid opening, the Recipient may take deductive alternatives if provided for in the bid documents, reject all bids and re-advertise if there is a rational basis to believe that such action will result in a lower bid, or augment the Matching Share by an amount sufficient to cover the excess cost. If EDA determines that these options are not feasible, the Recipient may submit a written request for additional EDA funding.	Construction Investments (0610–0096)
305.11	Recipients may issue a notice permitting construction under contract to commence prior to an EDA determination of award compliance and eligibility for cost reimbursement, but will proceed at their own risk until EDA review and concurrence. The EDA regional office may request information from the Recipient to make a determination of award compliance.	Construction Investments (0610–0096)
305.12	EDA requires a Recipient to erect a Project sign or signs at the Project construction site to indicate that the Federal government is participating in the Project. The regional office will provide mandatory specifications for Project signage.	Construction Investments (0610–0096)
305.13	Recipients involved in a contract change order must submit them to EDA for review.	Construction Investments (0610–0096)
306.2	EDA selects Projects for Local and National Technical Assistance based on the criteria in part 301 and the extent to which the Eligible Applicant demonstrates that the Project will achieve more specific objectives in the Region (as set forth in § 306.2) and meets the criteria in the applicable FFO.	ED–900, Application for Investment Assistance (0610–0094)
306.5	EDA provides Investment Assistance to University Center Projects based on the selection criteria in part 301, the competitive selection process outlined in the applicable FFO, and the extent to which the Eligible Applicant demonstrates other more specific, related criteria.	ED–900, Application for Investment Assistance (0610–0094)
307.5(a)	Each application for Economic Adjustment Assistance must include or incorporate by reference (if so approved by EDA) a CEDS.	ED–900, Application for Investment Assistance (0610–0094)
307.9	All RLF Recipients must submit to EDA an RLF Plan	RLF Standard Terms and Conditions (0610–0095)
307.11(a)	Prior to the disbursement of EDA funds, RLF Recipients must provide in a form acceptable to EDA evidence of fidelity bond coverage and evidence of certification in accordance with § 307.15(b)(1).	RLF Standard Terms and Conditions (0610–0095)
307.11(e)	If the Recipient receives Grant funds and the RLF loan disbursement is subsequently delayed beyond 30 days, the Recipient must notify the applicable grants officer and return such non-disbursed funds to EDA.	RLF Standard Terms and Conditions (0610–0095)
307.13(a)	RLF Recipients must maintain Closed Loan files and all related documents, books of account, computer data files, and other records over the term of the Closed Loan and for a three-year period from the date of final disposition of such Closed Loan.	RLF Standard Terms and Conditions (0610–0095)
307.13(b)	RLF Recipients must maintain adequate accounting records to substantiate the amount of RLF Income expended for eligible administrative costs and retain records of administrative expenses incurred for activities and equipment relating to the operation of the RLF.	RLF Standard Terms and Conditions (0610–0095)
307.14(a)	All RLF Recipients must submit semi-annual reports in electronic format to EDA, unless EDA approves a paper submission.	ED–209, Semi-Annual Report (0610–0095)

Part or section of this proposed rule	Nature of request	Form/title/OMB control number
307.14(b)	All RLF Recipients must certify as part of the semi-annual report that the RLF is operating in accordance with the RLF Plan, and describe any modifications to the RLF Plan to ensure effective use of the RLF.	ED–209, Semi-Annual Report (0610–0095) ED–209A, Annual Report (0610–0095)
307.14(c)	An RLF Recipient using either fifty percent or more (or more than $100,000) of RLF Income for administrative costs in a 12-month reporting period must submit a completed Income and Expense Statement annually to the appropriate EDA regional office. EDA may waive this requirement for an RLF Grant with a small RLF Capital Base.	ED–209I, Income and Expense Statement (0610–0095)
307.15(b)(1)	Within 60 days prior to the initial disbursement of EDA funds, a qualified independent accountant who preferably has audited the RLF Recipient in accordance with OMB Circular A–133 requirements, shall certify to EDA and the Recipient that such system is adequate to identify, safeguard, and account for all RLF operations.	RLF Standard Terms and Conditions (0610–0095)
307.15(b)(2)	Prior to the disbursement of any EDA funds, an RLF Recipient must certify that standard loan documents necessary for lending are in place and that these documents have been reviewed by its legal counsel for adequacy and compliance with the terms and conditions of the Grant and applicable State and local law.	RLF Standard Terms and Conditions (0610–0095)
307.16(b)	Recipients must promptly notify EDA in writing of any condition that may adversely affect their ability to meet prescribed schedule deadlines. Recipients must submit a written request for continued use of Grant funds beyond a missed deadline for disbursement of RLF funds.	RLF Standard Terms and Conditions (0610–0095)
307.19	With prior approval from EDA, a Recipient may enter into a Sale or Securitization of all or a portion of its RLF loan portfolio.	RLF Standard Terms and Conditions (0610–0095)
307.21(b)	EDA may approve a request from a Recipient to terminate an RLF Grant.	RLF Standard Terms and Conditions (0610–0095)
part 310	Upon the application of an Eligible Applicant, EDA may designate the Region which the Project will serve as a Special Impact Area and waive the CEDS requirement if the Eligible Applicant demonstrates that its proposed Project will directly fulfill a pressing need and assist in preventing excessive unemployment.	Comprehensive Economic Development Strategies and Planning Investments (0610–0093)
314.3(f)	With EDA's prior written approval, a Recipient may undertake an incidental use of Property that does not interfere with the scope of the Project or the economic purpose for which the Investment was made, provided it satisfies the conditions set forth in § 314.3(f).	Property Management 0610–0103
314.6(b)	In order to use EDA-funded Property to secure a mortgage or deed of trust or encumber the Property, the Recipient must provide information that satisfies one or more of the exceptions set forth in § 314.6(b).	ED–900, Application for Investment Assistance (0610–0094); Construction Investments (0610–0096)
314.7(a) and (c)	The Recipient must provide information that satisfies EDA that the Recipient has title to the Real Property and all easements, rights-of-way, permits, or long-term leases, unless it can provide information proving it meets an exception to the rule.	ED–900, Application for Investment Assistance (0610–0094); Construction Investments (0610–0096)
314.7(b)	The Recipient must provide information regarding all encumbrances on the Real Property to EDA.	ED–900, Application for Investment Assistance (0610–0094); Construction Investments (0610–0096)
314.8	Recipients must execute a lien, covenant, or other statement of EDA's interest in all Property acquired or improved with EDA Investment Assistance and record it in the proper jurisdiction.	ED–900, Application for Investment Assistance (0610–0094); Construction Investments (0610–0096)
314.9	Recipients must execute a security interest or other statement of EDA's interest in Personal Property acquired or improved by EDA funds and record the interest in accordance with applicable law.	ED–900, Application for Investment Assistance (0610–0094); Construction Investments (0610–0096)
314.10	If a Recipient wishes for EDA to release its Real Property or tangible Personal Property interest before or after the expiration of the Property's Estimated Useful Life, it must submit a request for such release to EDA. EDA's release is not automatic and may require some action on behalf of the Recipient.	Property Management 0610–0103
315.5(b)	Current or prospective TAACs must submit either a new or amended application to EDA, along with a proposed budget, narrative scope of work, and other information as may be requested by EDA.	ED–900, Application for Investment Assistance (0610–0094)
315.5(c)	TAACs must submit information regarding performance to be evaluated by EDA.	GPRA Performance Validation Form (0610–0098)
315.6(a)(1); 315.7; 315.8	Firms must provide specific information to EDA in order to be certified for participation in the TAAF program.	ED–840P, Petition by a Firm for Certification of Eligibility to Apply for Trade Adjustment Assistance (0610–0091)

Part or section of this proposed rule	Nature of request	Form/title/OMB control number
315.6(a)(2); 315.6(a)(3); 315.16	A Certified Firm must submit an Adjustment Proposal to EDA for approval. If EDA approves the Adjustment Proposal, the Firm may then request Adjustment Assistance from the TAAC.	ED–840P, Petition by a Firm for Certification of Eligibility to Apply for Trade Adjustment Assistance (0610–0091)
315.9	In order to have a public hearing, a Person with a Substantial Interest in an accepted petition for TAAF certification must submit a request that follows this section's procedures.	ED–840P, Petition by a Firm for Certification of Eligibility to Apply for Trade Adjustment Assistance (0610–0091)
315.12	Each TAAC shall keep records disclosing the use of all TAAF funds	GPRA Performance Validation Form (0610–0098)

List of Subjects

13 CFR Part 300

Distressed region, Financial assistance, Headquarters, Regional offices.

13 CFR Part 301

Applicant and application requirements, Economic distress levels, Eligibility requirements, Grant administration, Grant programs, Investment rates.

13 CFR Part 302

Civil rights, Conflicts-of-interest, Environmental review, Federal policy and procedures, Fees, Inter-governmental review, Post-approval requirements, Pre-approval requirements, Project administration, Reporting and audit requirements.

13 CFR Part 303

Award and application requirements, Comprehensive economic development strategy, Planning, Short-term planning investments, State plans.

13 CFR Part 304

District modification and termination, Economic development district, Organizational requirements, Performance evaluations.

13 CFR Part 305

Award and application requirements, Economic development, Public works, Requirements for approved projects.

13 CFR Part 306

Award and application requirements, Performance evaluations, Research, Technical assistance, Training, University centers.

13 CFR Part 307

Award and application requirements, Economic adjustment assistance, Income, Liquidation, Merger, Pre-loan requirements, Record and reporting requirements, Revolving loan fund, Sales and securitizations, Termination.

13 CFR Part 308

Performance awards, Planning performance awards.

13 CFR Part 310

Excessive unemployment, Special impact area, Special need.

13 CFR Part 311

America COMPETES.

13 CFR Part 314

Authorized use, Federal interest, Federal share, Property, Property interest, Release, Title.

Regulatory Text

For reasons stated in the preamble, this NPRM proposes amending title 13, chapter III of the *Code of Federal Regulations* as follows:

PART 300—GENERAL INFORMATION

1. The authority citation for part 300 continues to read as follows:

Authority: 42 U.S.C. 3121; 42 U.S.C. 3122; 42 U.S.C. 3211; Department of Commerce Organization Order 10–4.

2. Revise § 300.1 to read as follows:

§ 300.1 Introduction and mission.

EDA was created by Congress pursuant to the Public Works and Economic Development Act of 1965 to provide financial assistance to both rural and urban distressed communities. EDA's mission is to lead the Federal economic development agenda by promoting innovation and competitiveness, preparing American regions for growth and success in the worldwide economy. EDA will fulfill its mission by fostering entrepreneurship, innovation, and productivity through Investments in infrastructure development, capacity building, and business development in order to attract private capital investments and new and better jobs to Regions experiencing substantial and persistent economic distress. EDA works in partnership with distressed Regions to address problems associated with long-term economic distress as well as to assist those Regions experiencing sudden and severe economic dislocations, such as those resulting from natural disasters, conversions of military installations, changing trade patterns, and the depletion of natural resources. EDA Investments generally take the form of Grants to or Cooperative Agreements with Eligible Recipients.

3. Revise § 300.2 to read as follows:

§ 300.2 EDA Headquarters and regional offices.

(a) EDA's Headquarters Office is located at: U.S. Department of Commerce, Economic Development Administration, 1401 Constitution Avenue NW., Washington, DC 20230.

(b) EDA has regional offices throughout the United States and each regional office's contact information may be found on EDA's Internet Web site at *http://www.eda.gov* or in the applicable announcement of Federal Funding Opportunity issued by EDA. Please contact the appropriate regional office to learn about EDA Investment opportunities in your Region.

4. Amend § 300.3 to:

a. Revise the definition of *Cooperative Agreement,* paragraph (7) of the definition of *Eligible Recipient,* and the definition of *Federal Funding Opportunity* or *FFO, Federally-Declared Disaster, Grant, Indian Tribe, Investment* or *Investment Assistance, Investment Rate, Local Share* or *Matching Share, Presidentially-Declared Disaster, PWEDA, Region* or *Regional,* and *Trade Act;*

b. Add a definition of *Regional Innovation Clusters* or *RICs* in alphabetical order; and

c. Remove the definition of *Private Sector Representative.*

§ 300.3 Definitions.

* * * * *

Cooperative Agreement means the financial assistance award of EDA funds to an Eligible Recipient where substantial involvement is expected between EDA and the Eligible Recipient in carrying out a purpose or activity authorized under PWEDA or another statute. *See* 31 U.S.C. 6305.

* * * * *

Eligible Recipient * * *

(7) Private individual or for-profit organization, but only for Training, Research, and Technical Assistance Investments pursuant to § 306.1(d)(3) of this chapter.

* * * * *

Federal Funding Opportunity or *FFO* means an announcement EDA publishes during the fiscal year at *http://www.grants.gov* and on EDA's Internet Web site at *http://www.eda.gov* that provides the funding amounts, application and programmatic requirements, funding priorities, special circumstances, and other information concerning a specific competitive solicitation for EDA's economic development assistance programs. EDA also may periodically publish FFOs on specific programs or initiatives.

Federally Declared Disaster means a Presidentially Declared Disaster, a fisheries resource disaster pursuant to section 312(a) of the Magnuson-Stevens Fishery Conservation and Management Act, as amended (16 U.S.C. 1861a(a)), or other Federally declared disasters pursuant to applicable law.

Grant means the financial assistance award of EDA funds to an Eligible Recipient under which the Eligible Recipient bears responsibility for carrying out a purpose or activity authorized under PWEDA or another statute. *See* 31 U.S.C. 6304.

* * * * *

Indian Tribe means an entity on the list of recognized tribes published pursuant to the Federally Recognized Indian Tribe List Act of 1994, as amended (Pub. L. 103–454) (25 U.S.C. 479a *et seq.*), and any Alaska Native Village or Regional Corporation (as defined in or established under the Alaska Native Claims Settlement Act (43 U.S.C. 1601 *et seq.*). This term includes the governing body of an Indian Tribe, non-profit Indian corporation (restricted to Indians), Indian authority, or other non-profit Indian tribal organization or entity; provided that the Indian tribal organization or entity is wholly owned by, and established for the benefit of, the Indian Tribe or Alaska Native Village.

* * * * *

Investment or *Investment Assistance* means a Grant or Cooperative Agreement entered into by EDA and a Recipient.

Investment Rate means, as set forth in § 301.4 of this chapter, the amount of the EDA Investment in a particular Project expressed as a percentage of the total Project cost.

Local Share or *Matching Share* means the non-EDA funds and any In-Kind Contributions that are approved by EDA and provided by a Recipient or third party as a condition of an Investment. The Matching Share may include funds from another Federal Agency only if authorized by statute that allows such use, which may be determined by EDA's reasonable interpretation of such authority.

Presidentially Declared Disaster means a major disaster or emergency declared under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, as amended (42 U.S.C. 5121 *et seq.*).

* * * * *

PWEDA means the Public Works and Economic Development Act of 1965, as amended (42 U.S.C. 3121 *et seq.*).

* * * * *

Region or *Regional* means an economic unit of human, natural, technological, capital, or other resources, defined geographically. Geographic areas comprising a Region need not be contiguous or defined by political boundaries, but should constitute a cohesive area capable of undertaking self-sustained economic development. For the limited purposes of determining economic distress levels and Investment Rates pursuant to part 301 of this chapter, a Region also may comprise a specific geographic area defined solely by its level of economic distress, as set forth in §§ 301.3(a)(2) and 301.3(a)(3) of this chapter.

* * * * *

Regional Innovation Clusters or *RICs* means networks of similar, synergistic, or complementary entities that support a single industry sector and its various supply chains. In general, RICs:

(1) Are based on a geographic area that may cross municipal, county, and other jurisdictional boundaries;

(2) May include catalysts of innovation and drivers of Regional economic growth, such as universities, government research centers, and other research and development resources;

(3) Have active channels for business transactions and communication; and

(4) Depend upon specialized infrastructure, labor markets, and services that build on the unique competitive assets of a location, including talent, technology, services, and hard and soft infrastructure, to spur innovation, job creation, and business expansion.

* * * * *

Trade Act, for purposes of EDA, means title II, chapters 3, 4, and 5, of the Trade Act of 1974, as amended (19 U.S.C. 2341 *et seq.*).

* * * * *

PART 301—ELIGIBILITY, INVESTMENT RATE AND APPLICATION REQUIREMENTS

5. The authority section for part 301 continues to read as follows:

Authority: 42 U.S.C. 3121; 42 U.S.C. 3141–3147; 42 U.S.C. 3149; 42 U.S.C. 3161; 42 U.S.C. 3175; 42 U.S.C. 3192; 42 U.S.C. 3194; 42 U.S.C. 3211; 42 U.S.C. 3233; Department of Commerce Delegation Order 10–4.

6. Amend § 301.1 to:

a. Revise the introductory text and paragraphs (d) and (e); and

b. Add new paragraph (f) to read as follows:

§ 301.1 Overview of eligibility requirements.

In order to receive EDA Investment Assistance, the following requirements must be met:

* * * * *

(d) The Eligible Applicant must satisfy the formal application requirements set forth in subpart E of this part;

(e) The Project must meet the general requirements set forth in part 302 (General Terms and Conditions for Investment Assistance) and the specific program requirements (as applicable) set forth in part 303 (Planning Investments and Comprehensive Economic Development Strategies), part 304 (Economic Development Districts), part 305 (Public Works and Economic Development Investments), part 306 (Training, Research and Technical Assistance Investments), or part 307 (Economic Adjustment Assistance Investments) of this chapter; and

(f) EDA must select the Eligible Applicant's proposed Project.

7. Revise paragraphs (a)(1), (a)(2), (a)(4) introductory text, (a)(4)(i), and (c)(1) of § 301.3 to read as follows:

§ 301.3 Economic distress levels.

(a) *Part 305 (Public Works and Economic Development Investments) and part 307 (Economic Adjustment Assistance Investments).*

(1) Except as otherwise provided by this paragraph (a), for a Project to be eligible for Investment Assistance under parts 305 or 307 of this chapter, the Project must be located in a Region that, on the date EDA receives an application for Investment Assistance, is subject to one or more of the following economic distress criteria:

(i) An unemployment rate that is, for the most recent 24-month period for which data are available, at least one percentage point greater than the national average unemployment rate;

(ii) Per capita income that is, for the most recent period for which data are

available, 80 percent or less of the national average per capita income; or

(iii) A Special Need, as determined by EDA.

(2) A Project located within an Economic Development District, which is located in a Region that does not meet the economic distress criteria described in paragraph (a)(1) of this section, also is eligible for Investment Assistance under parts 305 or 307 of this chapter if EDA determines that the Project will be of ''substantial direct benefit'' to a geographic area within the District that meets the criteria of paragraph (a)(1) of this section. For this purpose, a Project provides a ''substantial direct benefit'' if it provides significant employment opportunities for unemployed, underemployed or low-income residents of the geographic area within the District.

* * * * *

(4) *Data requirements to demonstrate economic distress levels.* EDA will determine the economic distress levels pursuant to this subsection at the time EDA receives an application for Investment Assistance as follows:

(i) For economic distress levels based upon per capita income requirements, EDA will base its determination upon the most recent American Community Survey (''*ACS*'') published by the U.S. Census Bureau. For economic distress levels based upon the unemployment rate, EDA will base its determination upon the most recent data published by the Bureau of Labor Statistics (''*BLS*''), within the U.S. Department of Labor. For eligibility based upon either per capita income requirements or the unemployment rate, when the ACS or BLS data, as applicable, are not the most recent Federal data available, EDA will base its decision upon the most recent Federal data from other sources (including data available from the Census Bureau and the Bureaus of Economic Analysis, Labor Statistics, Indian Affairs, or any other Federal source determined by EDA to be appropriate). If no Federal data are available, an Eligible Applicant must submit to EDA the most recent data available from the State. The required data must be for the Region where the Project will be located (paragraph (a)(1) of this section), the geographic area where substantial direct Project benefits will occur (paragraph (a)(2) of this section), or the geographic area of poverty or high unemployment (paragraph (a)(3) of this section), as applicable.

* * * * *

(c) * * *

(1) Contain at least one geographic area that fulfills the economic distress criteria set forth in paragraph (a)(1) of this section and is identified in an approved CEDS; and

* * * * *

8. Revise paragraphs (b)(1) introductory text, (b)(1)(ii), (b)(2), (b)(3)(i) through (iii), (b)(4) introductory text, (b)(5), and (c) of § 301.4 as follows:

§ 301.4 Investment rates.

* * * * *

(b) *Maximum Investment Rate*—

(1) *General rule.* Except as otherwise provided by this paragraph (b) or paragraph (c) of this section, the maximum EDA Investment Rate for all Projects shall be determined in accordance with Table 1 in paragraph (b)(1)(ii) of this subsection. The maximum EDA Investment Rate shall not exceed the sum of 50 percent, plus up to an additional 30 percent based on the relative needs of the Region in which the Project is located, as determined by EDA.

* * * * *

(ii) *Table 1.* Table 1 of this paragraph sets forth the maximum allowable Investment Rate for Projects located in Regions subject to certain levels of economic distress. In cases where Table 1 produces divergent results (*i.e.,* where Table 1 produces more than one maximum allowable Investment Rate based on the Region's levels of economic distress), the higher Investment Rate produced by Table 1 shall be the maximum allowable Investment Rate for the Project.

TABLE 1

Projects located in Regions in which:	Maximum allowable investment rates (percentage)
(A) The 24-month unemployment rate is at least 225% of the national average; or	80
(B) The per capita income is not more than 50% of the national average	80
(C) The 24-month unemployment rate is at least 200% of the national average; or	70
(D) The per capita income is not more than 60% of the national average	70
(E) The 24-month unemployment rate is at least 175% of the national average; or	60
(F) The per capita income is not more than 65% of the national average	60
(G) The 24-month unemployment rate is at least one percentage point greater than the national average; or	50
(H) The per capita income is not more than 80% of the national average	50

(2) *Projects subject to a Special Need.* EDA shall determine the maximum allowable Investment Rate for Projects subject to a Special Need (as determined by EDA pursuant to § 301.3(a)(1)(iii)) based on the actual or threatened overall economic situation of the Region in which the Project is located. However, unless the Project is eligible for a higher Investment Rate pursuant to paragraph (b)(5) of this section, the maximum allowable Investment Rate for any Project subject to a Special Need shall be 80 percent.

(3) * * *

(i) The minimum Investment Rate for Projects under part 303 of this chapter shall be 50 percent.

(ii) Except as otherwise provided in paragraph (b)(3)(iii) of this section or in paragraph (b)(5) of this section, the maximum allowable Investment Rate for Projects under part 303 of this chapter shall be the maximum allowable Investment Rate set forth in Table 1 for the most economically distressed county or other equivalent political unit (e.g., parish) within the Region. The maximum allowable Investment Rate shall not exceed 80 percent.

(iii) In compelling circumstances, the Assistant Secretary may waive the application of the first sentence in paragraph (b)(3)(ii) of this section.

(4) *Projects under part 306.* Except as otherwise provided in paragraph (b)(5) of this section, the maximum allowable Investment Rate for Projects under part 306 of this chapter shall generally be determined based on the relative needs (as determined under paragraph (b)(1) of this section) of the Region which the

Project will serve. As specified in section 204(c)(3) of PWEDA, the Assistant Secretary has the discretion to establish a maximum Investment Rate of up to 100 percent where the Project:

* * * * *

(5) *Special Projects.* Table 2 of this paragraph sets forth the maximum allowable Investment Rate for certain special Projects as follows:

TABLE 2

Projects	Maximum allowable investment rates (percentage)
Projects that involve broad Regional planning and coordination with other entities outside the Eligible Applicant's political jurisdiction or area of authority, under special circumstances determined by EDA	
Projects that effectively leverage other Federal Agency resources	80
Projects of Indian Tribes	100
Projects for which EDA receives appropriations under section 703 of PWEDA (42 U.S.C. 3233) and Projects to address and implement post-disaster economic recovery efforts in Presidentially Declared Disaster areas in a timely manner	100
Projects of States or political subdivisions of States that the Assistant Secretary determines have exhausted their effective taxing and borrowing capacity, or Projects of non-profit organizations that the Assistant Secretary determines have exhausted their effective borrowing capacity	100
Projects under parts 305 or 307 that receive performance awards pursuant to § 308.2 of this chapter	100
Projects located in a District that receive planning performance awards pursuant to § 308.3 of this chapter	100

(c) Federal Funding Opportunity announcements may provide additional Investment Rate criteria and standards to ensure that the level of economic distress of a Region, rather than a preference for a geographic area or a specific type of economic distress, is the primary factor in allocating Investment Assistance.

9. Revise the section heading, paragraph (a) introductory text and paragraph (b) of § 301.6 to read as follows:

§ 301.6 Supplementary Investment Assistance.

(a) Pursuant to a request made by an Eligible Applicant, EDA Investment Assistance may supplement a grant awarded in another ''designated Federal grant program,'' if the Eligible Applicant qualifies for financial assistance under such program, but is unable to provide the required non-Federal share because of the Eligible Applicant's economic situation. For purposes of this section, a ''designated Federal grant program'' means a Federal grant program that:

* * * * *

(b) For a Project that meets the economic distress criteria provided in § 301.3(a), the Investment Assistance, combined with funds from a designated Federal grant program, may be at the maximum allowable Investment Rate, even if the designated Federal grant program has a lower grant rate. If the designated Federal grant program has a grant rate higher than the maximum EDA Investment Rate, the EDA Investment and other Federal funds together may exceed the EDA Investment Rate, provided that the EDA share of total funding does not exceed the maximum allowable Investment Rate.

10. Revise paragraph (a) of § 301.7 as follows:

§ 301.7 Investment Assistance application.

(a) The EDA Investment Assistance process begins with the submission of an application. The *Application for Investment Assistance* (Form ED–900 or any successor form) may be obtained electronically from *http://www.grants.gov* or from the appropriate regional office. In general, EDA accepts applications on a continuing basis and competitively evaluates all applications received in quarterly funding cycles throughout the fiscal year. Subject to the availability of funds, the timing in which EDA receives complete and competitive applications affects EDA's ability to participate in a given Project. EDA will evaluate all applications in accord with the criteria set forth in the applicable FFO and in § 301.8 and will:

(1) Return the application to the applicant for specified deficiencies and suggest resubmission after corrections are made; or

(2) Deny the application for specifically stated reasons and notify the applicant.

* * * * *

11. Revise § 301.8 to read as follows:

§ 301.8 Application evaluation criteria.

EDA will screen all applications for the feasibility of the budget presented and conformance with EDA's statutory and regulatory requirements. EDA will assess the economic development needs of the affected Region in which the proposed Project will be located (or will service), as well as the capability of the Eligible Applicant to implement the proposed Project. In addition to criteria set out in the applicable FFO, EDA will consider the degree to which an Investment in the proposed Project will satisfy one or more of the following criteria:

(a) *Ensures collaborative Regional innovation.* The Investment will support the development and growth of innovation clusters based on existing Regional competitive strengths. Such initiatives must engage stakeholders; facilitate collaboration among urban, suburban, and rural (including Tribal) areas; provide stability for economic development through long-term intergovernmental and public/private collaboration; and support the growth of existing and emerging industries.

(b) *Leverages public-private partnerships.* The Investment will use both public and private sector resources and leverage complementary investments by other government/public entities or non-profit organizations.

(c) *Advances national strategic priorities.* The Investment will encourage job growth and business expansion in clean energy; green technologies; sustainable manufacturing; information technology infrastructure; communities severely impacted by automotive industry restructuring; natural disaster mitigation and resiliency; access to capital for small- and medium-sized and ethnically diverse enterprises; and innovations in science, health care, and alternative fuel technologies.

(d) *Enhances global competitiveness.* The Investment will support high-growth businesses and innovation-based entrepreneurs to expand and compete in global markets.

(e) *Encourages environmentally sustainable development.* The Investment will encompass best practices in ''environmentally sustainable development,'' broadly defined to include projects that enhance environmental quality and develop and implement green products, processes, and buildings as part of the green economy.

(f) *Supports economically distressed and underserved communities.* The Investment will strengthen diverse communities that have suffered disproportionate economic and job losses or are rebuilding to become more competitive in the global economy.

12. Revise § 301.9 to read as follows:

§ 301.9 Application selection criteria.

(a) EDA will review completed application materials for compliance with the requirements set forth in PWEDA, this chapter, the applicable FFO, and other applicable Federal statutes and regulations. From those applications that meet EDA's technical and legal requirements, EDA will select applications based on the:

(1) Availability of funds;

(2) Competitiveness of the applications in accord with the criteria set forth in § 301.8; and

(3) Funding priority considerations identified in the applicable FFO.

(b) EDA will endeavor to notify applicants as soon as practicable regarding whether their applications are selected for funding.

13. Amend § 301.10 to revise paragraphs (b), (c) introductory text, and (c)(2), and add paragraph (d) to read as follows:

§ 301.10 Formal application requirements.

* * * * *

(b) Identify the sources of funds, both eligible Federal and non-EDA, and In-Kind Contributions that will constitute the required Matching Share for the Project (*see* the Matching Share requirements under § 301.5); and

(c) For Projects under parts 305 or 307 of this chapter, include a CEDS acceptable to EDA pursuant to part 303 of this chapter or otherwise incorporate by reference a current CEDS that EDA approves for the Project. The requirements stated in the preceding sentence shall not apply to:

* * * * *

(2) A Project located in a Region designated as a Special Impact Area pursuant to part 310 of this chapter.

(d) Projects that propose the construction of a business, technology, or other type of incubator or accelerator, must include a feasibility study demonstrating the need for the Project and an operational plan based on industry best practices demonstrating the Eligible Applicant's plan for ongoing successful operations. EDA will provide further guidance in the applicable FFO. EDA may require the Recipient to demonstrate that the feasibility study has been conducted by an impartial third party, as determined by EDA.

14. Add § 301.11 to subpart E of part 301 to read as follows:

§ 301.11 Infrastructure.

(a) EDA will fund both construction and non-construction infrastructure necessary to meet a Region's strategic economic development goals and needs, which in turn results in job creation. This includes infrastructure to develop and upgrade basic economic development assets as described in §§ 305.1 and 305.2 of this chapter, such as utility facilities, as well as infrastructure that supports innovation and entrepreneurship. The following are examples of innovation- and entrepreneurship-related infrastructure that support job creation:

(1) *Business Incubation.* Business incubation includes both physical facilities and business support services to advance the successful development of start-up companies by providing entrepreneurs with an array of targeted resources and services.

(2) *Business Acceleration.* Business acceleration includes both physical facilities and an array of business support services to help new and existing businesses develop new processes or products, get products and services to market more efficiently, expand market opportunities, or increase sales and exports.

(3) *Venture Development Organization.* A venture development organization (''*VDO*'') works to ensure that Regional economies operate as smoothly and efficiently as possible in support of innovation-based entrepreneurship. A VDO may make strategic investments of time, talent, and other resources toward innovation, entrepreneurship, and technology to help nurture and grow promising companies and ideas, thereby promoting and taking advantage of the innovation assets of a Region and addressing the needs of the high-growth, innovation-oriented start-up companies in the Region.

(4) *Proof of Concept Center.* A proof of concept center serves as a hub of collaborative and entrepreneurial activity designed to accelerate the commercialization of innovations into the marketplace. Such centers support innovation-based, high growth entrepreneurship through a range of services, including technology and market evaluation, business planning and mentorship, network development, and early stage access to capital.

(5) *Technology Transfer.* Technology transfer is the process of transferring scientific findings from one organization to another for the purpose of further development and commercialization. The process typically includes: Identifying new technologies; protecting technologies through patents and copyrights; and forming development and commercialization strategies, such as marketing and licensing, for existing private sector companies or creating start-up companies based on the technology.

(b) In general, successful Projects, including innovation- and entrepreneurship-related infrastructure, require the engagement of a broad range of Regional stakeholders and resources. Therefore through appropriate FFOs, EDA will seek to advance interagency coordination by funding Projects that demonstrate effective leveraging of other Federal Agency resources based on a Region's strategic economic development goals and needs. For all types of Projects, EDA assistance may not be used to provide direct venture capital to a for-profit entity because of the restrictions set out in section 217 of PWEDA (42 U.S.C. 3154c) and part 309 of this chapter. Nonetheless, EDA may consider an application more competitive if it includes measures to address the need to provide entrepreneurs with access to early stage capital outside of the proposed EDA Project budget. *See* § 301.8(b).

PART 302—GENERAL TERMS AND CONDITIONS FOR INVESTMENT ASSISTANCE

15. The authority citation for part 302 continues to read as follows:

Authority: 19 U.S.C. 2341 *et seq.;* 42 U.S.C. 3150; 42 U.S.C. 3152; 42 U.S.C. 3153; 42 U.S.C. 3192; 42 U.S.C. 3193; 42 U.S.C. 3194; 42 U.S.C. 3211; 42 U.S.C. 3212; 42 U.S.C. 3216; 42 U.S.C. 3218; 42 U.S.C. 3220; 42 U.S.C. 5141; Department of Commerce Delegation Order 10–4.

16. Revise § 302.1 to read as follows:

§ 302.1 Environment.

EDA will undertake environmental reviews of Projects in accordance with the requirements of the National Environmental Policy Act of 1969, as amended (Pub. L. 91–190; 42 U.S.C. 4321 *et seq.,* as implemented under 40 CFR chapter V) (''*NEPA*''), and all applicable Federal environmental statutes, regulations, and Executive Orders. These authorities include the

implementing regulations of NEPA requiring EDA to provide public notice of the availability of Project-specific environmental documents, such as environmental impact statements, environmental assessments, findings of no significant impact, and records of decision, to the affected or interested public, as specified in 40 CFR 1506.6(b). Depending on the Project's location, environmental information concerning specific Projects may be obtained from the individual serving as the Environmental Officer in the appropriate EDA regional office listed in the applicable FFO.

17. Revise the introductory text of § 302.3 to read as follows:

§ 302.3 Project servicing for loans, loan guaranties and Investment Assistance.

EDA will provide Project servicing to borrowers who received EDA loans or EDA-guaranteed loans and to lenders who received EDA loan guaranties under an EDA-administered program. Project servicing includes loans made under PWEDA prior to the effective date of the Economic Development Administration Reform Act of 1998, the Trade Act, and the Community Emergency Drought Relief Act of 1977 (Pub. L. 95–31; 42 U.S.C. 5184 note).

* * * * *

18. Revise § 302.6 to read as follows:

§ 302.6 Additional requirements; Federal policies and procedures.

Recipients are subject to all Federal laws and to Federal, Department, and EDA policies, regulations, and procedures applicable to Federal financial assistance awards, including 15 CFR part 14, the Uniform Administrative Requirements for Grants and Cooperative Agreements with Institutions of Higher Education, Hospitals, Other Non-Profit and Commercial Organizations, and 15 CFR part 24, the Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments, as applicable.

19. Revise § 302.8 to read as follows:

§ 302.8 Pre-approval Investment Assistance costs.

Project activities carried out before approval of Investment Assistance shall be carried out at the sole risk of the Eligible Applicant. Such activity is subject to the rejection of the application, the disallowance of costs, or other adverse consequences as a result of non-compliance with EDA or Federal requirements, including procurement requirements, civil rights requirements, Federal labor standards, or Federal environmental, historic preservation, and related requirements.

20. Revise § 302.9 to read as follows:

§ 302.9 Inter-governmental review of projects.

(a) When an Eligible Applicant is not a State, Indian Tribe, or other general purpose governmental authority, the Eligible Applicant must afford the appropriate general purpose local governmental authority (the ''*Authority*'') in the Region a minimum of 15 days to review and comment on a proposed Project under EDA's Public Works and Economic Development program or a proposed construction Project or RLF Grant under EDA's Economic Adjustment Assistance program. Under these programs, the Eligible Applicant shall furnish the following with its application:

(1) If no comments are received from the Authority, a statement of efforts made to obtain such comments; or

(2) If comments are received from the Authority, a copy of the comments and a statement of any actions taken to address such comments.

(b) As required by 15 CFR part 13 and Executive Order 12372, ''Intergovernmental Review of Federal Programs,'' as amended, if a State has adopted a process under Executive Order 12372 to review and coordinate proposed Federal financial assistance and direct Federal development (commonly referred to as the ''single point of contact review process''), all Eligible Applicants also must give State and local governments a reasonable opportunity to review and comment on the proposed Project, including review and comment from area-wide planning organizations in metropolitan areas, as provided for in 15 CFR part 13.

21. Revise § 302.10 to read as follows:

§ 302.10 Attorneys' and consultants' fees, employment of expediters, and post-employment restriction.

(a) *Employment of expediters.* Investment Assistance awarded under PWEDA shall not directly or indirectly reimburse any attorneys' or consultants' fees incurred in connection with obtaining Investment Assistance and contracts under PWEDA. Such Investment Assistance shall not be awarded to any Eligible Applicant, unless the owners, partners, or officers of the Eligible Applicant certify to EDA the names of any attorneys, agents, and other persons engaged by or on behalf of the Eligible Applicant for the purpose of expediting an application made to EDA in connection with obtaining Investment Assistance under PWEDA and the fees paid or to be paid to the person(s) for expediting the application.

(b) *Post-employment restriction.* (1) In general, any Eligible Applicant that is a non-profit organization, District Organization, or for-profit entity, for the two-year period beginning on the date on which the Investment Assistance under PWEDA is awarded to the Eligible Applicant, must refrain from employing, offering any office or employment to, or retaining for professional services any person who, on the date on which the Investment Assistance is awarded or within the one-year period ending on that date:

(i) Served as an officer, attorney, agent, or employee of the Department; and

(ii) Occupied a position or engaged in activities that the Assistant Secretary determines involved discretion with respect to the award of Investment Assistance under PWEDA.

(2) In addition to the types of Eligible Applicants noted in this paragraph (b), EDA may require another Eligible Applicant to execute an agreement to abide by the above-described post-employment restriction on a case-by-case basis; for example, when an institution of higher education implements activities under or related to the Investment Assistance through a separate non-profit organization or association.

22. Revise § 302.11 to read as follows:

§ 302.11 Economic development information clearinghouse.

Pursuant to section 502 of PWEDA, EDA maintains an economic development information clearinghouse on its Internet Web site at *http://www.eda.gov.*

23. Revise the heading of § 302.15 to read as follows:

§ 302.15 Acceptance of certifications made by Eligible Applicants.

* * * * *

24. Revise § 302.16 to read as follows:

§ 302.16 Accountability.

(a) *General.* Each Recipient must submit reports to EDA at intervals and in the manner that EDA shall require, except that EDA shall not require any report to be submitted more than ten years after the date of closeout of the Investment Assistance.

(b) *Data on Project effectiveness.* Each report must contain a data-specific evaluation of the effectiveness of the Investment Assistance provided in fulfilling the Project's purpose (including alleviation of economic distress and meeting Project goals) and in meeting the objectives of PWEDA. Data used by a Recipient in preparing reports shall be accurate and verifiable as determined by EDA, and from independent sources (whenever

possible). EDA will use this data and report to fulfill its performance measurement reporting requirements under the Government Performance and Results Act of 1993, as amended (Pub. L. 103–62) and to monitor internal, Investment, and Project performance through an internal performance measurement system.

(c) *Reporting Project service benefits.* To enable EDA to determine the economic development effect of a Project that provides service benefits, EDA may require the Recipient to submit a Project service map and information from which to determine whether services are provided to all segments of the Region being assisted.

(d) *Consequences for failure to undertake good faith efforts.* (1) The Recipient must undertake good faith efforts to fulfill the purpose of the Project as set out in the terms and conditions of the Investment Assistance and must report regularly on Project goals. In the event that EDA determines that the Recipient is failing to make good faith efforts to meet these goals, or otherwise is failing to meets its obligations under the Investment Assistance, EDA shall take necessary actions to protect EDA's interest in the Project, including the following:

(i) Discontinue disbursement of funds pending correction;

(ii) Suspend the Investment Assistance;

(iii) Terminate the Investment Assistance;

(iv) Require reimbursement of the EDA share of the Project; or

(v) Institute formal Government-wide debarment and suspension proceedings against the Recipient.

(2) Before making a determination under this subsection, EDA shall provide the Recipient with reasonable notice and opportunity to respond. A determination under this subsection is final and cannot be appealed.

25. Revise paragraphs (a), (b)(2), and (c)(2) and (3) of § 302.17 to read as follows:

§ 302.17 Conflicts of interest.

(a) *General.* It is EDA's and the Department's policy to maintain the highest standards of conduct to prevent conflicts of interest in connection with the award of Investment Assistance or its use for reimbursement or payment of costs (e.g., procurement of goods or services) by or to the Recipient. A conflict of interest generally exists when an Interested Party participates in a matter that has a direct and predictable effect on the Interested Party's personal or financial interests. A conflict also may exist where there is an appearance that an Interested Party's objectivity in performing his or her responsibilities under the Project is impaired. For example, an appearance of impairment of objectivity may result from an organizational conflict where, because of other activities or relationships with other persons or entities, an Interested Party is unable to render impartial assistance, services, or advice to the Recipient, a participant in the Project, or to the Federal government. Additionally, a conflict of interest may result from non-financial gain to an Interested Party, such as benefit to reputation or prestige in a professional field.

(b) * * *

(2) An Interested Party also shall not, directly or indirectly, solicit or accept any gift, gratuity, favor, entertainment, or other benefit having monetary value, for himself or herself or for another person or entity, from any person or organization which has obtained or seeks to obtain Investment Assistance from EDA.

* * * * *

(c) * * *

(2) A Recipient of an RLF Grant shall not lend RLF funds to an Interested Party; and

(3) Former board members of a Recipient of an RLF Grant and members of his or her Immediate Family shall not receive a loan from such RLF for a period of two years from the date that the board member last served on the RLF's board of directors.

26. Revise § 302.18 to read as follows:

§ 302.18 Post-approval requirements.

A Recipient must comply with all financial, performance, progress report, and other requirements set forth in the terms and conditions of the Investment Assistance, including any special award conditions and applicable Federal cost principles (collectively, ''*Post-Approval Requirements*''). A Recipient's failure to comply with Post-Approval Requirements may result in the disallowance of costs, termination of the Investment Assistance award, or other adverse consequences to the Recipient.

27. Revise paragraph (b)(1) of § 302.20 to read as follows:

§ 302.20 Civil rights.

* * * * *

(b) *Definitions.*

(1) For purposes of this section, an ''*Other Party*'' means an ''other party subject to this part,'' as defined in 15 CFR 8.3(l), and includes an entity which (or which is intended to) creates and/or saves 15 or more permanent jobs as a result of Investment Assistance; provided that such entity also is either specifically named in the application as benefiting from the Project, or is or will be located in an EDA building; port; facility; or industrial, commercial, or business park constructed or improved in whole or in part with Investment Assistance prior to EDA's final disbursement of award funds.

* * * * *

PART 303—PLANNING INVESTMENTS AND COMPREHENSIVE ECONOMIC DEVELOPMENT STRATEGIES

28. The authority citation for part 303 continues to read as follows:

Authority: 42 U.S.C. 3143; 42 U.S.C. 3162; 42 U.S.C. 3174; 42 U.S.C. 3211; Department of Commerce Organization Order 10–4.

29. Designate §§ 303.1 through 303.5 as subpart A and add a heading for subpart A to read as follows:

Subpart A—General

30. Revise the section heading and introductory text of § 303.1 to read as follows:

§ 303.1 Overview of EDA's Planning Program.

The purpose of EDA Planning Investments is to provide support to Planning Organizations for the development, implementation, revision, or replacement of Comprehensive Economic Development Strategies, and for related State plans and short-term Planning Investments designed to create and retain new and better jobs, particularly for the unemployed and underemployed in the nation's most economically distressed Regions. EDA's Planning Investments support partnerships with District Organizations, Indian Tribes, community development corporations, non-profit Regional planning organizations, and other Eligible Recipients. Planning activities supported by these Investments must be part of a continuous process involving the active participation of the private sector, public officials, non-profit organizations, educational institutions, and private citizens, and include:

* * * * *

31. Revise paragraphs (a)(5) and (c) of § 303.3 to read as follows:

§ 303.3 Application requirements and evaluation criteria.

(a) * * *

(5) Feasibility of the proposed scope of work to create and retain new and better jobs through implementation of the CEDS.

* * * * *

(c) For Planning Investment awards to a State, the Assistant Secretary also

shall consider the extent to which the State will integrate and coordinate its CEDS with local and Economic Development District plans.

* * * * *

32. Revise paragraphs (a) and (c) of § 303.4 to read as follows:

§ 303.4 Award requirements.

(a) Planning Investments shall be coordinated with and effectively leverage any other available Federal, State, or local planning assistance and private sector investments.

* * * * *

(c) EDA will provide a Planning Investment for the period of time required to develop, revise or replace, and implement a CEDS, generally in 36-month renewable Investment project periods.

33. Designate §§ 303.6 and 303.7 as subpart B and add a heading for subpart B to read as follows:

Subpart B—Partnership Planning Assistance

34. Revise § 303.6 to read as follows:

§ 303.6 Partnership Planning and the EDA-funded CEDS process.

(a) *Partnership Planning overview.* Partnership Planning Investments support a nationwide network of Planning Organizations to provide comprehensive economic development planning services to distressed Regions. EDA makes Partnership Planning Investments to enable Planning Organizations to manage and coordinate the development and implementation of CEDS to address the unique needs of their respective Regions.

(b) *CEDS process.* If EDA awards Investment Assistance to a Planning Organization to develop, revise, or replace a CEDS, the Planning Organization must follow the procedures set forth in this section:

(1) *CEDS Strategy Committee.* The Planning Organization must appoint a Strategy Committee. The Strategy Committee must represent the main economic interests of the Region, including the private sector, public officials, community leaders, private individuals, representatives of workforce development boards, institutions of higher education, minority and labor groups, and others who can contribute to and benefit from improved economic development in the relevant Region. In addition, the Strategy Committee must demonstrate the capacity to undertake a collaborative and effective planning process. The Strategy Committee representing Indian Tribes or States may vary.

(2) *Public notice and comment.* The Planning Organization must develop and submit to EDA a CEDS that complies with the requirements of § 303.7. Before submission of the CEDS to EDA, the Planning Organization must provide the public and appropriate governments and interest groups in the relevant Region with adequate notice of and opportunity to comment on the CEDS. The comment period shall be at least 30 days and the Planning Organization shall make the CEDS readily available through appropriate means of distribution, electronically and otherwise, throughout the comment period. The Planning Organization also shall make the CEDS available in hardcopy upon request. EDA may require the Planning Organization to provide any comments received and demonstrate how the comments were resolved.

(3) *Reports and updates.*

(i) After obtaining EDA approval of the CEDS, the Planning Organization must submit annually an updated CEDS performance report to EDA.

(ii) The Planning Organization must submit a new or revised CEDS to EDA at least every five years, unless EDA or the Planning Organization determines that a new or revised CEDS is required earlier due to changed circumstances.

(iii) Any updated CEDS performance report that results in a change of the requirements set forth in § 303.7(b)(1)(iii) of the EDA-accepted CEDS or any new or revised CEDS, must be available for review and comment by the public in accordance with paragraph (b)(2) of this section.

(4) *Inadequate CEDS.* If EDA determines that implementation of the CEDS is inadequate, it will notify the Planning Organization in writing and the Planning Organization shall submit to EDA a new or revised CEDS.

(5) *Regional Commission notification.* If any part of a Region is covered by one or more of the Regional Commissions as set forth in section 404 of PWEDA, the Planning Organization shall ensure that a copy of the CEDS is provided to the Regional Commission(s).

35. Revise paragraph (b) of § 303.7 to read as follows:

§ 303.7 Requirements for Comprehensive Economic Development Strategies.

* * * * *

(b) *Strategy requirements.* (1) A CEDS must be the result of a comprehensive and continuous economic development planning process, developed with broad-based and diverse public and private sector participation. Consistent with section 302 of PWEDA, each CEDS must promote Regional economic resiliency and be unique and responsive to the relevant Region. Each CEDS must include:

(i) A summary of economic development conditions of the Region;

(ii) An in-depth analysis of economic and community strengths, weaknesses, opportunities, and threats (commonly known as a ''*SWOT*'' analysis);

(iii) Strategies and an implementation plan to build upon the Region's strengths and opportunities and resolve the weaknesses and threats facing the Region, which should not be inconsistent with applicable State and local economic development or workforce development strategies; and

(iv) Performance measures used to evaluate the Planning Organization's successful development and implementation of the CEDS.

(2) EDA will publish and periodically update specific CEDS content guidelines.

* * * * *

36. Designate §§ 303.8 and 303.9 as subpart C and add a heading for subpart C to read as follows:

Subpart C—State and Short-Term Planning Assistance

37. Revise paragraphs (a) introductory text and (b) of § 303.9 to read as follows:

§ 303.9 Requirements for short-term Planning Investments.

(a) In addition to providing support for CEDS and State plans, EDA also may provide Investment Assistance to support short-term planning activities. EDA may provide such Investment Assistance to:

* * * * *

(b) Eligible activities may include updating a portion of a CEDS, economic analysis, development of economic development policies and procedures, and development of economic development goals.

* * * * *

PART 304—ECONOMIC DEVELOPMENT DISTRICTS

38. The authority citation for part 304 continues to read as follows:

Authority: 42 U.S.C. 3122; 42 U.S.C. 3171; 42 U.S.C. 3172; 42 U.S.C. 3196; Department of Commerce Organization Order 10–4.

39. Revise paragraph (a) and the introductory text to paragraph (c) of § 304.1 to read as follows:

§ 304.1 Designation of Economic Development Districts: Regional eligibility.

* * * * *

(a) Contains at least one geographic area that is subject to the economic

distress criteria set forth in § 301.3(a)(1) of this chapter and is identified in an approved CEDS;

* * * * *

(c) Has an EDA-approved CEDS that:

* * * * *

40. Revise paragraphs (c)(1), (c)(2), and (c)(4)(i) of § 304.2 to read as follows:

§ 304.2 District Organizations: Formation, organizational requirements and operations.

* * * * *

(c) *Organization and governance.*

(1) Each District Organization must meet the requirements of this paragraph (c) concerning membership composition, the maintenance of adequate staff support to perform its economic development functions, and its authorities and responsibilities for carrying out economic development functions. The District Organization's board of directors (or other governing body) also must meet these requirements.

(2) The District Organization must demonstrate that its governing body is broadly representative of the principal economic interests of the Region, including the private sector, public officials, community leaders, representatives of workforce development boards, institutions of higher education, minority and labor groups, and private individuals. In addition, the governing body must demonstrate the capacity to implement the EDA-approved CEDS.

* * * * *

(4) * * *

(i) The District Organization must hold meetings open to the public at least twice a year and also shall publish the date and agenda of such meetings sufficiently in advance to allow the public a reasonable time to prepare in order to participate effectively.

* * * * *

41. Revise paragraph (b) introductory text of § 304.3 to read as follows:

§ 304.3 District modification and termination.

* * * * *

(b) *Termination.* EDA may, upon 60 days prior written notice to the District Organization, member counties, and other areas determined by EDA and each affected State, terminate a Region's designation as an Economic Development District when:

* * * * *

42. Revise paragraphs (a) introductory text, (a)(3), and (b) of § 304.4 to read as follows:

§ 304.4 Performance evaluations.

(a) EDA shall evaluate the management standards, financial accountability and program performance of each District Organization within three years after the initial Investment award and at least once every three years thereafter, so long as the District Organization continues to receive Investment Assistance. EDA's evaluation shall assess:

* * * * *

(3) The implementation of the CEDS, including the District Organization's performance and contribution towards the retention and creation of employment, as set forth in § 303.7 of this chapter.

(b) For peer review, EDA shall ensure the participation of at least one other District Organization in the performance evaluation on a cost-reimbursement basis.

PART 305—PUBLIC WORKS AND ECONOMIC DEVELOPMENT INVESTMENTS

43. The authority citation for part 305 continues to read as follows:

Authority: 42 U.S.C. 3211; 42 U.S.C. 3141; Department of Commerce Organization Order 10–4.

44. Revise § 305.1 to read as follows:

§ 305.1 Purpose and scope.

Public Works and Economic Development Investments (''*Public Works Investments*'') intend to help the nation's most distressed communities revitalize, expand, and upgrade their physical infrastructure to attract new industry, encourage business expansion, diversify local economies, and generate or retain long-term private sector jobs and investments. The primary goal of these Investments is to create new or retain existing, long-term private sector job opportunities in communities experiencing significant economic distress as evidenced by chronic high unemployment, underemployment, low per capita income, outmigration, or a Special Need. These Investments also intend to assist communities in attracting private capital investment and new and better job opportunities and to promote the successful long-term economic recovery of a Region.

45. Revise paragraph (c) of § 305.2 to read as follows:

§ 305.2 Award requirements.

* * * * *

(c) Not more than 15 percent of the annual appropriations made available to EDA to fund Public Works Investments may be made in any one State.

46. Revise paragraphs (a) introductory text, (a)(1), and (b) of § 305.6 to read as follows:

§ 305.6 Allowable methods of procurement for construction services.

(a) Recipients shall seek EDA's prior written approval to use alternate construction procurement methods to the traditional design/bid/build procedures (including lump sum or unit price-type construction contracts). These alternate methods may include design/build, construction management at risk, and force account. If an alternate method is used, the Recipient shall submit to EDA for approval a construction services procurement plan and the Recipient must use a design professional to oversee the process. The Recipient shall submit the plan to EDA prior to advertisement for bids and shall include the following, as applicable:

(1) Justification for the proposed method for procurement of construction services, including a brief analysis of the appropriateness and benefits of using the method to successfully execute the Project and the Recipient's experience in using the method;

* * * * *

(b) For all procurement methods, the Recipient must comply with the procedures and standards set forth in 15 CFR parts 14 or 24, as applicable.

47. Revise paragraphs (a) and (c) of § 305.8 to read as follows:

§ 305.8 Recipient-furnished equipment and materials.

* * * * *

(a) EDA must approve any use of Recipient-furnished equipment and materials. EDA may require that major equipment items be subject to a lien in favor of EDA and also may require a statement from the Recipient regarding expected useful life and salvage value of such equipment;

* * * * *

(c) Acquisition of Recipient-furnished equipment or materials under this section also is subject to the requirements of 15 CFR parts 14 or 24, as applicable.

48. Revise § 305.10 to read as follows:

§ 305.10 Bid underrun and overrun.

(a) *Underrun.* If at the construction contract bid opening, the lowest responsive bid is less than the total Project cost, the Recipient shall notify EDA immediately to determine relevant procedures.

(b) *Overrun.*

(1) In the case of an overrun at the construction contract bid opening, the Recipient may:

(i) If provided for in the bid documents, take deductive alternatives

to eliminate certain Project elements in case of insufficient funds in the exact order shown on the invitation for bid until at least one of the responsive bids, less deductive alternative(s), results in a price within the budget for that item of work;

(ii) Reject all bids and re-advertise if there is a rational basis to expect that re-advertising will result in a lower bid; or

(iii) Augment the Matching Share by an amount sufficient to cover the excess cost. The Recipient must furnish a letter to EDA identifying the source of the additional funds and confirming that the Matching Share meets the requirements of § 301.5 of this chapter.

(2) If the Recipient demonstrates to EDA's satisfaction that the options listed in paragraph (b)(1) of this section are not feasible and the Project cannot be completed otherwise, the Recipient may submit a written request to EDA for additional funding in accordance with applicable EDA guidance. The award of additional Investment Assistance is at EDA's sole discretion and will be considered in accord with EDA's competitive process requirements. EDA's consideration of a request for additional Investment Assistance does not indicate approval.

PART 306—TRAINING, RESEARCH AND TECHNICAL ASSISTANCE INVESTMENTS

49. The authority citation for part 306 continues to read as follows:

Authority: 42 U.S.C. 3147; 42 U.S.C. 3196; 42 U.S.C. 3211; Department of Commerce Organization Order 10–4.

50. Revise paragraph (a) introductory text of § 306.1 to read as follows:

§ 306.1 Purpose and scope.

(a) Local and National Technical Assistance Investments may be awarded to:

* * * * *

51. Revise paragraph (a) of § 306.3 to read as follows:

§ 306.3 Application requirements.

(a) EDA will provide Investment Assistance under this subpart for the period of time required to complete the Project's scope of work, generally not to exceed 12 to 18 months.

* * * * *

52. Revise § 306.4 to read as follows:

§ 306.4 Purpose and scope.

The University Center Economic Development Program is intended to help improve the economies of distressed Regions. Institutions of higher education have many assets, such as faculty, staff, libraries, laboratories, and computer systems that can address local economic problems and opportunities. With Investment Assistance, institutions of higher education establish and operate research centers (''*University Centers*'') that provide technical assistance to public and private sector organizations with the goal of enhancing local economic development.

53. Revise paragraph (d) of § 306.6 to read as follows:

§ 306.6 Application requirements.

* * * * *

(d) At least 80 percent of EDA funding must be allocated to direct costs of program delivery.

54. Revise paragraphs (a)(1) and (c) of § 306.7 to read as follows:

§ 306.7 Performance evaluations of University Centers.

(a) * * *

(1) Evaluate each University Center within three years after the initial Investment award and at least once every three years thereafter, so long as such University Center continues to receive Investment Assistance; and

* * * * *

(c) For peer review, EDA shall ensure the participation of at least one other University Center in the performance evaluation on a cost-reimbursement basis.

PART 307—ECONOMIC ADJUSTMENT ASSISTANCE INVESTMENTS

55. The authority citation of part 307 continues to read as follows:

Authority: 42 U.S.C. 3211; 42 U.S.C. 3149; 42 U.S.C. 3161; 42 U.S.C. 3162; 42 U.S.C. 3233; Department of Commerce Organization Order 10–4.

56. Revise the introductory text and paragraph (b) of § 307.1 to read as follows:

§ 307.1 Purpose.

The purpose of Economic Adjustment Assistance Investments is to address the needs of communities experiencing adverse economic changes that may occur suddenly or over time, including those caused by:

* * * * *

(b) Federally Declared Disasters;

* * * * *

57. Revise paragraph (b)(2) of § 307.3 as follows:

§ 307.3 Use of Economic Adjustment Assistance Investments.

* * * * *

(b) * * *

(2) Provision of business or infrastructure financing through the capitalization of Recipient-administered Revolving Loan Funds (''*RLFs*''), which may include loans and interest rate buy-downs to facilitate business lending activities;

* * * * *

58. Amend § 307.4 to:

a. Revise paragraphs (a), (b), (c)(2), and (d); and

b. Add paragraph (c)(3) to read as follows:

§ 307.4 Award requirements.

(a) *General.* EDA will select Economic Adjustment Assistance Projects in accordance with part 301 of this chapter and the additional criteria provided in paragraphs (b), (c), and (d) of this section, as applicable. Funding priority considerations for Economic Adjustment Assistance, including RLF Grants, may be set forth in an FFO.

(b) *Strategy Grants.* EDA will review Strategy Grant applications to ensure that the proposed activities conform to the CEDS requirements set forth in § 303.7 of this chapter. Strategy Grants shall comply with the applicable provisions of part 303 of this chapter.

(c) * * *

(2) Implementation Grants involving construction shall comply with the provisions of subpart B of part 305 of this chapter.

(3) Implementation Grants that do not involve construction shall comply with the applicable provisions of subpart A of part 306 of this chapter.

(d) *See* § 307.7 for RLF award requirements.

§ 307.6 [Removed]

59. Remove § 307.6.

60. Revise the heading of subpart B to read as follows:

Subpart B—Revolving Loan Fund Program

61. Redesignate § 307.7 as § 307.6 and revise newly redesignated § 307.6 to read as follows:

§ 307.6 Revolving Loan Funds established for business lending.

Economic Adjustment Assistance Grants to capitalize or recapitalize RLFs most commonly fund business lending, but also may fund public infrastructure or other authorized lending activities. The requirements in this subpart B apply to RLFs established for business lending activities. Special award conditions may contain appropriate modifications of these requirements to accommodate non-business RLF awards.

62. Add § 307.7 to read as follows:

§ 307.7 Revolving Loan Fund award requirements.

(a) For Eligible Applicants seeking to capitalize or recapitalize an RLF, EDA will review applications for the following, as applicable:

(1) Need for a new or expanded public financing tool to:

(i) Enhance other business assistance programs and services targeting economic sectors and locations described in the CEDS; or

(ii) Provide appropriate support for post-disaster economic recovery efforts in Presidentially Declared Disaster areas;

(2) Types of financing activities anticipated; and

(3) Capacity of the RLF organization to manage lending activities, create networks between the business community and other financial providers, and implement the CEDS.

(b) RLF Grants shall comply with the requirements set forth in this part and in the following publications:

(1) EDA's RLF Standard Terms and Conditions; and

(2) The Compliance Supplement to OMB Circular A–133. The Compliance Supplement is available via the Internet at *http://www.omb.gov.*

63. Revise paragraphs (a)(2), (b)(2)(ii), (b)(3), (c)(1), and (c)(2) of § 307.9 to read as follows:

§ 307.9 Revolving Loan Fund Plan.

* * * * *

(a) * * *

(2) Part II of the Plan titled ''Operational Procedures'' must serve as the RLF Recipient's internal operating manual and set out administrative procedures for operating the RLF consistent with ''Prudent Lending Practices,'' as defined in § 307.8, the RLF Recipient's environmental review and compliance procedures as set out in § 307.10, and EDA's conflicts of interest rules set out in § 302.17 of this chapter.

(b) * * *

(2) * * *

(ii) Financing policies and portfolio standards that are consistent with EDA's policies and requirements; and

(3) The Plan must demonstrate an adequate understanding of commercial loan portfolio management procedures, including loan processing, underwriting, closing, disbursements, collections, monitoring, and foreclosures. It also shall provide sufficient administrative procedures to prevent conflicts of interest and to ensure accountability, safeguarding of assets, and compliance with Federal and local laws.

(c) * * *

(1) An RLF Recipient must update its Plan as necessary in accordance with changing economic conditions in the Region; however, at a minimum, an RLF Recipient must submit an updated Plan to EDA every five years.

(2) An RLF Recipient must notify EDA of any change(s) to its Plan. Any material modification, such as a merger, consolidation, or change in the EDA-approved lending area under § 307.18, a change in critical management staff, or a change to the strategic purpose of the RLF, must be submitted to EDA for approval prior to any revision of the Plan. If EDA approves the modification, the RLF Recipient must submit an updated Plan to EDA in electronic format, unless EDA approves a paper submission.

64. Revise paragraphs (a) and (b) of § 307.10 to read as follows:

§ 307.10 Pre-loan requirements.

(a) RLF Recipients must adopt procedures to review the impacts of prospective loan proposals on the physical environment. The Plan must provide for compliance with applicable environmental laws and other regulations, including parts 302 and 314 of this chapter. The RLF Recipient also must adopt procedures to comply, and ensure that potential borrowers comply, with applicable environmental laws and regulations.

(b) RLF Recipients must ensure that prospective borrowers, consultants, or contractors are aware of and comply with the Federal statutory and regulatory requirements that apply to activities carried out with RLF loans. Accordingly, RLF loan agreements shall include applicable Federal requirements to ensure compliance and RLF Recipients must adopt procedures to diligently correct instances of non-compliance, including loan call stipulations.

* * * * *

65. Revise paragraphs (b), (d), (e), and (f)(2) of § 307.11 to read as follows:

§ 307.11 Disbursement of funds to Revolving Loan Funds.

* * * * *

(b) *Timing of request for disbursements.* An RLF Recipient shall request disbursements of Grant funds only to close a loan or disburse RLF funds to a borrower. The RLF Recipient must disburse the RLF funds to a borrower within 30 days of receipt of the Grant funds. Any Grant funds not disbursed within the 30 day period shall be refunded to EDA pursuant to paragraph (e) of this section.

* * * * *

(d) *Interest-bearing account.* All grant funds disbursed by EDA to the RLF Recipient for loan obligations incurred but not yet disbursed to an eligible RLF borrower must be deposited and held in an interest-bearing account by the Recipient until an RLF loan is made to a borrower.

(e) *Delays.* If the RLF Recipient receives Grant funds and the RLF loan disbursement is subsequently delayed beyond 30 days, the RLF Recipient must notify the applicable grants officer and return such non-disbursed funds to EDA. Grant funds returned to EDA shall be available to the RLF Recipient for future draw-downs. When returning prematurely drawn Grant funds, the RLF Recipient must clearly identify on the face of the check or in the written notification to the applicable grants officer ''EDA,'' the Grant award number, the words ''Premature Draw,'' and a brief description of the reason for returning the Grant funds.

(f) * * *

(2) When an RLF has a combination of In-Kind Contributions and cash Local Share, the cash Local Share and the Grant funds will be disbursed proportionately as needed for lending activities, provided that the last 20 percent of the Grant funds may not be disbursed until all cash Local Share has been expended. The full amount of the cash Local Share shall remain for use in the RLF.

66. Revise paragraphs (a)(1), (a)(2), and (b) introductory text of § 307.12 to read as follows:

§ 307.12 Revolving Loan Fund Income.

(a) * * *

(1) Such RLF Income and the administrative costs are incurred in the same six-month Reporting Period;

(2) RLF Income that is not used for administrative costs during the six-month Reporting Period is made available for lending activities;

* * * * *

(b) *Compliance guidance.* When charging costs against RLF Income, RLF Recipients must comply with applicable Federal cost principles and audit requirements as found in:

* * * * *

67. Revise paragraphs (a) introductory text, (b)(2), and (b)(3) of § 307.13 to read as follows:

§ 307.13 Records and retention.

(a) *Closed Loan files and related documents.* The RLF Recipient shall maintain Closed Loan files and all related documents, books of account, computer data files, and other records over the term of the Closed Loan and for a three-year period from the date of final disposition of such Closed Loan. The

date of final disposition of a Closed Loan is the date:

* * * * *

(b) * * *

(2) Retain records of administrative expenses incurred for activities and equipment relating to the operation of the RLF for three years from the actual submission date of the last semi-annual report that covers the Reporting Period in which such costs were claimed.

(3) Make available for inspection retained records, including those retained for longer than the required period. The record retention periods described in this section are minimum periods and such prescription does not limit any other record retention requirement of law or agreement. In no event will EDA question claimed administrative costs that are more than three years old, unless fraud is at issue.

68. Revise paragraph (c) of § 307.14 to read as follows:

§ 307.14 Revolving Loan Fund semi-annual report and Income and Expense Statement.

* * * * *

(c) *RLF Income and Expense Statement.* An RLF Recipient using either 50 percent or more (or more than $100,000) of RLF Income for administrative costs in a six-month Reporting Period must submit to EDA a completed Income and Expense Statement (Form ED–209I or any successor form) for that Reporting Period in electronic format, unless EDA approves a paper submission. EDA may waive this requirement for an RLF Grant with a small RLF Capital base, as determined by EDA.

69. Revise paragraphs (b)(1), (c)(1), (c)(2), and (d)(1) introductory text, and (d)(1)(iii) of § 307.15 to read as follows:

§ 307.15 Prudent management of Revolving Loan Funds.

* * * * *

(b) * * *

(1) Within 60 days prior to the initial disbursement of EDA funds, a qualified independent accountant who preferably has audited the RLF Recipient in accordance with OMB Circular A–133 requirements, shall certify to EDA and the RLF Recipient that such system is adequate to identify, safeguard, and account for all RLF Capital, outstanding RLF loans, and other RLF operations.

* * * * *

(c) * * *

(1) *General rule.* An RLF Recipient may make loans to eligible borrowers at interest rates and under conditions determined by the RLF Recipient to be appropriate in achieving the goals of the RLF. The minimum interest rate an RLF Recipient may charge is four percentage points below the lesser of the current money center prime interest rate quoted in the *Wall Street Journal,* or the maximum interest rate allowed under State law. In no event shall the interest rate be less than the lower of four percent or 75 percent of the prime interest rate listed in the *Wall Street Journal.*

(2) *Exception.* Should the prime interest rate listed in the *Wall Street Journal* exceed 14 percent, the minimum RLF interest rate is not required to be raised above 10 percent if doing so compromises the ability of the RLF Recipient to implement its financing strategy.

(d) * * *

(1) RLF loans must leverage private investment of at least two dollars for every one dollar of such RLF loans. This leveraging requirement applies to the RLF portfolio as a whole rather than to individual loans and is effective for the duration of the RLF's operation. To be classified as leveraged, private investment must be made within 12 months of approval of an RLF loan, as part of the same business development project, and may include:

* * * * *

(iii) The non-guaranteed portions and 90 percent of the guaranteed portions of a Federal loan, including the U.S. Small Business Administration's 7(A) loans and 504 debenture loans and U.S. Department of Agriculture loans.

* * * * *

70. Revise paragraphs (a)(1), (a)(2)(i), (c)(1), (c)(2)(i), (d)(1) introductory text, and (d)(1)(i) of § 307.16 to read as follows:

§ 307.16 Effective utilization of Revolving Loan Funds.

(a) * * *

(1) RLF loan activity must be sufficient to draw down Grant funds in accordance with the schedule prescribed in the award conditions for loan closings and disbursements to eligible RLF borrowers. The schedule usually requires that the RLF Recipient lend the entire amount of the initial RLF Capital base within three years of the Grant award.

(2) * * *

(i) Closed Loans approved prior to the schedule deadline will commence and complete disbursements within 45 days of the deadline;

* * * * *

(c) * * *

(1) During the Revolving Phase, RLF Recipients must manage their repayment and lending schedules to provide that at all times at least 75 percent of the RLF Capital is loaned or committed, except that EDA may require an RLF Recipient with an RLF Capital base in excess of $4 million to adopt a Plan that maintains a proportionately higher percentage of its funds loaned.

(2) * * *

(i) *Sequestration of excess funds.* If the RLF Recipient fails to satisfy the capital utilization standard for two consecutive Reporting Periods, EDA may require the RLF Recipient to deposit excess funds in an interest-bearing account. The portion of interest earned on the account holding excess funds attributable to the Federal Share (as defined in § 314.5 of this chapter) of the RLF Grant shall be remitted to the U.S. Treasury. The RLF Recipient must obtain EDA's written authorization to withdraw any sequestered funds.

* * * * *

(d) * * *

(1) EDA shall monitor the RLF Recipient's loan default rate to ensure proper protection of the Federal Share of the RLF property, and request information from the RLF Recipient as necessary to determine whether it is collecting loan repayments and complying with the financial obligations under the RLF Grant. Such information may include:

(i) A written analysis of the RLF Recipient's portfolio, which shall consider the Recipient's RLF Plan, loan and collateral policies, loan servicing and collection policies and procedures, the rate of growth of the RLF Capital base, and

* * * * *

71. Revise paragraphs (b)(6)(ii) and (c) of § 307.17 to read as follows:

§ 307.17 Uses of capital.

* * * * *

(b) * * *

(6) * * *

(ii) RLF Capital will finance the purchase of the rights of a prior lien holder during a foreclosure action which is necessary to preclude a significant loss on an RLF loan. RLF Capital may be used for this purpose only if there is a high probability of receiving compensation from the sale of assets sufficient to cover an RLF's costs plus a reasonable portion of the outstanding RLF loan within a reasonable period of time, as determined by EDA, following the date of refinancing.

(c) *Compliance and Loan Quality Review.* To ensure that the RLF Recipient makes eligible RLF loans consistent with its RLF Plan or such other purposes approved by EDA, EDA

may require an independent third party to conduct a compliance and loan quality review for the RLF Grant every three years. The RLF Recipient may undertake this review as an administrative cost associated with the RLF's operations provided the requirements set forth in § 307.12 are satisfied.

* * * * *

72. Amend § 307.18 to revise the section heading, the heading of paragraph (b), and paragraphs (a)(1), (b)(1) introductory text, (b)(1)(ii), (b)(1)(iii), and (b)(2) introductory text to read as follows:

§ 307.18 Addition of lending areas; consolidation and merger of RLFs.

(a)(1) *Addition of lending areas.* An RLF Recipient shall make loans only within its EDA-approved lending area, as set forth and defined in the RLF Grant and the Plan. An RLF Recipient may add a lending area (an ''*Additional Lending Area''*) to its existing lending area to create a new merged lending area (the ''*New Lending Area''*) only with EDA's prior written approval and subject to the following provisions and conditions:

(i) The Additional Lending Area must meet the economic distress criteria for Economic Adjustment Assistance Investments under this part and in accordance with § 301.3(a) of this chapter;

(ii) Prior to EDA's disbursement of additional funds to the RLF Recipient (for example, through a recapitalization), EDA shall determine a new Investment Rate for the New Lending Area based on the criteria set forth in § 301.4 of this chapter;

(iii) The RLF Recipient must demonstrate that the Additional Lending Area is consistent with its CEDS, or modify its CEDS for any such Additional Lending Area, in accordance with § 307.9(b)(1);

(iv) The RLF Recipient shall modify its Plan to incorporate the Additional Lending Area and revise its lending strategy, as necessary;

(v) The RLF Recipient shall execute an amended financial assistance award, as necessary; and

(vi) The RLF Recipient fulfills any other conditions reasonably requested by EDA.

* * * * *

(b) *Consolidation and merger of RLFs—*

(1) *Single RLF Recipient.* An RLF Recipient with more than one EDA-funded RLF Grant may consolidate two or more EDA-funded RLFs into one surviving RLF with EDA's prior written approval and provided:

* * * * *

(ii) It demonstrates a rational basis for undertaking the consolidation (for example, the lending area(s) and borrower criteria identified in different RLF Plans are compatible, or will be compatible, for all RLFs to be consolidated);

(iii) It amends and consolidates its Plan to account for the consolidation of RLFs, including items such as the New Lending Area (including any Additional Lending Area(s)), its lending strategy, and borrower criteria;

* * * * *

(2) *Multiple RLF Recipients.* Two or more RLF Recipients may merge their EDA-funded RLFs into one surviving RLF with EDA's prior written approval and provided:

* * * * *

73. Amend § 307.19 to remove paragraph (b), redesignate paragraphs (c) and (d) as paragraphs (b) and (c), and revise newly designated paragraph (c) to read as follows:

§ 307.19 RLF loan portfolio Sales and Securitizations.

* * * * *

(c) Except as provided in paragraph (b), no provision of this section supersedes or otherwise affects the application of the ''securities laws'' (as such term is defined in section 3(a)(47) of the Exchange Act) or the rules, regulations or orders issued by the Commission or a self-regulatory organization under the Commission.

74. Revise paragraphs (a) introductory text, (a)(1), (a)(2), and (c)(3) of § 307.20 to read as follows:

§ 307.20 Partial liquidation; liquidation upon termination.

(a) *Partial liquidation or disallowance of a portion of an RLF Grant.* If the RLF Recipient engages in certain problematic practices, EDA may disallow a corresponding proportion of the Grant or direct the RLF Recipient to transfer loans to an RLF Third Party for liquidation. Problematic practices for which EDA may disallow a portion of an RLF Grant and recover the pro-rata Federal Share (as defined in § 314.5 of this chapter) include the RLF Recipient:

(1) Having RLF loans that are more than 120 days delinquent;

(2) Having excess cash sequestered for 12 months or longer and EDA has not approved an extension request;

* * * * *

(c) * * *

(3) EDA may enter into an agreement with the RLF Third Party to liquidate the assets of one or more RLFs or RLF Recipients;

* * * * *

75. Revise paragraphs (a)(1) introductory text and (a)(1)(viii) of § 307.21 to read as follows:

§ 307.21 Termination of Revolving Loan Funds.

(a)(1) EDA may suspend or terminate an RLF Grant for cause, including the RLF Recipient's failure to:

* * * * *

(viii) Comply with the audit requirements set forth in OMB Circular A–133 and the related Compliance Supplement, including reference to the correctly valued EDA RLF Federal expenditures in the Schedule of Expenditures of Federal Awards (''*SEFA''*), timely submission of audit reports to the Federal Audit Clearinghouse, and the correct designation of the RLF as a ''major program'' (as that term is defined in OMB Circular A–133);

* * * * *

PART 308—PERFORMANCE INCENTIVES

76. The authority citation for part 308 continues to read as follows:

Authority: 42 U.S.C. 3151; 42 U.S.C. 3154a; 42 U.S.C. 3154b; Department of Commerce Delegation Order 10–4.

77. Revise paragraphs (a), (b) introductory text, (c), and (d) of § 308.2 to read as follows:

§ 308.2 Performance awards.

(a) A Recipient of Investment Assistance under parts 305 or 307 of this chapter may receive a performance award in connection with an Investment made on or after the date of enactment of section 215 of PWEDA in an amount not to exceed 10 percent of the amount of the Investment award.

(b) To receive a performance award, a Recipient must demonstrate Project performance in one or more of the areas listed in this paragraph, weighted at the discretion of the Assistant Secretary:

* * * * *

(c) A Recipient may receive a performance award no later than three years following the Project's closeout.

(d) A performance award may fund up to 100 percent of the cost of an eligible Project or any other authorized activity under PWEDA. For the purpose of meeting the non-Federal share requirement of PWEDA or any other statute, the amount of a performance award shall be treated as non-Federal funds.

* * * * *

78. Revise paragraphs (a) introductory text, (a)(2), (a)(3), and (b) of § 308.3 to read as follows:

§ 308.3 Planning performance awards.

(a) A Recipient of Investment Assistance awarded on or after the date of enactment of section 216 of PWEDA for a Project located in an EDA-funded Economic Development District may, at the discretion of the Assistant Secretary, receive a planning performance award in an amount not to exceed five percent of the amount of the applicable Investment award if EDA determines before closeout of the Project that:

* * * * *

(2) The Project demonstrated exceptional fulfillment of one or more components of, and is otherwise in accordance with, the applicable CEDS, including any job creation or job retention requirements; and

(3) The Recipient demonstrated exceptional collaboration with Federal, State, and local economic development entities throughout the development of the Project.

(b) The Recipient shall use the planning performance award to increase, up to 100 percent, the Federal share of the cost of a Project under this chapter.

* * * * *

PART 310—SPECIAL IMPACT AREAS

79. The authority citation for part 310 continues to read as follows:

Authority: 42 U.S.C. 3154; Department of Commerce Organization Order 10–4.

80. Revise the introductory text of § 310.1 to read as follows:

§ 310.1 Special Impact Area.

Upon the application of an Eligible Applicant, and with respect to that Eligible Applicant's Project only, the Assistant Secretary may designate the Region which the Project will serve as a Special Impact Area if the Eligible Applicant demonstrates that its proposed Project will:

* * * * *

81. Revise paragraphs (a)(6), (b), and (c) introductory text of § 310.2 to read as follows:

§ 310.2 Pressing need; alleviation of unemployment or underemployment.

(a) * * *

(6) Has been designated as a Federally Declared Disaster area; or

* * * * *

(b) For purposes of this part, excessive unemployment exists if the 24-month unemployment rate is at least 225 percent of the national average or the per capita income is not more than 50 percent of the national average. A Region demonstrates excessive underemployment if the employment of a substantial percentage of workers in the Region is less than full-time or at less skilled tasks than their training or abilities would otherwise permit. Eligible Applicants seeking a Special Impact Area designation under this criterion must present appropriate and compelling economic and demographic data.

(c) Eligible Applicants may demonstrate the provision of useful employment opportunities by quantifying and evidencing the Project's prospective:

* * * * *

82. Revise the heading of reserved part 311 to read as follows:

PART 311—AMERICA COMPETES [RESERVED]

PART 314—PROPERTY

83. The authority citation for part 314 continues to read as follows:

Authority: 42 U.S.C. 3211; Department of Commerce Organization Order 10–4.

84. Amend part 314 so that §§ 314.1 through 314.6 are no longer designated as subpart A. and remove the heading ''Subpart A—General.''

85. Revise the definition of *Real Property* in § 314.1 to read as follows:

§ 314.1 Definitions.

* * * * *

Real Property means any land, whether raw or improved, and includes structures, fixtures, appurtenances, and other permanent improvements, excluding moveable machinery and equipment. Real Property includes land that is improved by the construction of Project infrastructure such as roads, sewers, and water lines that are not situated on or under the land, where the infrastructure contributes to the value of such land as a specific purpose of the Project.

* * * * *

86. Revise paragraphs (a), (b), and (c) of § 314.3 to read as follows:

§ 314.3 Authorized Use of Property.

(a) During the Estimated Useful Life of the Project, the Recipient or Owner must use any Property acquired or improved in whole or in part with Investment Assistance only for authorized Project purposes as set out in the terms and conditions of the Investment Assistance. Such Property must not be Disposed of or encumbered without EDA's prior written authorization.

(b) Where EDA and the Recipient determine during the Estimated Useful Life of the Project that Property acquired or improved in whole or in part with Investment Assistance is no longer needed for the original purpose of the Investment Assistance, EDA, in its sole discretion, may approve the use of such Property in other Federal grant programs or in programs that have purposes consistent with those authorized by PWEDA and by this chapter.

(c) Where EDA determines that the authorized purpose of the Investment Assistance is to develop Real Property to be leased or sold, such sale or lease is permitted provided it is for Adequate Consideration and the sale is consistent with the authorized purpose of the Investment Assistance and with all applicable Investment Assistance requirements, including nondiscrimination and environmental compliance.

* * * * *

87. Revise paragraph (c) of § 314.4 to read as follows:

§ 314.4 Unauthorized Use of Property.

* * * * *

(c) Where the Disposition, encumbrance, or use of any Property violates paragraphs (a) or (b) of this section, EDA may assert its interest in the Property to recover the Federal Share for the Federal government and may take such actions as authorized by PWEDA and this chapter, including the actions provided in §§ 302.3, 302.16, and 307.21 of this chapter. EDA may pursue its rights under paragraph (a) of this section and this paragraph (c) to recover the Federal Share, plus costs and interest. When the Federal government is fully compensated for the Federal Share, the Federal Interest is extinguished as provided in § 314.2(b), and EDA will have no further interest in the ownership, use, or Disposition of the Property.

88. Revise paragraph (b) of § 314.5 to read as follows:

§ 314.5 Federal Share.

* * * * *

(b) The Federal Share excludes that portion of the current fair market value of the Property attributable to acquisition or improvements before or after EDA's participation in the Project, which are not included in the total Project costs. For example, if the total Project costs are $100, consisting of $50 of Investment Assistance and $50 of Matching Share, the Federal Share is 50 percent. If the Property is disposed of when its current fair market is $250, the Federal Share is $125 (i.e., 50 percent of

$250). If $10 is spent to put the Property into salable condition, the Federal Share is $120 (i.e., 50 percent of ($250 − $10)).

89. Revise paragraph (b) of § 314.6 to read as follows:

§ 314.6 Encumbrances.

* * * * *

(b) *Exceptions.* Subject to EDA's approval, which will not be unreasonably withheld or unduly delayed, paragraph (a) of this section does not apply in the following circumstances:

(1) *Shared first lien position.* EDA, at its discretion, may approve an encumbrance on Project Property where a lien holder and EDA enter into an inter-creditor agreement pursuant to which EDA and the other lien holder share a first lien position on terms satisfactory to EDA.

(2) *Utility encumbrances.* Encumbrances arising solely from the requirements of a pre-existing water or sewer facility or other utility encumbrances, which by their terms extend to additional Property connected to such facilities.

(3) *Pre-existing encumbrances.* Encumbrances already in place at the time EDA approves the Project, where EDA determines that the requirements of § 314.7(b) of this chapter are met.

(4) *Encumbrances proposed proximate to Project approval.* Encumbrances required to secure debt, including time and maturity-limited debt, that finances the Project Property at the same proximate time that EDA approves the Project when all of the following are met:

(i) EDA, in its sole discretion, determines that there is good cause and legal authority to waive paragraph (a) of this section;

(ii) All proceeds secured by the encumbrance on the Property shall be available only to the Recipient and shall be used only for the Project for which the Investment Assistance applies, for related activities of which the Project is an essential part, or other activities that EDA determines are authorized under PWEDA;

(iii) A grantor or lender will not provide funds without the security of a lien on the Property;

(iv) The terms and conditions of the encumbrance are satisfactory to EDA; and

(v) There is a reasonable expectation, as determined by EDA, that the Recipient will not default on its obligations. In determining whether an expectation is reasonable for purposes of this paragraph, EDA shall take into account whether:

(A) A Recipient that is a non-profit organization is joined in the Project with a co-Recipient that is a public body and all co-Recipients are jointly and severally responsible;

(B) The non-profit organization is financially strong and is an established organization with sufficient organizational life to demonstrate stability over time;

(C) The approximate value of the Project Property so that the total amount of all debt plus the Federal share of cost as reflected on the EDA Investment award, and any amendments as applicable, does not exceed the value of the Project Property as improved; and

(D) Such other factors as EDA deems appropriate.

(5) *Encumbrances proposed after Project approval.* Encumbrances proposed to be incurred after Project approval where all of the following are met:

(i) EDA, in its sole discretion, determines that there is good cause and legal authority to waive paragraph (a) of this section;

(ii) All proceeds secured by the encumbrance on the Property shall be available only to the Recipient and shall be used only for the Project for which the Investment Assistance applies, for related activities of which the Project is an essential part, or other activities that EDA determines are authorized under PWEDA;

(iii) A grantor or lender will not provide funds without the security of a lien on the Property;

(iv) The terms and conditions of the encumbrance are satisfactory to EDA; and

(v) There is a reasonable expectation, as determined by EDA, that the Recipient will not default on its obligations. In determining whether an expectation is reasonable for purposes of this paragraph, EDA shall take into account whether:

(A) A Recipient that is a non-profit organization is joined in the Project with a co-Recipient that is a public body and all co-Recipients are jointly and severally responsible;

(B) The non-profit organization is financially strong and is an established organization with sufficient organizational life to demonstrate stability over time;

(C) The Recipient's equity in the Project Property based on the appraised value of the Project Property at the time the encumbrance is requested so that the total amount of all debt plus the Federal share of cost as reflected on the EDA Investment award, and any amendments as applicable, does not exceed the value of the Project Property as improved; and

(D) Such other factors as EDA deems appropriate.

* * * * *

90. Amend part 314 so that §§ 314.7 and 314.8 are no longer designated as subpart B, and remove the heading ''Subpart B—Real Property.''

91. Amend § 314.7 to:

a. Revise paragraph (a), the heading of (b), paragraphs (b)(1) introductory text, (c)(1) introductory text, (c)(2) introductory text, (c)(3), (c)(4) introductory text, and (c)(5); and

b. Remove paragraph (c)(6) to read as follows:

§ 314.7 Title.

(a) *General title requirement.* The Recipient must hold title to the Real Property required for a Project at the time the Investment Assistance is awarded or as provided by paragraph (c) of this section and must maintain title at all times during the Estimated Useful Life of the Project, except in those limited circumstances as provided in paragraph (c) of this section. The Recipient also must furnish evidence, satisfactory in form and substance to EDA, that title to Real Property required for a Project (other than property of the United States) is vested in the Recipient and that any easements, rights-of-way, State or local government permits, long-term leases, or other items required for the Project have been or will be obtained by the Recipient within an acceptable time, as determined by EDA.

(b) *Disclosure of encumbrances.*

(1) The Recipient must disclose to EDA all encumbrances, including the following:

* * * * *

(c) * * *

(1) *Real Property acquisition.* Where the acquisition of Real Property required for a Project is contemplated as part of an Investment Assistance award, EDA may determine that an agreement for the Recipient to purchase the Real Property will be acceptable for purposes of paragraph (a) of this section if:

* * * * *

(2) *Leasehold interests.* EDA may determine that a long-term leasehold interest for a period not less than the Estimated Useful Life of the Real Property required for a Project will be acceptable for purposes of paragraph (a) of this section if:

* * * * *

(3) *Railroad right-of-way construction.* When a Project includes construction within a railroad's right-of-way or over a railroad crossing, EDA may find it acceptable for the work to be completed

by the railroad and for the railroad to continue to own, operate, and maintain that portion of the Project, if required by the railroad; and provided that, the construction is a minor but essential component of the Project.

(4) *Public highway construction.* When the Project includes construction on a public highway the owner of which is not the Recipient, EDA may allow the Project to be constructed in whole or in part in the right-of-way of such public highway, provided that:

* * * * *

(5) *Construction of Recipient-owned facilities to serve Recipient or privately owned Real Property.*

(i) *General.* At EDA's discretion, when an authorized purpose of the Project is to construct Recipient-owned facilities to serve Recipient or privately owned Real Property, including industrial or commercial parks, for sale or lease to private parties, such ownership, sale, or lease, as applicable, is permitted so long as:

(A) In cases where an authorized purpose of the Project is to sell Real Property, the Recipient or Owner, as applicable, provides evidence sufficient to EDA that it holds title to the Real Property required for such Project prior to the disbursement of any portion of the Investment Assistance and will retain title until the sale of the Property;

(B) In cases where an authorized purpose of the Project is to lease Real Property, the Recipient or Owner, as applicable, provides evidence sufficient to EDA that it holds title to the Real Property required for such Project prior to the EDA disbursement of any portion of the Investment Assistance and will retain title for the entire Estimated Useful Life of the Project;

(C) The Recipient provides adequate assurances that the Project and the development of land and improvements on the Recipient or privately owned Real Property to be served by or that provides the economic justification for the Project will be completed according to the terms of the Investment Assistance;

(D) The sale or lease of any portion of the Project or of Real Property served by the Project or that provides the economic justification for the Project during the Project's Estimated Useful Life must be for Adequate Consideration and the terms and conditions of the Investment Assistance and the purpose(s) of the Project must continue to be fulfilled after such sale or lease; and

(E) The Recipient agrees that EDA may deem the termination, cessation, abandonment, or other failure on behalf of the Recipient, Owner, purchaser, or lessee (as the case may be) to complete the Project or the development of land and improvements on Real Property served by or that provides the economic justification for the Project by the five-year anniversary of the award date of the Investment Assistance constitutes a failure on behalf of the Recipient to use the Real Property for the economic purposes justifying the Project.

(ii) *Additional conditions on sale or lease.* EDA also may condition the sale or lease on the satisfaction by the Recipient, Owner, purchaser, or lessee (as the case may be) of any additional requirements that EDA may impose, including EDA's pre-approval of the sale or lease.

(iii) *Agreement between Recipient and Owner.* In addition to paragraphs (c)(5)(i) and (ii) of this section, when an authorized purpose of the Project is to construct facilities to serve privately owned Real Property, the Recipient and the Owner must agree to use the Real Property improved or benefited by the EDA Investment Assistance only for the authorized purposes of the Project and in a manner consistent with the terms and conditions of the EDA Investment Assistance for the Estimated Useful Life of the Project.

(iv) *Unauthorized Use and compensation of Federal Share.* EDA may deem that a violation of this paragraph (c)(5) by the Recipient, Owner, purchaser, or lessee (as the case may be) constitutes an Unauthorized Use of the Real Property and the Recipient must agree to compensate EDA for the Federal government's Federal Share of the Project in the case of such Unauthorized Use.

92. Amend § 314.8 to revise the section heading and add paragraph (d) to read as follows:

§ 314.8 Recorded statement for Real Property.

* * * * *

(d) In extraordinary circumstances and at EDA's sole discretion, EDA may choose to accept another instrument to protect EDA's interest in Project Property, such as an escrow agreement or letter of credit, provided that EDA determines such instrument is adequate and a recorded statement in accord with paragraph (a) of this section is not reasonably available. The terms and provisions of the relevant instrument shall be satisfactory to EDA in EDA's sole judgment. The costs and fees for escrow services and letters of credit shall be paid by the Recipient.

93. Amend part 314 so that § 314.9 is no longer designated as subpart C, and remove the heading ''Subpart C—Personal Property.''

94. Revise § 314.9 to read as follows:

§ 314.9 Recorded statement for Personal Property.

For all Projects which EDA determines involve the acquisition or improvement of significant items of Personal Property, including ships, machinery, equipment, removable fixtures, or structural components of buildings, the Recipient shall execute a Uniform Commercial Code Financing Statement (Form UCC–1, as provided by State law) or other statement of EDA's interest in the Personal Property, acceptable in form and substance to EDA, which statement must be perfected and placed of record in accordance with applicable law, with continuances re-filed as appropriate. Whether or not a statement is required by EDA to be recorded, the Recipient must hold title to the Personal Property acquired or improved as part of the Project, except as otherwise provided in this part.

95. Amend part 314 so that § 314.10 is no longer designated as subpart D, and remove heading ''Subpart D—Release of EDA's Property Interest.''

96. Revise § 314.10 to read as follows:

§ 314.10 Procedures for release of EDA's Property interest.

(a) *General.* As provided in § 314.2 of this chapter, the Federal Interest in Property acquired or improved with Investment Assistance extends for the duration of the Estimated Useful Life of the Project. While EDA determines the length of the Estimated Useful Life at the time of Investment award, in recent years, the length generally extends for 15 to 20 years, depending on the nature of the improvement. Prior to 1999, the Estimated Useful Life of some Projects, such as water and wastewater Projects, could extend for 40 years or more. Upon request of the Recipient, EDA will release the Federal Interest in Project Property upon expiration of the Estimated Useful Life as established in the terms and conditions of the Investment Assistance and in accord with the requirements of this section and part. This section provides procedures to govern the manner of obtaining a release of the Federal Interest.

(b) *Release of Property after the expiration of the Estimated Useful Life.* At the expiration of a Project's Estimated Useful Life and upon the written request of a Recipient, the Assistant Secretary may release the Federal Interest in Project Property if EDA determines that the Recipient has

made a good faith effort to fulfill all terms and conditions of the Investment Assistance. The determination provided for in this paragraph shall be established at the time of the Recipient's written request and shall be based, at least in part, on the facts and circumstances provided in writing by the Recipient. For a Project in which a Recorded Statement as provided for in §§ 314.8 and 314.9 of this chapter has been recorded, EDA will provide for the release by executing an instrument in recordable form. The release will terminate the Investment as of the date of its execution and satisfy the Recorded Statement.

(c) *Release prior to expiration of the Estimated Useful Life.* If the Recipient will no longer use the Project Property in accord with the requirements of the terms and conditions of the Investment within the time period of the Estimated Useful Life, EDA will determine if such use by the Recipient constitutes an Unauthorized Use of Property and require compensation for the Federal Interest as provided in § 314.4 and this part. EDA may release the Federal Interest in connection with such Property upon receipt of full payment in compensation of the Federal Interest.

(d) *Release of certain Property after 20 years.* In accord with section 601(d)(2) PWEDA, upon the request of a Recipient and before the expiration of the Estimated Useful Life of a Project that exceeds 20 years, EDA may release any Real Property or tangible Personal Property interest held by EDA, in connection with Investment Assistance after the date that is 20 years after the date on which the Investment Assistance was awarded.

(e) *Limitations and Covenant of Use.*

(1) EDA's release of the Federal Interest pursuant to this section is not automatic; it requires EDA's approval, which will not be withheld except for good cause or as otherwise required by law, as determined in EDA's sole discretion. As deemed appropriate, EDA may require the Recipient to take some action as a condition of the release.

(2) In determining whether to release the Federal Interest, EDA will review EDA's legal authority to release its interest, including governing Establishment Clause law; the Recipient's performance under and conformance with the terms and conditions of the Investment Assistance; any use of Project Property in violation of §§ 314.3 or 314.4 of this part; and other such factors as EDA deems appropriate.

(3) Notwithstanding any release of the Federal Interest under this section, a Recipient must ensure that Project Property is not used in violation of nondiscrimination requirements. *See* Department of Commerce regulations at 15 CFR part 8. Accordingly, upon the release of the Federal Interest, the Recipient must execute a covenant of use that prohibits use of Real Property or tangible Personal Property for any purpose that would violate the nondiscrimination requirements set forth in § 302.20 of this chapter.

(i) With respect to Real Property, the Recipient must record a covenant under this subsection in the jurisdiction where the Real Property is located in accordance with § 314.8.

(ii) With respect to items of tangible Personal Property, the Recipient must perfect and record a covenant under this subsection in accordance with applicable law, with continuances re-filed as appropriate, in accordance with § 314.9.

Dated: November 21, 2011.

John Fernandez,

Assistant Secretary for Economic Development, Economic Development Administration.

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 401

Medicare Program; Availability of Medicare Data for Performance Measurement; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 401

[CMS–5059–F]

RIN 0938–AQ17

Medicare Program; Availability of Medicare Data for Performance Measurement

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule implements Section 10332 of the Affordable Care Act regarding the release and use of standardized extracts of Medicare claims data for qualified entities to measure the performance of providers of services (referred to as providers) and suppliers. This rule explains how entities can become qualified by CMS to receive standardized extracts of claims data under Medicare Parts A, B, and D for the purpose of evaluation of the performance of providers and suppliers. This rule also lays out the criteria qualified entities must follow to protect the privacy of Medicare beneficiaries.

DATES: *Effective Date*: These regulations are effective January 6, 2012.

FOR FURTHER INFORMATION CONTACT: Colleen Bruce, (410) 786–5529.

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010, are collectively referred to in this final rule as the ''Affordable Care Act.'' Effective January 1, 2012, section 10332 of the Affordable Care Act would amend section 1874 of the Social Security Act (the Act) by adding a new subsection (e) requiring standardized extracts of Medicare claims data under parts A, B, and D to be made available to ''qualified entities'' for the evaluation of the performance of providers and suppliers. Qualified entities may use the information obtained under section 1874(e) of the Act for the purpose of evaluating the performance of providers and suppliers, and to generate public reports regarding such performance. Qualified entities may receive data for one or more specified geographic areas and must pay a fee equal to the cost of making the data available. Congress also required that qualified entities combine claims data from sources other than Medicare with the Medicare data when evaluating the performance of providers and suppliers.

Section 1874(e) of the Act requires potential qualified entities that wish to request data under this provision to submit an application to the Secretary that includes, among other things, a description of the methodologies that the applicant proposes to use to evaluate the performance of providers and suppliers in the geographic area(s) they select. Qualified entities generally must use standard measures for evaluating the performance of providers and suppliers unless the Secretary, in consultation with appropriate stakeholders, determines that use of alternative measures would be more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by standard measures. Reports generated by the qualified entities may only include information on individual providers and suppliers in aggregate form, that is, at the provider or supplier level, and may not be released to the public until the providers and suppliers have had an opportunity to review them and, if necessary, ask for corrections. Congress included a provision at section 1874(e)(3) of the Act to allow the Secretary to take such actions as may be necessary to protect the identity of individuals entitled to or enrolled in Medicare.

We believe the sharing of Medicare data with qualified entities through this program and the resulting reports produced by qualified entities will be an important driver of improving quality and reducing costs in Medicare, as well as for the health care system in general. Additionally, we believe this program will increase the transparency of provider and supplier performance, while ensuring beneficiary privacy.

II. Provisions of the Proposed Rule and Analysis of and Responses to Public Comments

We received approximately 100 comments from a wide variety of individuals and organizations. About half of the comments were from providers and suppliers, or organizations representing providers and suppliers. The other half of the comments were from organizations engaged in performance measurement or data aggregation that may potentially be approved to receive Medicare data as qualified entities under this program. We also received a number of comments from consumer advocacy organizations.

A. Definition, Eligibility Criteria, and Operating Requirements of Qualified Entities

Almost all of the comments were positive and praised CMS' proposals regarding how the qualified entity program would operate. Commenters also had a range of suggestions for how CMS should administer the program, including several comments on performance measurement in general. We also received numerous comments on data privacy and security, which are discussed in more detail in subsection D below.

1. Definitions

In the proposed rule, we defined a qualified entity as a public or private entity that meets two standards. The first is that the entity is qualified, as determined by the Secretary, to use claims data to evaluate the performance of providers and suppliers on measures of quality, efficiency, effectiveness, and resource use. The second is that the entity agrees to meet the requirements described in Section 1874(e) of the Social Security Act and at §§ 401.703–401.710 of the proposed rule.

Comment: We received several comments, suggestions, and questions regarding the use of the Medicare data qualified entities receive through this program. Section 1874(e)(4)(B) of the Act specifies the uses of the Medicare data. Some commenters requested that qualified entities be allowed to use the data for purposes other than performance reporting, such as internal analyses, pay-for-performance initiatives, and provider tiering; other commenters requested that CMS clarify that the data provided would be used for performance reporting only.

Response: The statute bars the re-use of the Medicare claims data provided to qualified entities under section 1874(e) of the Social Security Act (the Act). Section 1874(e)(4)(D) provides that the qualified entity ''shall only use such data, and information derived from such evaluation'' for performance reports on providers and suppliers. Additionally, the Data Use Agreement (DUA, discussed in more detail below) bars re-use of the data for other purposes; violation of the DUA may result in a qualified entity's access to data under 1874(e) of the Act being terminated. However, while the data itself and any derivative data may only be used for creating the prescribed reports, section 1874(e) does not address the use of the publically reported result. Subject to any limitations imposed by other applicable laws (for example, copyright laws), these publicly reported results

could be used by any party, including the qualified entity, for activities such as internal analyses, pay-for-performance initiatives, or provider tiering.

Qualified entities will not be allowed to do performance measurement with Medicare data alone. Section 1874(e)(4)(B)(iii) specifically provides that qualified entities must include ''claims data from sources other than claims data under this title in the evaluation of performance of providers of services and suppliers.'' We have added a definition of ''claims data from other sources'' at § 401.703(h).

We have made several technical changes to the definitions at § 401.703 to reflect the regulatory interpretation of the statutory provisions cited in the proposed rule. We have modified the definition of a qualified entity to require the entity to agree to meet the requirements in §§ 401.705–401.721 of the final rule, removing the proposed rule's reference to section 1874(e) of the Act. We have also modified the definitions of provider and supplier; specifically we have defined both terms in terms of the definitions for the identical terms at § 400.202.

We have also added a definition of clinical data. This addition is discussed in further detail below.

2. Eligibility Criteria

In determining the eligibility standards for qualified entities we sought to balance the needs to: (1) Ensure the production of timely, high quality, and actionable reports on the performance of providers and suppliers, (2) protect beneficiary privacy and security, and (3) ensure providers and suppliers have an appropriate amount of time to review the reports, appeal, and, if necessary, correct errors prior to public reporting. We therefore proposed to evaluate an organization's eligibility to serve as a qualified entity across three areas: Organizational and governance capabilities, addition of claims data from other sources, and data privacy and security.

Additionally, we proposed not to limit the number of qualified entities eligible to serve in an area. Any entity that satisfactorily meets the eligibility criteria would be able to participate in the program.

Comment: We received several comments on the eligibility criteria as a whole. Many commenters supported the proposed eligibility standards; however others said the eligibility standards were too prescriptive. Several commenters asked CMS to clarify qualified entities' ability to combine expertise across more than one entity to meet the requirements in the rule related to experience or amount of other claims data.

Response: We thank commenters for their support for the eligibility standards. While we understand that the eligibility standards necessitate that prospective qualified entities have extensive experience in performance measurement, access to data, and appropriate privacy and security protocols, we believe these standards are essential to ensure both the privacy and security of beneficiary data and the acceptance of the program by providers and suppliers.

We clarify, however, that qualified entities do not need to be composed of a single legal entity. A qualified entity applicant may contract with other entities to achieve the ability to meet the eligibility criteria. If an entity chooses to contract with one or more other entities to meet the eligibility standards, the application must be submitted by one lead entity. This lead entity must submit documentation describing the contractual relationships that exist between and among all entities applying together under the lead entity to become a qualified entity. In addition, as discussed in subsection D.1. below, contractors will be required to abide by the same privacy and security requirements as the lead entity, including signing a data use agreement prior to being given access to Medicare claims data or beneficiary information. Contractors will also be subject to CMS monitoring and their actions may result in sanctions and/or termination of the qualified entity.

We believe that requiring contractual arrangements among the members of such a group will ultimately protect both the providers and suppliers receiving reports, as well as the beneficiaries seeking to use this information to make health care decisions by ensuring that the lead entity has partners with the necessary expertise to carry out the duties of a qualified entity and that the qualified entity's partners are committed to the project through legally enforceable agreements.

In a contractual arrangement, there would be breach of contract liability if one of the members of the group fails to deliver, and there would be the potential of collecting damages for that failure to perform. Such damages would potentially provide the lead entity with the resources that would be necessary for finding and hiring another entity to carry out the functions of a contractor/subcontractor that failed to perform. Any other less formal arrangement among a group of entities that, in sum, possessed the requisite traits required of a qualified entity, such as a partnership or other consortium-like affiliation, would not offer the breach of contract protections that would provide assurances that the entities listed as participants in the group would in fact provide the services/skills/resources that the qualified entity applicant asserts. In a non-contractual arrangement, participating members of the group could stop performing at any time, leaving the remainder of the group with little recourse and, possibly, not qualified to carry on as a qualified entity. This could prevent the issuance of the desired reports. It could also leave providers and suppliers, as well as beneficiaries, without any recourse for remedying reporting errors or answering questions related to the reports. This would have a very negative effect on the program as a whole, and jeopardize this important transparency effort.

We emphasize that a single entity may seek to fulfill all of the eligibility standards; there is no requirement that a qualified entity must be a group of two or more entities. However, we believe that more potential qualified entities would apply if they use contractual relationships to address any requirements that they may be lacking.

Comment: Several commenters suggested additions to the eligibility standards. A handful of commenters recommended adding a public input component as part of the eligibility process. Commenters also suggested evaluating provider complaints against applicants when making determinations about qualified entity eligibility. One commenter asked CMS to create a provisional track for entities without the necessary experience or the non-Medicare data to serve as a qualified entity in the general program.

Response: Through evaluating each entity's (including the lead entity's and any contractors') past experience, other claims data, and privacy and security protocols, we are confident that entities approved as qualified entities will meet the requirements of the program. Extensive monitoring requirements for the lead entity and any contractors, as well as the ability to terminate our agreement with a qualified entity, will ensure that the highest standards are adhered to by all qualified entities. However, we are interested in beneficiary and/or provider complaints against a qualified entity once that entity is approved. As discussed below in section II.F., we have included an analysis of beneficiary and/or provider complaints as part of the monitoring and performance assessment of qualified entities.

While we appreciate the interest in allowing a variety of organizations to serve as qualified entities, we believe a provisional track is not consistent with the requirement in the statute that entities be qualified, as determined by the Secretary, to use claims data to evaluate provider and supplier performance. We hope that the discussion above, which notes that potential qualified entity applicants may form contractual agreements to meet the eligibility requirements, will allow entities with less experience or limited other claims data to gain the necessary expertise or gather the needed data to be approved as a qualified entities. We also have added a conditional approval process, discussed in more detail below, for those applicants that do not have access to claims data from other sources at the time of their application.

Comment: We received several comments requesting CMS limit the organizations eligible to serve as qualified entities to non-profit and government organizations. However, we also received comments asking CMS to continue to allow any organization that meets the eligibility requirements and submits an application to serve as a qualified entity.

Response: On balance, we believe it is appropriate for CMS to continue to allow any organization that meets the eligibility requirements and the requirements at sections §§ 401.703–401.710 of the proposed rule to serve as a qualified entity, which appear, as modified in the following discussion, in sections §§ 401.705–401.721 of this final rule.

Comment: While we received several comments supporting our proposal not to limit the number of qualified entities in a geographic region, we also received comments suggesting we limit the number of qualified entities eligible to serve in an area. Many of those who suggested limiting the number of qualified entities in an area expressed concern that allowing multiple qualified entities in a region would lead to multiple reports on the same provider or supplier, which would confuse both the individual or entity being measured and the consumer. One commenter suggested CMS take a phased approach to the number of qualified entities, allowing providers to get accustomed to measurement before expanding the number of qualified entities.

Response: We acknowledge commenters' desire to limit the number of reports on a provider or supplier; however, we do not anticipate many regions will have multiple entities that meet the requirements to serve as qualified entities. Specifically, it is difficult to imagine there will be many areas where multiple organizations will possess sufficient claims data from other sources. Additionally, we believe allowing all eligible organizations to serve as qualified entities will encourage innovation in measure development and performance reporting. In the case that there are multiple organizations in an area that could serve as individual qualified entities, we would like to reiterate that these organizations could form contractual arrangements with each other and apply for the program under a lead applicant.

a. Organizational and Governance Capabilities

Under organizational and governance capabilities, we proposed to evaluate the applicant's capability to perform a variety of tasks related to serving as a qualified entity. Tasks included the ability to accurately calculate measures from claims data, successfully combine claims data from different payers, design performance reports, prepare an understandable description of measures, implement a report review process for providers and suppliers, maintain a rigorous data privacy and security program, and make reports containing provider and supplier level data available to the public. We proposed to generally require applicants to demonstrate expertise and sustained experience on each of the criteria, which could be demonstrated by three or more years of experience in each area. We also proposed to consider applications with fewer years experience handling claims data and calculating measures, and/or limited experience implementing or maintaining a report review process for providers and suppliers as long as the applicant has sufficient experience in all other areas.

Comment: Commenters had mixed opinions about the proposed requirement of three or more years of experience. Commenters who did not support a minimum three years experience were concerned about limiting eligibility of otherwise viable entities. On the other hand, commenters who strongly supported the eligibility criteria suggested lengthening the time requirement to five years.

Response: While we are sensitive to the desire to allow all interested organizations to serve as qualified entities, we believe that many viable entities will possess three years of experience, particularly now that we have clarified that a qualified entity may contract with other entities in order to demonstrate required experience. It is essential for the success of the qualified entity program that organizations approved as qualified entities have the necessary expertise and experience to successfully perform all the functions required in the statute. We believe the experience requirements we have included are sufficient to ensure organizations approved as qualified entities possess the necessary experience to successfully meet the requirements of the program.

Comment: Commenters suggested changes to specific tasks in the organizational and governance capabilities section of the eligibility criteria. Several commenters asked CMS to only require expertise in the areas of measurement the entity is proposing to use instead of all four areas of measurement: Quality, efficiency, effectiveness, and resource use. Similarly, commenters also noted that not all measures require risk-adjustment and requested CMS only require experience in risk-adjustment if the entity is planning on using measures that incorporate risk-adjustment. Commenters also recommended removing the requirement that organizations have experience successfully combining claims data from different payers, arguing that this requirement would necessitate that applicants currently have data from two or more payers other than Medicare.

Response: We agree with commenters about the proposal that would have required expertise in all four areas of measurement. As a result, we are modifying the eligibility requirements related to these areas of performance measurement and will require all applicants to have experience calculating quality measures, and, to the extent that they propose using such measures, experience calculating efficiency, effectiveness and resource use measures. Similarly, we will only require entities to have experience with risk-adjustment, if they propose using measures requiring risk adjustment. Finally, the law requires that a qualified entity combine data from different payers, so we will retain that requirement in this final rule.

Comment: One commenter requested that CMS only approve applicants with a demonstrated track record of working with providers and suppliers and helping them with quality improvement.

Response: While we hope this program will support quality improvement efforts, the statute only requires qualified entities to confidentially make reports available prior to publication and to allow

providers and suppliers the opportunity to request error correction. We believe that our requirement that applicants submit documentation of experience in both maintaining a process for providers and suppliers to review their reports prior to publication, and providing timely response to requests for error correction will be adequate to ensure an applicant's ability to work with providers and suppliers to ensure the availability of reports and appropriate correction mechanisms.

Comment: We received several comments on our proposal to require applicants to disclose inappropriate disclosures of beneficiary identifiable information. Specifically, one commenter suggested that requiring disclosure of a 10-year privacy breach history is unreasonable. Another commenter requested that CMS include a requirement that applicants disclose confirmed violations of State privacy laws, in addition to inappropriate disclosures of beneficiary identifiable information.

Response: We believe that requiring an applicant to disclose 10 years' worth of inappropriate disclosures of beneficiary information is a reasonable requirement, but we recognize that some applicants may not have a 10 year history. For those entities that do not have a 10 year history, we will require reporting the required information for the length of time the organization has been in existence. We clarify, however, that a qualified entity's application to receive Medicare data will be evaluated based on all of the information submitted; a past inappropriate disclosure of beneficiary identifiable information will not automatically disqualify an entity from participation in the program. If an entity's application lists these events, CMS will engage in further discussions with that applicant to determine what corrective processes the entity has put in place to avoid future inappropriate disclosure of beneficiary identifiable information. We agree that violations of State, as well as federal, privacy and security laws should also be submitted to CMS and will add this requirement to the eligibility criteria. For clarity, we have rephrased the proposed language in § 410.705(a)(1)(vii) that referred to violations of State privacy laws or HIPAA violations to read ''violations of applicable federal and State privacy and security laws and regulations'' to encompass the full range of information privacy and security laws and regulations at both the federal and State levels with which the applicant may have to comply. In addition to demonstrating experience and expertise, we also proposed to require qualified entities to submit a business model for covering the cost of required functions.

Comment: Some commenters argued that requiring prospective applicants to submit a business model is too prescriptive, while others were supportive of this requirement. A handful of commenters asked CMS for guidance on financing mechanisms, as well as whether they could change a fee for the reports or license the data for secondary use.

Response: In requiring submission of a business model, it was not our intent to be overly prescriptive. Rather, we were seeking to ensure that the qualified entities would have the resources necessary to carry out what we expect would be a relatively resource-intensive and important undertaking. We expect that by requiring submission of a business plan qualified entities would be more likely to have a viable business model under which they would be able to carry out their obligations under the qualified entity program. We do not intend to limit an organization's ability to change or adapt its business plan once approved as a qualified entity. We only ask that the qualified entity demonstrate that it has thought through what it would need to do to succeed. Finally, as for financing mechanisms, we note that the qualified entity program regulations do not generally place any added limitations on what is otherwise feasible under applicable laws. For example, the content of the publicly released reports will be subject to existing laws on copyright. Qualified entities cannot, however, charge providers or suppliers for the confidential copies of the pre-publication reports that qualified entities are required to provide in advance of publication. Furthermore, qualified entities must publically report measure results free of charge and in a manner that is consistent with the requirements in Section 1874(e)(4)(C) of the Act. We encourage qualified entities to be innovative in creating business models to support their efforts.

b. Addition of Claims Data From Other Sources

In accordance with the statutory requirements at section 1874(e)(4)(B)(iii), we proposed to require entities to have claims data from non-title 18 (Medicare) sources to combine with Medicare data. We proposed to require possession of such other data at the time of their application. We defined claims data as administrative claims, meaning data that is not chart-abstracted data, registry data, or data from electronic health records. We proposed to require entities to demonstrate to CMS that the other claims data they possess is sufficient to address issues of sample size and reliability expressed by stakeholders regarding the calculation of performance measures from a single payer source. We also requested comment on whether CMS should require entities to possess claims data from two or more other sources to be eligible to serve as a qualified entity.

Comments: Some commenters were supportive of the requirement that entities possess claims data from other sources at the time of application, but others argued that this requirement is too restrictive and not consistent with the intent of the statute. Specifically, commenters argued that it might be difficult to acquire claims data from other sources without approval from CMS to serve as a qualified entity. Other commenters sought clarification on whether qualified entities had to physically possess claims data from other sources or whether agreements with owners of claims data from other sources and proof of a functioning distributed data approach, meaning that claims data from different sources residing at different physical locations as long as measure results could be securely and accurately aggregated, would suffice.

Response: While most organizations that are experienced in performance measurement will already have claims data they are using for performance measurement, we understand commenters' concerns about the requirement that entities possess claims data from other sources at the time of application. Therefore, for those applicants that do not have access to other claims data at the time of their application, we will create a conditional approval process. First, applicants that are found to meet all the requirements of the program, but do not have access to other claims data at the time of their application, will receive a conditional acceptance. Then, once an entity with a conditional acceptance gets access to adequate claims data from other sources, it will submit documentation that the claims data from other sources that it intends to combine with the Medicare data received under this subpart address the methodological concerns regarding sample size and reliability that have been expressed by stakeholders regarding the calculation of performance measures from a single payer source. CMS will review the documentation and if the amount of other claims data is found to be sufficient, the entity will pay a fee equal to the cost of CMS making the data

available and execute a Data Use Agreement (DUA) with CMS to be approved as a qualified entity. A conditionally approved qualified entity will not be eligible to receive Medicare claims data or the beneficiary crosswalk (discussed further in Section D.1) until it has received full approval, pays a fee equal to the cost of making the data available, and signs a DUA.

This conditional approval process will be in addition to the normal approval process that will remain in place for those applicants that have access to a sufficient amount of other claims data at the time of their application. Additionally, we want to clarify that distributed data approaches, as described above, are permissible under the scope of this program.

Comment: We received several comments asking CMS to clarify the amount of other claims data applicants must possess. Commenters also asked if CMS would consider Medicaid data to be other claims data.

Response: As stated in the proposed rule, we do not believe it is feasible to establish an absolute threshold for a minimum amount of additional claims data. Rather, we ask applicants to explain how the data they do have for use in the qualified entity program will be adequate to address the concerns about small sample size and reliability that have been expressed by stakeholders regarding the calculation of performance measures from a single payer source. Each application will be evaluated on its collective merits, including the amount of claims data from other sources and its explanation on why that data, in combination with the requested Medicare data, is adequate for the stated purposes of this program. ''Other claims data'' can include Medicaid data as well as any private payer claims data.

Comment: We also received mixed comments on our proposal to require organizations to have two or more data sources at the time of application. Some commenters said this requirement seemed appropriate, while others argued it was too burdensome. One commenter argued that unless combined data represents at least 90 percent of a provider's practice, any resulting quality measurements will not be meaningful.

Response: We based our proposal about acquiring data from two or more sources on the interests of providers, suppliers, and consumers to have reports that provide valid results that cover an adequate portion of the providers' or suppliers' patients. However, in certain cases, one source may provide a sufficient amount of other claims data such that, when the other claims data is combined with Medicare data, it covers a considerable portion of a provider's or supplier's patients. We will therefore not require an applicant to have two sources of additional claims data, but we note that claims data from two or more sources is preferable to data from only one other source. We acknowledge that it is important for the combined data to represent a large portion of a provider's business, but believe an arbitrary requirement of 90 percent is unnecessarily high, especially given that the program is just beginning.

c. Data Privacy and Security

We proposed to require applicants to demonstrate their capabilities to establish, maintain, and monitor a rigorous privacy and security program, including programs to educate staff on privacy and data security protocols.

Comments related to the proposed data privacy and security eligibility criteria requirements are covered in the Data Security and Privacy section below in section II.D. of this final rule.

3. Operating and Governance Requirements for Serving as a Qualified Entity

We require documentation of operating and governance requirements at the time of application for several key activities. We proposed that applicants would submit as part of their application: (1) The measures they intend to use, including methodologies and a rationale for using the measure; (2) the report review process they would use with providers and suppliers, including addressing requests for data and error correction; and (3) a prototype for required reports, including the methods for disseminating reports.

Comments: We received several comments that the submission of measures and methodologies, as well as a prototype for reports at the time of application is too burdensome. Additionally, commenters argued that 90 days notice for approval of changes was too long and that certain types of minor changes to the report prototype need not trigger CMS approval. Several commenters also argued that submitting specifications on standard measures is unnecessary since these measures have established specifications and are generally publically available.

Response: We understand organizations' desire to have flexibility in selecting measures and report formats. We also believe that making these decisions is a key aspect of serving as a qualified entity and is important enough to require the submission of proposed plans prior to being approved as a qualified entity. However, we recognize commenters' desire to ensure measures and report formats are approved and available for use as quickly as possible. Therefore, we will change the timeframe for CMS approval to 30 days. Qualified entities may change selected measures, and may modify their report prototype, with 30 days notice to CMS and CMS approval of the changes or modifications. We believe that the majority of changes proposed by qualified entities will be straightforward and CMS will be able to comfortably conduct a review and approval within 30 days of submission; however, in certain circumstances CMS may request an additional 30 days to approve more wide-reaching changes or modifications. If a CMS decision on approval or disapproval for a change or modification is not forthcoming within 30 days and CMS does not request an additional 30 days for review, the change or modification shall be deemed to be approved.

We acknowledge the interest in only requiring CMS approval for substantive changes in the prototype reports. However, as it is the first year of the program, we are still determining the types of changes to the prototype reports that qualified entities will need to submit to CMS for approval. CMS is considering releasing guidance on the types of changes to the report prototype that need not be submitted once the qualified entity program has started.

We agree with commenters that including standard measure specifications is unnecessary. Thus far, available standard measures only include measures endorsed by the National Quality Forum and CMS measures; and the specifications for these measures are available to the public. Therefore, we will only require applicants to include measure specifications for alternative measures. We will use future rulemaking to address the submission of specifications for standard measures if the public availability of standard measure specifications changes in the future.

Comment: One commenter requested that CMS require each applicant to submit an analytic plan clarifying its goals relative to the statute.

Response: We believe that the requirement for entities to submit a rationale for selecting each measure, including its relationship to existing measurement efforts, addresses the issue of an organization's goals as they relate to the statute. We believe this is sufficient documentation of an organization's plans.

Comment: One commenter requested that CMS require applicants to submit

conflict of interest information. Commenters were concerned that conflicts of interest could result in inaccurate or misleading reporting. One commenter specifically requested that qualified entities be required to attest that they have no relationship or affiliation with any health plans, insurers, providers, suppliers, manufacturers or other entities that may have an interest in or use for the data.

Response: We do not believe it is necessary for applicants to submit information on conflicts of interest to CMS. We expect that many qualified entities will have relationships with health plans, insurers, providers and suppliers, and other entities that have an interest in or use for the data in order to meet the requirements of the qualified entity program, such as obtaining other claims data or disseminating performance results. We believe the eligibility requirements and monitoring requirements will ensure that the organizations who serve as qualified entities comply with the requirements of the program.

B. Definition, Selection, and Use of Performance Measures

1. Standard and Alternative Measures

The statute permits qualified entities to use both standard and alternative measures. We proposed to define standard measures as any claims-based measure endorsed (or time-limited endorsed) by the entity with a contract under section 1890(a) of the Act (currently the National Quality Forum), any claims-based measure that is currently being used in a CMS program that includes quality measurement, or any measure developed pursuant to Section 931 of the Public Health Service Act. The statute requires the Secretary to consult with appropriate stakeholders as to whether the use of alternative measures would be more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by standard measures. In light of these requirements, we proposed to define alternative measures as any claims-based measure that, while not a standard measure, was adopted by the Secretary through a notice and comment rulemaking process. Qualified entities would submit proposed alternative measures to CMS who would then make the proposed alternative measures available for stakeholder input via a proposed rule, and, where appropriate, following receipt of public comments, the Secretary would determine which alternative measures to approve for use in the program.

Comment: Some commenters suggested that qualified entities be allowed to calculate measures that are not based solely on claims data. Specifically, commenters were interested in calculating measures that involve combining claims data with clinical data (for example, registry data or chart-abstracted data). Commenters argued that allowing qualified entities to use these measures would expand the list of available measures. Several commenters also expressed that the use of these types of measures would help produce a more accurate picture of provider and supplier performance.

Response: We recognize commenters' desire to use clinical data combined with claims data when calculating standard and alternative measures. Given the added value that clinical data brings to performance measurement, whenever standard or alternative measures provide for the use of clinical data, we will allow qualified entities to use clinical data in combination with Medicare and other claims data to calculate those standard and alternative measures. We have added a definition of clinical data at § 401.703(i), specifically clinical data is registry data, chart-abstracted data, laboratory results, electronic health record information, or other information relating to the care or services provided to patients that is not included in administrative claims data. Measurement efforts using clinical data would only be supported under the qualified entity program if the clinical data is combined with the qualified entity's Medicare and other claims data to calculate the measures. These regulations do not address the use and publication of purely clinical-based measures.

Furthermore, we recognize the near impossibility of combining Medicare claims data with clinical data without an identifier to link them. As a result, we are changing the proposed process for releasing beneficiary identifiable information to allow—with strict privacy and security standards—for the disclosure of identifiers to qualified entities; this change is discussed in more detail in the Privacy and Security requirements section below.

Comment: Many commenters were supportive of the alternative measure review process. However, several commenters argued that the notice and comment rulemaking process was overly burdensome on qualified entities, would significantly restrict innovation in measure development and use, and was contrary to the overall goals of the provision. Some commenters proposed that qualified entities only be required to seek the permission of local stakeholders before calculating and reporting alternative measures. However, other commenters argued that the notice and comment rulemaking process provided appropriate safeguards against the public reporting of untested measures.

Response: We believe that the intent of the alternative measure provision in statute is to promote innovation in claims-based performance measurement, while ensuring that measures are not used in the qualified entity program without proper testing and validation. That said, in light of the comments received, we believe that greater flexibility could be afforded to qualified entities to better balance innovation with appropriate use. We are therefore adding additional flexibility into the alternative measure process by adding a second avenue by which to seek Secretarial approval of alternative measures. In order to receive approval to use an alternative measure under this new avenue, a qualified entity will need to submit documentation to CMS outlining consultation and agreement with stakeholders in the geographic region the qualified entity serves, and evidence that the measure is ''more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by such standard measures'' in accordance with the statutory requirements at Section 1874(e)(4)(B)(ii)(II). Stakeholders must include a valid cross representation of providers, suppliers, employers, payers, and consumers. At a minimum, a qualified entity must submit:

- A description of the process by which the qualified entity notified stakeholders of its intent to seek approval of an alternative measure.
- A list of stakeholders from whom feedback was solicited, including the stakeholder names and each stakeholder's role in the community.
- A description of the discussion about the proposed alternative measure, including a summary of all pertinent arguments for and against use of the measure.
- An explanation backed by scientific evidence that demonstrates why the measure is ''more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by [a] standard measure.''

CMS will review the submission and make a decision as to whether the qualified entity has consulted the appropriate stakeholders and whether the new measure meets the requirements for alternative measures at Section 1874(e)(4)(B)(ii)(II) of the Act.

Qualified entities must send all the information required for approval of an alternative measure to CMS at least 60 days prior to its intended use of the measure. CMS will make every effort to ensure that measures are approved during the 60 day period. If a CMS decision on approval or disapproval for an alternative measure is not forthcoming within 60 days, the measure shall be deemed to be approved. However, CMS retains the right to disapprove a measure if, even after 60 days, in accordance with the statutory requirements at Section 1874(e)(4)(B)(ii)(II) it is found to not be ''more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource'' than a standard measure. Once a measure is approved CMS will release the name of the measure, as well as the scientific evidence that demonstrates why the measure is ''more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by [a] standard measure.''

Alternative measures submitted and approved using this process may only be used by the qualified entity that submitted the measure for consideration because the stakeholder consultation approval process only requires consultation with stakeholders in the geographic region the qualified entity serves. If another qualified entity wishes to use the same measure, it would need to consult with stakeholders in its own community, and submit its own request for alternative measure approval under the rulemaking or stakeholder consultation approval process. However, we recognize that scientific evidence demonstrating that the measure is ''more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by [a] standard measure'' will not differ for a measure in use across communities. Therefore, once an alternative measure is approved for use via the stakeholder consultation approval process, future requests for use of an identical measure will not need to include the same explanation backed by scientific evidence that demonstrates why the measure is ''more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by [a] standard measure.'' However, if there is scientific evidence that has become available since the measure was approved by CMS, the qualified entity seeking to use that measure must conduct the necessary research and provide that new scientific evidence to CMS.

We will also retain the notice and comment rulemaking process as a second option for the approval of alternative measures. As discussed in the proposed rule, alternative measures approved through notice and comment rulemaking may be used by any qualified entity up until the point that an equivalent standard measure for the particular clinical area or condition becomes available.

Comment: One commenter suggested that the alternative measure process as outlined conflicted with the process under Section 3014 of the Affordable Care Act.

Response: Section 1874(e)(4)(B)(ii)(I) provides for the use of standard measures such as the measures endorsed by the entity with a contract under section 1890(a) of the Act (currently NQF) and measures developed pursuant to section 931 of the Public Health Service Act. Section 1874(e)(4)(B)(ii)(II) provides for use of additional measures that are not approved by such entities. This latter category explicitly provides for the approval and use of non-NQF standards. Furthermore, section 3014 of the Affordable Care Act does not require the Secretary to use the recognized standards by the entity with a contract under section 1890(a) of the Act. It merely serves to provide recommendations on appropriate standards to consider.

Comment: Several commenters questioned whether the requirement for qualified entities to cease using alternative measures within six months of an equivalent standard measure being endorsed was reasonable.

Response: We believe six months is a reasonable time period for qualified entities to transition to using newly endorsed standard measures equivalent to existing alternative measures or to submit scientific justification to file a request for alternative measure approval.

Comment: We received several comments on our definition of standard measures. While many commenters were supportive of our definition, one commenter suggested that we change our definition of standard measures to include measures endorsed by consensus-based entities other than the NQF. The commenter specifically mentioned the Patient Charter, a 2008 agreement among consumer, purchaser, provider and insurer groups on principles to guide performance reporting. Other commenters asked if all NQF-endorsed measures were standard measures. One commenter asked that standard measures be limited to true outcome measures in order to measure the effectiveness of care.

Response: We appreciate the suggestion to include measures endorsed by consensus-based entities other than the NQF and have changed our definition of standard measures to include such measures. Specifically, we will now include as a standard measure any measure calculated in full or in part from claims data that is endorsed by a consensus-based entity, providing that the consensus-based entity has been approved as such by CMS. Rather than defining consensus-based entities in advance, CMS will approve organizations as consensus based entities on an as needed basis.

To receive approval as a consensus-based entity, an organization will need to submit information to CMS documenting their processes for stakeholder consultation and measure approval. Such documentation must show that the entity has a prescribed process for vetting and approving measures that includes representation from all types of stakeholders relevant to the topic being measured. The description of the approval process must be publicly available and the stakeholder consultation must be open to any that are interested in participating. Additionally, organizations will only receive approval as a consensus-based entity if all measure specifications are publicly available. Consensus-based entities will receive approval for a time period of three years and their endorsed measures will be made available to all qualified entities. CMS will also make a list of approved consensus-based entities available publicly. After three years, organizations will simply have to resubmit documentation on their processes for stakeholder consultation and measure again, noting any changes from their original submission.

Regarding the request that we add a requirement that standard measures be ''outcome measures,'' which we understand to mean measures that evaluate final results, such as mortality rates, we feel that imposing this requirement would substantially reduce the number of available standard measures. Additionally, while we agree that outcome measures may be better indicators of the effectiveness of care, we feel process measures will also offer the public, as well as providers and suppliers, important information on performance. Therefore, we have not incorporated this suggestion.

Comment: One commenter suggested that the rule should permit the use of composite measures.

Response: We believe that composite measures can be calculated and reported under the revised alternative measure process we established in this final rule.

Comment: One commenter suggested that the rule should permit qualified entities to withdraw measures prior to public reporting if the measure results turn out to be unreliable.

Response: We appreciate this suggestion; however, the statute requires public reporting of all measures. Specifically, Section 1874(e)(4)(C)(iv) requires the reports be made available to the public, while allowing for confidential review by providers and suppliers. We note that this does not prohibit commentary on the measure and results in the report. We hope that qualified entities will take the requirement of public reporting into consideration when determining which measures should be calculated under this program. We recognize that there may be errors in measure calculation and believe that the confidential reporting and appeals process will help qualified entities discover and correct any errors in the calculation of measures.

Comment: We received a variety of comments on measurement methodologies. Several commenters suggested that CMS should be more proscriptive regarding the types of attribution, risk adjustment, and benchmarking methods qualified entities should employ and that methodology descriptions should be standardized across payers and qualified entities. Commenters were also concerned about payment standardization as it relates to efficiency and resource use measures. Payment standardization is viewed as an important methodological approach to normalize comparisons of resource use across providers and suppliers. Several commenters also stressed the need for accurate attribution and risk adjustment in general. One commenter asked if methodologies employed by the qualified entity could change during the three-year agreement period. One commenter urged CMS to require qualified entities to submit to CMS a specific description of how it will handle outlier providers and ensure that a report of a provider's or supplier's performance is accurately adjusted as appropriate to reflect characteristics of the patient population.

Response: The statute does not require CMS to be proscriptive in this regard. Consistent with the statute, the proposed rule would require qualified entities to submit to the Secretary a description of methodologies that the qualified entity proposes to use to evaluate the performance of providers and suppliers. The proposed rule would also require qualified entities to include an understandable description of their attribution, risk adjustment, and benchmarking methods so that report recipients can properly assess such reports. We agree with commenters that payment standardization is an important aspect of measurement methodologies, and agree that payment standardization methodologies should be included where appropriate. Therefore, we have added a requirement that qualified entities include information on payment standardization when appropriate.

Additionally, we feel that performance measurement is evolving, and that clear standards for attribution, risk adjustment, and benchmarking have not yet emerged, and therefore it would be inappropriate for CMS to preemptively determine such standards. We are confident that as qualified entities and the performance measurement environment matures over the coming years methodologies will begin to coalesce around clearly defined standards. As discussed above, qualified entities can change methodologies during the three year agreement period provided they give appropriate notice to CMS and receive CMS' approval. Regarding outliers, we feel that this issue will be adequately addressed in the requirements at § 401.707(b)(5)(ii) for a qualified entity to provide details on methodologies it intends to use in creating reports with respect to benchmarking performance data, including methods for creating peer groups, justification of minimum sample size determinations, and methods for handling statistical outliers, to both CMS and users of the reports.

Comment: One commenter asked about the release of the details of proprietary methodologies and proprietary measure specifications to CMS.

Response: While we understand the concerns about releasing methodologies for proprietary measures, we believe that the goal of this program is to increase transparency. As discussed above in section II.A.3., we are not requiring qualified entities to submit measure specifications for standard measures because, thus far, all specifications for these measures are available to the public. However, we believe that, in order for CMS to evaluate a qualified entity's proposed plan for calculating measures, disclosure of proprietary measure methodologies and proprietary specifications for alternative measures to CMS as part of the application process is warranted. The Trade Secrets Act (18 U.S.C. 1905) bars CMS from re-disclosing proprietary information unless it is authorized to do so by law. Any disclosure to CMS regarding measurement methodologies or specifications will generally not be made public by CMS. As a result, we feel it is appropriate to require the disclosure of detailed methodologies and specifications for alternative measures to CMS as part of the application.

Additionally, qualified entities will be required to disclose proprietary measure methodologies to providers and suppliers as a part of the confidential review process. We believe it is essential for providers and suppliers to understand exactly how the measure is calculated in order to review their results. To protect proprietary methodologies, a qualified entity may choose to limit further disclosure of proprietary measure methodologies, perhaps by requiring a provider or supplier to execute a non-disclosure agreement as a condition of that disclosure; however, the qualified entity must share the proprietary measure methodologies with the provider or supplier regardless of whether they are willing to execute a non-disclosure agreement. If a qualified entity does not wish to share proprietary measure methodologies with both CMS and providers or suppliers, it should not seek approval to use those measures in the qualified entity program.

Comment: One commenter suggested that all proposed measures, both standard and alternative, be open for public review by providers and suppliers prior to approval.

Response: We do not feel that this requirement is necessary. Standard measures as currently defined have already been subject to multi stakeholder input and approval either through the entity with a contract under section 1890(a) of the Act (currently NQF) or through public comment via notice and comment rulemaking in the case of CMS measures. Also, any measures developed by a consensus based entity will have gone through some form of stakeholder consultation. Thus far, there have been no measures developed pursuant to section 931 of the Public Health Service Act; however, section 931 requires consultation with stakeholders during the quality measure development process. Further, both of the alternative measure processes include requirements regarding stakeholder input.

Comment: Several commenters urged CMS to provide a comprehensive list of

the standard and alternative measures that qualified entities may use.

Response: We plan to release a list of standard measures to potential qualified entity applicants prior to the start of the program. We would like to note, however, that this list will be dynamic since the entity with the contract under section 1890(a) of the Act (currently NQF) is continually reviewing measures for endorsement and CMS is continually undergoing rulemaking to add measures to our programs. Additionally, as new consensus based entities are approved by CMS, additional standard measures will be available for use by qualified entities. We will also release a list of approved alternative measures once alternative measures are approved. Qualified entities are encouraged to check these lists frequently to ensure they have the most accurate information regarding acceptable measures.

2. Reports and Reporting

Section 1874(e)(4)(C)(ii) of the Act requires qualified entities to make their draft reports available in a confidential manner to providers and suppliers identified in the reports before such reports are released publicly in order to offer them an opportunity to review these reports, and, if appropriate, appeal to request correction of any errors. After reports have been shared confidentially with providers and suppliers, and there has been an opportunity to have any errors corrected, Section 1874(e)(4)(C)(iv) of the Act requires the reports to be made available to the public.

As stated in the statute at Section 1874(e)(4)(C)(i) of the Act, the reports must include ''an understandable description'' of the measures, rationale for use, methodology (including risk-adjustment and physician attribution methods), data specifications and limitations, and sponsors. We interpreted ''an understandable description'' to mean any descriptions that can be easily read and understood by a lay person. Additionally, the reports to the public may only include data on providers or suppliers at the provider or supplier level with no claim or patient-level information to ensure beneficiary privacy.

We proposed requiring qualified entities to submit prototype reports for both the reports they would send to providers and suppliers, and the reports they would release to the public (if they are different) in their application, including the narrative language they plan to use in the reports to describe the data and results.

Comment: We received several comments about the reporting process generally. One commenter asked that qualified entities be required to report less frequently than once per year, as proposed. Other commenters asked that qualified entities be required to report more frequently than once per year. Yet other commenters expressed concern about public reporting and asked that no measurement data be publicly reported at all.

Response: The statute, at 1874(e)(C)(iv), requires qualified entity reports to be made available to the public after they are made available to providers and suppliers for review and requests for corrections. We have no discretion to allow qualified entities to produce reports for confidential use only. While the statute does not mention any specific frequency of public reporting, we believe that once per year is an appropriate requirement. Requiring public reporting once per year strikes a balance between reporting frequently enough that the information is actionable for consumers, and not reporting so frequently that providers and suppliers constantly have to confidentially review reports. However, we note that reporting once per year is the minimum requirement. A qualified entity may choose to report more frequently than once per year, as long as it is still able to meet the requirement of allowing providers and suppliers the opportunity to review and request error correction.

Comment: Commenters raised questions about the possibility of providers and suppliers receiving multiple reports, which may potentially contain contradictory or confusing performance measure results. Some commenters requested that CMS standardize the report formats among qualified entities to make them easier to interpret, and others simply asked CMS to clarify how we will address this issue.

Response: As discussed in the proposed rule and above, we do not intend to limit the number of qualified entities accepted for participation into this program, and therefore, it is possible that there will be more than one qualified entity working in the same geographic area. While we are requiring qualified entities to submit prototype reports for CMS approval before use, we do not intend to standardize the reports. We believe this program is intended to supplement measurement activity already ongoing at the community level, and excessive CMS involvement will erode the relationships qualified entities either already have, or will develop, with providers and suppliers. This is precisely why providers and suppliers are afforded the opportunity to review their reports and work through any issues directly with the qualified entity, and not with CMS.

Comment: We received several comments regarding the provider or supplier's role in the reporting process. One commenter stated that providers and suppliers should be allowed to petition CMS to require qualified entities to modify report formats. Another commenter requested that qualified entities should be required to include providers' or suppliers' comments in the public reports. And finally, one commenter requested that qualified entities be required to be capable of allowing providers and suppliers to download reports electronically.

Response: As stated in the proposed rule, and discussed elsewhere in this final rule, CMS' direct role in this program is relatively limited, and includes only the functions necessary for reviewing applications from qualified entities and providing standardized data extracts to those entities that meet the requirements, as well as describing the program to the public. We believe these comments about issues related to how the qualified entities publicly report data are outside the scope of CMS' statutory authority under section 1874(e). Therefore, providers and suppliers will not be allowed to petition CMS to change the reports, and a qualified entity will decide itself whether to post comments in a public report or make its reports available for download in an electronic format.

Comment: One commenter noted that the proposed rule could be interpreted as requiring qualified entities to do all reporting at the individual physician level. Another commenter noted that, in terms of performance measurement, specialty hospitals need to be accounted for differently.

Response: The statute does not specify the level at which reports are to be generated (that is, individual physician, physician group, integrated delivery system, *etc.*), nor does it specify the types of providers and suppliers to be measured. A qualified entity may choose to which providers and/or suppliers it will apply measures, and in so doing, for which entities its reports will be generated. Reporting may be at any level for which the measures can be used, but reports must be devoid of patient identifiers to protect the identity of the beneficiaries.

Comment: One commenter requested that CMS require qualified entities to license or otherwise make available quality measures to other entities that

have the ability to publish performance measurement information.

Response: As stated above, these regulations will generally not place any added limitations on what is otherwise feasible under applicable law (such as copyright law). Qualified entities cannot, however, charge providers or suppliers for the confidential pre-publication reports, and they must make reports available to the public free of charge in accordance with section 1874(e)(4)(c)(iv).

C. Data Extraction and Dissemination

Section 1874(e)(3) of the Act requires the Secretary to provide qualified entities with standardized extracts of claims data from Medicare parts A, B, and D for one or more specified geographic areas and time periods. For Medicare parts A and B, we proposed that these data extracts would include information from all seven claim types that are submitted for payment in the Medicare Fee-For-Service Program, including both institutional and non-institutional claims. Institutional claim types include inpatient hospital, outpatient hospital, skilled nursing facility, home health, and hospice services, whereas non-institutional claim types include physician/supplier and durable medical equipment claims. Medicare institutional and non-institutional claims include, but are not limited to, the following data elements: Beneficiary ID, claim ID, the start and end dates of service, the provider or supplier ID, the principal procedure and diagnosis codes, the attending physician, other physicians, and the claim payment type.

We proposed that qualified entities would also receive certain Part D information for beneficiaries enrolled in the Medicare Fee-For-Service Program. The Part D information is known as ''drug event'' information, as opposed to ''claims'' information, because prescription drug coverage under Part D is provided by private insurance plans or ''Part D plan sponsors.'' Part D plans are responsible for paying a claim for benefits at the pharmacy. The Part D plan then submits a Prescription Drug Event record or ''PDE'' to CMS. The key data elements in the Part D prescription drug event database include: Beneficiary ID, prescriber ID, drug service date, drug product service ID, quantity dispensed, days' supply, gross drug cost, brand name, generic name, and drug strength. CMS will also include an indication if the drug is on the formulary of the Part D plan.

In order to allow qualified entities to link Medicare claims for an individual beneficiary, with appropriate security and privacy protections, we proposed that all claims files would contain a unique encrypted beneficiary identification (ID) number, rather than the actual beneficiary Medicare Health Insurance Claim Number (HICN).

Comment: We received several comments regarding data extract structure. A number of commenters requested clarification on how the data linkage across data sets will be accomplished. Several comments asked how qualified entities would identify the provider or supplier associated with a claim. One commenter expressed concern that no accurate or acceptable physician contact data base or directory is currently available on a nationwide level. An additional comment asked if CMS plans to make changes to the data in the CMS database if a qualified entity, provider, or supplier determines there is an error in the Medicare claims data.

Response: CMS understands the importance of linking beneficiaries across Medicare data sets in a way that is secure and protects beneficiaries' privacy. All claims files provided to qualified entities will contain a unique encrypted beneficiary identification number that will allow a qualified entity to link claims for an individual beneficiary across all Medicare claim types and across all years. That is, a unique encrypted beneficiary ID number will be assigned to an individual beneficiary and will remain the same for that individual beneficiary across Medicare claim types and years. This encrypted beneficiary ID is unique to the qualified entity program and will be included on each file the qualified entity receives. With appropriate security and privacy protections, these files will also contain beneficiary date of birth, race, and gender, important elements for calculating performance measures.

Additionally, to allow qualified entities to identify the provider or supplier associated with a claim, the files will contain the actual provider or supplier ID or, where required by law, the National Provider Identifier (NPI). Although, in HIPAA standard transactions the NPI must be used in lieu of other provider numbers, CMS will also make the Unique Physician Identification Number (UPIN) associated with the claim available to qualified entities. CMS maintains both a publically available query-only database and a publically available downloadable file that links the NPI to other information on a provider such as the provider name and mailing address. We believe that this national-level database and downloadable file will allow qualified entities to identify the provider or supplier associated with the claim. Furthermore, given the eligibility requirements described above in Section II.A.1.a., we expect approved qualified entities to have experience in accurately identifying a provider or supplier across multiple data sources.

As to reporting suspected issues with CMS data, CMS currently has a process in place for reporting, tracking, and resolving potential errors or issues identified in CMS data. Once approved, each qualified entity will receive guidance and training in this area.

Comment: Several commenters raised concerns about some of the data elements we proposed to release. A number of commenters expressed concern on the release of drug cost information in the Part D data, as well as the release of Part D plan identifiers. Additionally, a handful of commenters suggested that private physician financial information contained in the Part B data is protected from disclosure under the Privacy Act.

Response: CMS is aware of the concerns and restrictions on releasing certain Part D drug cost information. Given these concerns, in the files provided to qualified entities, CMS will release the Total Drug Cost element, which is derived from the sum of four elements: Ingredient Cost, Dispensing Fee, Vaccine Administration Fee, and Total Amount Attributable to Sales Tax. However, to protect the Part D plans' proprietary cost information, these individual component costs will not be released. We believe the aggregation of cost information will help to ensure that the most confidential information—the separate amounts paid by Part D sponsors for ingredient cost or dispensing fee—will not be released. This approach is also consistent with the treatment of these data under the regulations governing the use and disclosure of Part D data for non-payment related purposes. *See* 73 FR 30,664, 30669 (May 28, 2008). Furthermore, the Part D data will not identify individual Part D plans, but will include an encrypted plan ID number. We believe this encryption will afford further protection for Part D drug cost information.

While certain physician payment information contained in the Part B claims data is protected from disclosure to the general public by court injunctions entered in *Florida Medical Association, Inc.* v. *Department of Health, Education & Welfare,* 479 F. Supp. 1291 (M.D. Fla. 1979), and *American Ass'n of Councils of Medical Staffs of Private Hospitals, Inc.* v. *Health Care Financing Administration,* No. 78–

1373 (E.D. La 1980), that protection is specific to disclosures under the Freedom of Information Act (FOIA) exception to the Privacy Act at 5 U.S.C. 552a(b)(2). Disclosures made under the qualified entity program under section 1874(e) of the Act are not FOIA-based disclosures. Rather, they are ''routine use'' disclosures from the National Claims History (NCH)—System No. 09–70–0558, Medicare Drug Data Processing System (DDPS)—System No. 09–70–0553, Medicare Integrated Data Repository (IDR)—System No. 09–70–0571, and Chronic Condition Data Repository (CCDR)—System No. 09–70–0573 systems of records under the Privacy Act and these implementing regulations. As such, they are not subject to the injunction.

Comment: We received a variety of comments on technical assistance for qualified entities. Several commenters asked that CMS provide technical assistance, but not include it in the fee charged for the data. Other commenters suggested that technical assistance would not be needed.

Response: We plan to provide qualified entities with the option to request technical assistance. Since we are removing all program management costs from the fee we will charge qualified entities, see discussion below at II.C.3., we do not plan to charge for these services.

1. Number of Years of Data

CMS proposed to provide qualified entities with the most recent three calendar years of Medicare final action data available at the time the qualified entity is approved for participation in the program.

Comment: Comments from both potential qualified entities and provider groups raised concerns about the timeliness of the data. Commenters generally requested that CMS release data on a quarterly basis or a rolling 12 month basis, with no more than a quarterly time lag. One commenter suggested that CMS only provide qualified entities with two calendar years of data because performance information regarding care provided in 2008 is too outdated to be relevant for providers or consumers.

Response: We agree with commenters, so we are modifying what we proposed to make more timely data available to qualified entities. CMS will provide qualified entities with the most recent available historical data, which, for qualified entities approved at the beginning of the program, we expect would include data for CY2009, CY2010, and the first two quarters of 2011. Then, we would provide quarterly data updates on a rolling basis.

2. Geographic Areas

CMS proposed to provide qualified entities with standardized data extracts for either a single geographic area or multiple regions, and to limit the provision of Medicare data to the geographic spread of the qualified entity's other claims data. In the proposed rule, we sought comment on releasing nationwide extracts of Medicare data.

Comment: Several commenters requested that CMS release nationwide Medicare claims data. Some expected to conduct a nationwide performance review program, but many were interested in calculating national benchmarks. Commenters expressed feelings that national Medicare benchmarks would foster greater consumer and provider understanding of local measure results.

Response: For entities interested in conducting a nationwide performance review program, we are unsure about the ability of any one entity to assemble a sufficient amount of data nationally to justify a nationwide release of Medicare data. If a qualified entity can demonstrate it has a sufficient amount of data nationwide, however, CMS will provide a 100% national extract.

We agree that nationwide data may assist qualified entities in benchmarking their results. As a result, qualified entities will be allowed to request a 5% national sample of Medicare claims for the purposes of calculating national benchmarks. The 5% national sample of claims will not include a crosswalk to beneficiary names and Health Insurance Claim Numbers, discussed below in Section D.1, only the encrypted beneficiary ID to allow linking across Medicare claims data for measure calculation purposes. Qualified entities should provide a justification of needing a 5% national sample with their request. We will include a requirement in the Data Use Agreement (DUA, discussed in more detail below) prohibiting qualified entities from re-identifying claims included in the national sample they receive. Additionally, as these files are already in existence because they are used for other purposes, we anticipate that the cost of making this data available will be nominal.

Comment: We received several comments on how CMS would determine which claims apply to a certain geographic region. We also received comments requesting that CMS not limit the provision of Medicare data to the geographic spread of the qualified entity's other claims data.

Response: We will release claims based on the location of the beneficiary residence, not the location of the provider or supplier rendering the services. This will mean the qualified entity might not receive all of the Medicare claims for a given provider or supplier.

While we recognize the desire to calculate performance measures for areas outside the geographic spread of the qualified entity's other claims data, we believe the intent of statute is for qualified entities to combine other claims data from an area with Medicare claims data for that same area to produce robust and actionable performance measures for providers, suppliers, and consumers.

3. Cost To Obtain Data

Section 1874(e)(4)(A) of the Act requires qualified entities to pay a fee for obtaining the data that is equal to the cost of making such data available. In the proposed rule CMS interpreted the cost of making the data available to include two parts: (1) The cost of running the qualified entity program, including costs for processing applications, monitoring qualified entities, and providing technical assistance, and (2) the cost of creating a data set specific to each qualified entity's requested geographic area and securely transmitting the data set to the qualified entity. We estimated that the approximate cost to provide data for 2.5 million beneficiaries to a qualified entity would be $200,000. Approximately $75,000 of the $200,000 is cost of the claims data and approximately $125,000 is the cost of making the data available. We proposed that data costs would vary depending on the amount of data requested.

Comment: Many commenters stated that CMS was being too broad in our interpretation of the statutory requirement to charge qualified entities for the cost of making the data available. Commenters suggested that CMS only charge qualified entities for the cost of generating the data, and not the cost of running the program. The comments also noted that high cost would be a barrier to entry for non-profit organizations and states.

Response: CMS concurs that there are public interests at stake that justify narrowing the scope of what constitutes the cost of making this data available. As such, we will drop the program management portion of the costs from what is included in the data fee we will charge qualified entities. We have also worked to identify several efficiencies in data preparation and distribution that will significantly reduce our initial

estimates for data costs. Our initial estimates were based on the fee we charge researchers for similar data. However, because all qualified entities will receive a standardized extract of the Medicare data, we will not need to address each request for data on an individual basis as we do with researchers, thereby significantly reducing the cost of making the data available, particularly the costs of encrypting the data.

We estimate that the total approximate costs to provide data for 2.5 million beneficiaries to qualified entities would be $40,000 in the first year of the program. We estimate that the cost to provide ten quarters (CY 2009, CY 2010, and Q1–Q2 CY2011) of data when the qualified entity is first approved would be $24,000. Thereafter, in 2012 qualified entities would get 2 additional quarterly updates covering the remainder of CY 2011, each for a fee of $8,000, bringing the total cost of data for the first year of the program to $40,000. After the first year, qualified entities would get quarterly updates, each for a fee of $8,000, bringing the total cost to a qualified entity for subsequent years of the program to $32,000. It is important to note that all estimates of data costs are currently predicated on an estimate of 25 qualified entities, so if fewer than 25 qualified entities are approved, data costs per qualified entity will be higher, and conversely, if greater than 25 are approved, the costs will be lower. Additionally, data costs for qualified entities will vary depending on the amount of Medicare claims data the qualified entity requests (for example, more than one State, or a nationwide extract). CMS also reserves the right to revise the cost of the data if unanticipated expenses are determined in the future.

D. Data Security and Privacy

The subpart created by these regulations will create a new program that provides for the release of Medicare beneficiary level data, with appropriate privacy and security protections. We recognize that many qualified entities will have had many years of experience using claims data to produce performance reports on providers and suppliers. Additionally, many qualified entities will have received data from private health plans through agreements that will require that the qualified entities observe certain security and privacy standards. We also recognize that new organizations or combinations of organizations may want to serve as qualified entities to produce performance reports. While CMS is committed to ensuring the success of qualified entities in combining Medicare data with claims data from other sources to create comprehensive performance reports for providers and suppliers, CMS is also committed to ensuring that the beneficiary-level data provided to qualified entities is subject to stringent security and privacy standards throughout all phases of the performance measure calculation, confidential reporting, appeal, and public reporting processes.

In 2008, we published a regulation to permit Part D prescription drug event data to be used for program monitoring, research, public health, care coordination, quality improvement, population of personal health records, and other purposes. *See* 73 FR 30664. We intend to ensure that the release of Part D prescription drug event data under this program complies with the requirements in the Part D data regulation, including the minimum necessary data policy, and that qualified entities take the necessary steps to ensure that any prescription drug event data released to providers and suppliers as part of the review, appeal, and error correction process are also safeguarded to ensure the privacy and security of beneficiary information.

Comment: Commenters were generally supportive of our intent to ensure the privacy and security of Medicare data under this program. A few commenters made specific suggestions regarding data privacy in general. One commenter suggested we clarify the interaction of this program and its data privacy and security requirements with State data privacy laws and specifically requested that CMS promulgate regulations that would preempt State law.

Response: On the issue of the interaction of this program with State laws, we believe the issuance of universally applicable privacy regulations that would preempt State laws is outside the scope of the qualified entity program. Qualified entities will need to abide by applicable state laws in addition to the requirements in this subpart.

1. Privacy and Security Requirements for Qualified Entities

We proposed to require that qualified entities have in place security protections for all data released by CMS, and any derivative files, including any Medicare claims data and any beneficiary identifiable data.

We proposed that in order to be eligible to apply to receive Medicare data as a qualified entity, the applicant must demonstrate its capabilities to establish, maintain, and monitor a rigorous data privacy and security program, including ensuring compliance with submitted plans related to the privacy and security of data. Additionally, we proposed a requirement that the applicant submit to CMS a description of its rigorous data privacy and security policies including enforcement mechanisms. As part of their applications, qualified entities will also have to explain how they would ensure that only the minimum necessary beneficiary identifiable data would be disclosed to the provider or supplier in the event of a request by a provider or supplier in the context of a confidential review of a report, and how data would be securely transmitted to the provider or supplier.

Comment: Commenters were generally supportive of requiring that qualified entities have rigorous data privacy and security protocols in place. Several commenters recommended that CMS require qualified entities to impose the same data and security requirements on the qualified entity's non-Medicare claims data as we require on the Medicare claims data. One commenter suggested CMS require qualified entities and other non-covered entities (that is, the small fraction of providers who do not submit claims electronically, and are therefore not subject to HIPAA) to enter into business associate agreements with CMS, pursuant to HIPAA.

Response: We agree that the integrity of performance measurement depends on the integrity of the data, and CMS intends to take very seriously its role in ensuring qualified entities use Medicare data appropriately. However, we do not have the statutory authority to impose specific requirements on qualified entities with regard to the privacy and security of their non-Medicare claims data. It is our understanding that organizations will have executed contracts or other agreements with the entities from which they receive the non-Medicare claims data (for example, commercial insurance plans) that will contain the privacy and security requirements regarding that data. Similarly, we also cannot prescribe how or where a qualified entity stores its non-Medicare data.

We seek to clarify the interaction between this program and HIPAA. Some commenters thought that we could address the privacy and security concerns related to qualified entities and other entities that are not directly subject to HIPAA by making them CMS' business associates (BAs). BAs are persons who or entities that use or disclose individually identifiable health information in conducting functions or

activities on behalf of a covered entity (see the definition of a BA at 45 CFR 160.103), but qualified entities and providers and suppliers subject to the qualified entity program cannot serve as BAs because they are not doing their work on behalf of CMS as part of the Medicare program. CMS is merely providing data to qualified entities in accordance with the mandate in the Affordable Care Act, and, as such, its disclosure of protected health information is permitted by the HIPAA Privacy Rule as ''required by law'' (45 CFR 164.512(a)). That said, we believe our thorough evaluation of applicant qualified entities, the requirement to sign a Data Use Agreement (DUA), and subjecting the qualified entities to ongoing monitoring will be sufficient to ensure that qualified entities are appropriately using the Medicare data, as well as appropriately disclosing the Medicare data to providers and suppliers who request it.

We proposed to require each approved qualified entity sign a DUA, which requires a level and scope of security that is not less than the level and scope of security requirements established by the Office of Management and Budget (OMB) in OMB Circular No. A–130, Appendix III—Security of Federal Automated Information Systems (*http://www.whitehouse.gov/omb/circulars/a130/a130.html*) as well as Federal Information Processing Standard 200 entitled ''Minimum Security Requirements for Federal Information Systems'' (*http://csrc.nist.gov/publications/fips/fips200/FIPS-200-final-march.pdf*); and Special Publication 800–53 ''Recommended Security Controls for Federal Information Systems'' (*http://csrc.nist.gov/publications/nistpubs/800-53-Rev2/sp800-53-rev2-final.pdf*).

Comment: Commenters were in support of requiring qualified entities to sign a DUA with CMS. One commenter suggested we ensure the DUA is appropriate for this program, since the DUA cited in the proposed rule was the current DUA used for research purposes. Another commenter suggested CMS impose civil and criminal penalties on any qualified entity that causes a data privacy breach or violation. In addition, one commenter requested that we discuss how a qualified entity's existing DUAs might interact with this program.

Response: We believe the requirement for each qualified entity to sign a DUA will ensure a high level of privacy and security of the Medicare data given to qualified entities. Because we have clarified that qualified entities do not need to be composed of a single legal entity, but may contract with other entities to achieve the ability to meet the eligibility criteria, we also clarify that both the lead entity as well as its contractors that are anticipated to use Medicare claims data or beneficiary identifiable data are required to sign the DUA. As discussed in the proposed rule, the DUA cited in the proposed rule is the current research DUA. We intend to use the addendum feature provided for in paragraph 12 of the document to address the specific needs of the qualified entity program. With regard to the comment suggesting imposition of civil and criminal penalties, we point out that the DUA currently does, and will continue to have, enforcement mechanisms including criminal penalties. CMS intends to make use of these provisions in the event of a breach or violation. We do not have the statutory authority to impose penalties beyond those already listed in the DUA. Finally, we note that DUAs are specific to a particular data disclosure from CMS to a data recipient. Any existing DUAs a qualified entity may have in place will only affect the data received under those DUAs. The qualified entity program DUA will govern qualified entity program Medicare data.

Comment: We received some comments containing suggestions for requirements CMS should impose on qualified entities with regard to internal qualified entity operations. These suggestions included requiring that qualified entities limit the number of staff with access to identifiable information, and that qualified entities store Medicare data separately from other claims data.

Response: The DUA, discussed above, contains provisions regarding access to and storage of CMS data. The DUA requires the qualified entity to limit access to the identifiable Medicare data to the minimum number of individuals required to create the performance reports. The DUA also requires the qualified entity to specify the site where the data is to be stored and to grant CMS access to the site to confirm compliance with the DUA. Additionally, as stated in the preamble to the proposed rule, we believe the entities that will be successful applicants to this program are entities that are experienced in handling sensitive information and will have the appropriate internal protocols and procedures in place.

We also sought public comment on the appropriateness of accepting some form of independent accreditation or certification of compliance with data privacy and security requirements from qualified entities, and what that accreditation or certification might entail. The accreditation or certification would need to be at a level and scope of security that is not less than the level and scope of security requirements described above.

Comment: We received no comments on this proposal.

Response: Since we received no comments, we will not require qualified entities to have any kind of accreditation or certification separate from CMS' process in reviewing the application and requiring a signed DUA.

We proposed that all the Medicare claims data provided to qualified entities would contain a unique encrypted beneficiary identification number, which would enable the qualified entities to link all Medicare claims for an individual beneficiary without knowing the identity (that is, name or Medicare Health Insurance Claim Number) of the beneficiary. We did not propose to send patient names with the claims data that would be initially disclosed to qualified entities. However, we recognized the need for beneficiary names to facilitate provider and supplier appeals.

In the proposed rule, we considered three potential options for sharing beneficiary identifiers with qualified entities, and by extension, providers and suppliers. Under the first option, all qualified entities would be provided with a crosswalk file, with appropriate privacy and security protections, linking all encrypted beneficiary identifiers to the patients' names for their Medicare data. This would provide the qualified entity with identifiable data, but qualified entities would be permitted to give to a provider or supplier only the names of the beneficiaries included in that requester's performance report. Under the second option, CMS would only provide beneficiary names to qualified entities on a transactional basis for the purposes of responding to specific requests for data by providers and suppliers. Each request for beneficiary names would be addressed on a case-by-case basis through the forwarding of each data request by the qualified entity to CMS. CMS would then allow the qualified entity access to the beneficiary names for the specific data request. Under the third option, a provider or supplier who wishes to receive beneficiary names would request the encrypted claims data from the qualified entity as permitted under the statute. Then, the provider or supplier would submit a request to CMS for the beneficiary names for those specific claims and CMS would share the beneficiary names directly with the provider or supplier. Under the third

option, the qualified entity would never have access to the beneficiary names.

Comment: Comments were mixed between favoring the first option and the second option. Very few commenters supported the third option. As discussed above in Section II.B.1., some commenters were interested in using measures that incorporate clinical data. A number of these commenters noted that the information contained in the crosswalk under option one (beneficiary names) would be necessary to their being able to link claims data to clinical data. Several commenters also noted that they would need an additional identifier, like the Medicare Health Insurance Claim Number (HICN), if they were to ensure the accurate linkage. Among other things, they asserted that the inclusion of multiple identifiers would ensure that they could differentiate amongst individuals with similar or identical names. Additionally, several commenters noted that, in instances in which an individual moved from coverage under one plan (for example, a private plan) to coverage under another (for example, Medicare), they would need patient identifiers in order to track the care provided to a patient over time. These commenters also supported the first option since it would allow qualified entities to match an individual's claims from other sources with their Medicare claims data. Commenters also supported the first option because it would allow qualified entities to quickly respond to requests for the data from providers and suppliers, and argued that the first option would be the least burdensome for qualified entities.

One commenter suggested we phase-in release of beneficiary-identifiable information: In the first year, qualified entities would receive the full crosswalk so they can easily respond to the anticipated high volume of requests from providers and suppliers, but in later years, after recipients are more familiar with the reports, beneficiary-identifiable information would only be released on a transactional basis. Still other commenters supported the second option because they felt it offered an appropriate balance between ensuring beneficiary privacy and allowing qualified entities to respond to specific provider or supplier requests for beneficiary names.

Response: In response to the insights offered by the comments, we plan to implement a modified version of the first option. While we had thought that ''If one approaches this issue purely from the point of view of the ability of qualified entities to engage in measure calculation and reporting, beneficiary identifiable data is not required'' (76 FR 33574), it is clear from the comments noted above that beneficiary identifiable data, with appropriate privacy and security protections, is required if clinical data is to be used or if a qualified entity needs to link an individual's claims records across plans as they move over time from plan to plan.

For example, a qualified entity could have private plan data for a patient who was enrolled in a private health plan in 2009 and early 2010, but then in May 2010 enrolled in Medicare. To accurately calculate measures, the qualified entity may need to be able to match the private payer claims data that covers 2009 and January to April of 2010 for the patient with the Medicare claims data that covers May 2010 forward for the same patient. The beneficiary name alone would not be sufficient to match patients between claims data sources because of the high likelihood of duplicative names or naming variations in the data. To accurately match claims data from multiple sources, the patient social security number would be ideal. However, Medicare claims contain the Medicare HICN, which for many beneficiaries is the beneficiary's social security number plus a letter. In most cases the HICN will allow qualified entities to differentiate between individuals, and may allow for accurately matching claims data between sources in those instances in which it does include the beneficiary's own social security number. We acknowledge that there are cases where the HICN does not include the beneficiary's social security number, for example, for beneficiaries who qualify for Medicare through their spouse. In these cases, the beneficiary name will be the best available identifier to use to match records from multiple sources, but even if the HICN cannot be used to match claims data between sources, it will still be needed to differentiate individuals with similar names or naming variations.

In light of the overwhelming support for the release of a crosswalk file in the comments, the likelihood that entities will need the identifiers to combine clinical data or link claims records across plans over time, the need for the identifiers to conduct the provider and supplier review and appeal process, and the considerable costs that would be entailed in building a case-by-case inquiry capability for qualified entities, we will amend our proposal and adopt the policy of automatically releasing a crosswalk file with appropriate privacy and security protections linking the encrypted ID to both the beneficiary name and the beneficiary Medicare HICN to all qualified entities. This constitutes a modified version of option one.

We expect that our rigorous eligibility requirements, the requirement that the lead entity, as well as any contractors who use the data, sign a DUA, and comprehensive monitoring process will ensure that any data shared with qualified entities are kept in a manner that will not compromise beneficiary privacy. As noted above, an applicant must have strict data privacy and security protocols in place to be eligible to serve as a qualified entity. Furthermore, the DUA contains a requirement that the qualified entity establish the ''appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data and to prevent unauthorized use or access to it'' and does not allow the data to be physically moved, transmitted, or disclosed without written approval from CMS. The DUA also allows CMS or the Office of the Inspector General to access the site where the data is stored to confirm compliance with required security standards. The DUA requires the qualified entity to limit access to the data to the minimum amount of data and minimum number of individuals necessary to achieve the purposes of the qualified entity program. In the event that CMS determines or has a reasonable belief that unauthorized uses, reuses, or disclosures of the data may have taken place, the DUA allows CMS, among other things, to require the destruction of all data files and to refuse to release further CMS data to the qualified entity for any period of time. As noted above, the DUA also contains criminal penalties, including fines and imprisonment, for unauthorized disclosures of the data. The comprehensive qualified entity monitoring program is discussed in more detail below in section II.F. and includes CMS audits of qualified entities' use of the data, site visits, and analysis of beneficiary and/or provider complaints among other things.

As a result of the decision to release a crosswalk with appropriate privacy and security protections to all qualified entities, qualified entities will already be in possession of patients' names and HICNs at the time providers and suppliers are reviewing draft reports and making correction requests. We will ensure that the qualified entity program DUA (discussed above) provides for qualified entities releasing names only upon request by providers and suppliers

when that information is relevant to their review and requests for correction.

We recognize that some may question why we are retaining our plan to include an encrypted beneficiary identifier in the claims data if every qualified entity will receive the crosswalk. We have two reasons to separate the claims data from the beneficiary names and HICNs. First, shipping the claims data separate from the crosswalk file adds an additional level of security while the data is in transit. Second, we believe that qualified entities may want to limit access to the crosswalk file to ensure the utmost privacy and security of this data and having two separate files will make this much easier.

It is also worth noting that CMS does not ship claims data without first encrypting the data. Unlike encrypting an individual data element, this process involves cryptographically scrambling the data so that it cannot be correctly re-assembled (that is, deciphered) unless the receiving party has the correct key. This protects the data while it is in transit.

We hope that through implementing this modified version of option one with appropriate privacy and security protections, qualified entities will be able to link clinical data to claims data and match claims data from other sources to Medicare claims data for the same patient. Additionally, implementing a modified version of option one allows qualified entities to quickly respond to requests from providers or suppliers for beneficiary identifiers during the report review and correction request process.

2. Privacy and Security Requirements of Data Released to Providers and Suppliers

Section 1874(e)(4)(B)(v) of the Act requires qualified entities to make the Medicare claims data they receive available to providers and suppliers upon their request. We do not interpret this requirement to mean that providers or suppliers could receive all Medicare claims data for a given patient or patients. Rather, we proposed to require qualified entities to provide, with appropriate privacy and security protections, only the claims relevant to the particular measure or measure results being appealed. Therefore, for example, a provider or supplier requesting claims data in relation to a diabetes quality measure would only receive the claims related to the calculation of that quality measure. We realize this may result in providers or suppliers receiving data related to claims submitted by another provider or supplier. We solicited comment on any privacy or security issues related to release of data to providers or suppliers.

Comment: We received several comments concerning the privacy and security of the data released to providers and suppliers. One commenter suggested we clarify exactly what data can be requested from the qualified entity. And, as stated above, comments included the suggestion that CMS require non-covered entities (that is, the small fraction of providers who do not submit claims electronically, and are therefore not subject to HIPAA) to enter into business associate agreements with CMS, pursuant to HIPAA.

Response: Regarding the request for clarification about what data can be released, we stated in the preamble to the proposed rule (at 76 FR 33577), that we believe that for many providers and suppliers, the beneficiary name may be of more practical use in determining the accuracy of the measure results than the underlying claims used to calculate the measures. However, the statute does explicitly acknowledge that upon request qualified entities would need to share with providers or suppliers ''data made available under this subsection.'' We would like to reiterate that we do not interpret this provision to mean that providers or suppliers could receive all Medicare claims data for a given patient or patients. Rather, we interpret this to mean that, at the request of providers or suppliers, qualified entities will provide only claims and/or beneficiary names relevant to the particular measure or measure results that the provider or supplier is appealing.

Since we made a technical change in the regulation text and removed the reference to section 1874(e) from the definition of a qualified entity (as noted above in Section II.A.1.), we have added the requirement that qualified entities release Medicare claims to providers and suppliers to the regulation text. We have added a requirement in § 401.717(c) that qualified entities, at the request of a provider or supplier and with appropriate privacy and security protections, release the Medicare claims and/or beneficiary names to the provider or supplier, but we require qualified entities to only release those claims and/or beneficiary names relevant to the measure or measure results being appealed.

As stated above, we acknowledge that the providers and suppliers who request data may or may not be covered entities under HIPAA. Also, as noted above, a BA is limited to a person or an entity using or disclosing individually identifiable health information on behalf of a HIPAA covered entity. The qualified entity and providers and suppliers in the qualified entity program are not going to be doing anything on behalf of CMS or the Medicare program. They therefore cannot be BAs of CMS by virtue of the qualified entity program.

3. Beneficiary Privacy and Security

Following provision of the performance reports on a confidential basis to providers or suppliers, qualified entities are required to make performance information public. In accordance with the statute, we proposed to require that qualified entities ensure that all publicly available reports do not contain beneficiary identifiable information. Additionally, we proposed to prohibit qualified entities from disclosing information in their publicly available reports that there is a reasonable basis to believe can be used in combination with other publicly available information to re-identify individual patients.

Comment: One commenter suggested we allow beneficiaries to opt-out of having their data released under this program.

Response: We do not have the statutory authority to permit beneficiaries to opt out of this program. However, we also note that the intent of this program is to increase transparency and promote innovation in measure development which we believe will contribute significantly to improving beneficiary care in the long run. As mentioned above, we also believe the final rule contains appropriate beneficiary privacy protections and penalties for any misuse of the data by qualified entities.

E. Confidential Opportunities To Review, Appeal, and Correct Errors

One important aspect of this program is ensuring that providers and suppliers are afforded an opportunity to correct errors in the reporting of their performance metrics. To meet the requirements in the statute related to appeal and error correction, we proposed to require applicants to include a plan for their report review, appeals, and error correction process in their application. This plan would contain several elements, including the means for sharing results confidentially and the means by which a provider or supplier can request and receive Medicare claims data. We proposed that qualified entities would need to confidentially share measure results with providers and suppliers at least 30 days prior to making the reports public. We also proposed that qualified entities must inform providers and suppliers

that the report would be made public on a certain date (at least 30 days after confidentially sharing the measure results), regardless of the status of error correction.

Comment: We received several comments on the overall review, appeals, and error correction process. Some commenters asked CMS to standardize the process across qualified entities. On the other hand, one commenter argued that if CMS both approves and audits the claims and the qualified entity process for creating the reports, review by providers and suppliers is unnecessary. Another commenter asked CMS to require qualified entities to automatically provide the beneficiary names to providers and suppliers. Several commenters asked CMS to require qualified entities to announce publically on a Web site supported by HHS or in notifications to major organizations that represent providers and suppliers that have been evaluated by the qualified entity, the availability of reports for confidential review. Finally, several commenters suggested allowing qualified entities to require that a provider or supplier document and authenticate their identity and, if requesting data, their legal right to see the data, as well as provide a secure communication process for transmission of requested information.

Response: We believe an important aspect of the qualified entity program is innovation, not only in the development of measures, but also in the process for sharing measure results with physicians, as well as the process for responding to requests for data and for error correction. To reiterate, this is not a Medicare quality measurement program—we are merely a data source for those who meet the requirements laid out in this subpart. Qualified entities design their programs within the statutory and regulatory limits, including crafting their own confidential review, appeals, and error correction processes. This will result in innovations that will improve the way providers and suppliers receive reports and interact with the qualified entity. The statute is clear in the requirement that qualified entities develop a confidential review, appeals, and error correction process, so we do not agree that this is an unnecessary part of the qualified entity program. Furthermore, while we understand the interest in obtaining beneficiary names automatically, protecting the privacy and security of beneficiary identifiable information is required by the statute, as well as being of the utmost importance to CMS. We feel that releasing beneficiary names only at the request of a provider or supplier and only for the measure or measure results being appealed strikes the appropriate balance between protecting beneficiary privacy and allowing providers and suppliers the opportunity to provide input on their reports.

The statute requires that qualified entities make reports available to providers and suppliers prior to the public release of reports. Since each provider or supplier will confidentially receive any report where they are identified, we see no need for qualified entities to announce publically the availability of reports. Additionally, we acknowledge the importance of ensuring the data is securely transmitted to the correct provider or supplier. However, we believe that it is the responsibility of the qualified entity to ensure that the data is delivered using a secure method to the appropriate provider or supplier and require applicants to describe their means of confidentially sharing reports with providers and suppliers as part of their application.

Comment: Many commenters argued that the proposed time period between providers and suppliers confidentially receiving reports and the qualified entity publically reporting results is too short. Commenters suggested a time period of 60 or 90 days.

Response: We recognize, in light of the comments, that our proposal may not have allowed providers and suppliers an appropriate amount of time to review their confidential reports. However, we also recognize the importance of ensuring that report results are released to the public in a timely manner. Therefore, qualified entities must share measures, measurement methodology, and measure results with providers and suppliers at least 60 calendar days prior to making the measure results public. Beginning on the date on which the qualified entity sends the confidential reports to a provider or supplier, that provider and supplier will have a minimum of 60 calendar days to review the reports, make a request for the data, review the data, and, if necessary, make a request for error correction. Qualified entities also must inform providers and suppliers of the date the reports would be made public at least 60 calendar days before making the reports public. Additionally, the qualified entity must publically release reports on the specified date regardless of the status of any requests for error correction. We recognize that this process allows providers and suppliers to make a request for the data or a request for error correction up to the point the reports are made public; however, we believe that it is up to the qualified entity and provider or supplier to manage the timing of this process to ensure that they have adequate time to request the data and, if necessary, request error correction(s).

Comment: We received several comments on our proposal that qualified entities publish reports on a certain date, regardless of the status of requests for appeals or error correction. Several commenters requested that CMS not allow qualified entities to publish measure results until the request for error correction is resolved. Other commenters recommended that we create a two-step track where if a request cannot be resolved between the qualified entity and a provider or supplier, the request is elevated to CMS for a final decision. Furthermore, some commenters wanted CMS to require qualified entities to publish provider or supplier comments in the report if a request is not resolved at the time of report publication. One commenter requested that CMS allow providers or suppliers to publicly defend themselves if reports are published prior to resolving error correction requests. We also received a comment suggesting CMS allow providers or suppliers to appeal after reports are made public. Finally, one commenter asked CMS to ensure that qualified entities have the appropriate amount of staff to respond to appeals.

Response: We acknowledge the interest of providers and suppliers in ensuring that any measure results reported publicly are correct. However, as we mentioned in the proposed rule, we included this requirement to prevent providers or suppliers from making spurious requests for error correction to prevent the publication of measure results. We will maintain our requirement that qualified entities publicly report measure results on the date specified to the provider or supplier when the report is sent for review (at least 60 days after the date on which the confidential reports are sent to a provider or supplier), regardless of the status of a request for error correction. We hope that by extending the amount of time between confidentially sharing reports with providers and suppliers and publically reporting results to at least 60 calendar days, we are allowing both providers and suppliers ample opportunity to resolve the appeals process. If an appeal request is still outstanding at the time of public reporting, we will maintain the requirement that qualified entities post publicly the name and category of the appeal request for providers or suppliers

with outstanding requests for error correction, if feasible, but do not believe that qualified entities should be required to publicly post comments from providers or suppliers.

Additionally, since this program does not involve CMS contracting with qualified entities to carry out a quality measurement program on behalf of CMS, we do not believe it is appropriate for CMS to become involved in the appeals and error correction process or to offer a public forum for providers or suppliers to defend themselves. We recognize the concern about ensuring that a qualified entity has the appropriate staff to respond to requests for error correction. However, we are certain that the rigorous application process will guarantee that only qualified organizations receive Medicare claims data. Additionally, we will be monitoring qualified entities to determine if they are promptly responding to requests for data and requests for error correction.

In the proposed rule, we acknowledged that CMS does not have the statutory authority to require qualified entities to share their claims data from other sources. We encouraged qualified entities to share this data with providers or suppliers upon request.

Comment: We received multiple comments asking CMS to require qualified entities to release their non-Medicare claims data to providers or suppliers upon request. Some commenters requested that CMS only approve entities who agreed to release their other claims data.

Response: We do not have the statutory authority to require qualified entities to release their non-Medicare data. We hope that qualified entities will choose to do so whenever it is legally permitted, but are aware that their ability to release other claims data is partially dependent on the terms of the arrangement the qualified entity has with the entity from whom they received the data.

Comment: Commenters suggested we implement 2012 as a ''test year'' for the program and allow qualified entities to only produce confidential performance reports without any public reporting.

Response: We do not have the statutory authority to implement a ''test year'' for this program. The statutory effective date of this provision is January 1, 2012, and all requirements under the law are applicable on that date.

F. Monitoring, Oversight, Sanctioning, and Termination

To ensure that qualified entities adhere to the highest standards, we proposed a monitoring program that would assess compliance with the requirements of the program and assess sanctions or termination as deemed appropriate by CMS. We proposed that CMS, or one of its designated contractors, would periodically audit (including site visits) qualified entities for their use of the Medicare data to ensure that the data is only being used for its intended purpose. We also proposed to monitor the amount of claims data from other sources the qualified entity is using in the production of performance reports using documentation produced by the qualified entity or, at the discretion of CMS, site visits. Additionally, we proposed to use analysis of beneficiary and/or provider complaints to monitor and assess the performance of qualified entities. We also proposed to require qualified entities to submit an annual report covering program adherence (for example, number of claims, market share, number of measures) and engagement of providers and suppliers (for example, requests for data, number of corrections, time to respond to requests for appeal or error correction). Finally, we proposed requiring qualified entities to submit to CMS information regarding any inappropriate disclosures or uses of beneficiary identifiable data pursuant to the requirements in the DUA.

Comment: We received many comments supporting our monitoring program. Some commenters specifically supported the requirement that qualified entities submit a report covering the engagement of providers and suppliers. One commenter asked CMS to ensure that there is appropriate funding for CMS to conduct the necessary qualified entity monitoring activities.

Response: We would like to reiterate our commitment to ensuring the successful implementation of this program and that all qualified entities adhere to the highest standards, which includes ensuring that we have the necessary funding to support a monitoring program.

Comment: Some commenters made suggestions about specific aspects of the monitoring plan. One commenter suggested that qualified entities only submit reports on program adherence and engagement of providers and suppliers once every two years. Additionally, several commenters requested CMS not include site visits as a part of monitoring because it is too burdensome.

Response: We plan to maintain our proposed monitoring process and note that, in the cases where a qualified entity is composed of a lead entity and contractors, contractors will also be subject to CMS monitoring. We believe that annual reports and site visits are essential to allow CMS to best monitor the program and to both maximize the appropriate use of Medicare data for the production of performance reports and minimize the risk of inappropriate disclosure of beneficiary information.

We proposed that a qualified entity must immediately inform CMS if its amount of claims data from other sources decreases. We also proposed to require that the qualified entity provide documentation that the remaining non-Medicare claims data is still sufficient to address methodological concerns regarding sample size and reliability expressed by stakeholders regarding the calculation of performance measures from a single source. As reflected at § 401.706(c) of the proposed rule, the qualified entity would no longer be able to issue a report, use a measure, or share a report after the amount of claims data from other sources decreases until CMS made an assessment as to the sufficiency of the remaining data. If CMS determined that the qualified entity's remaining claims data was not sufficient, we proposed that the qualified entity would have 60 days to acquire new data and submit new documentation to CMS. The qualified entity would not be able to use Medicare data to issue reports, use measures, share measures, or share a report during this time. If after re-submission of documentation, CMS determined the qualified entity still did not possess adequate data, we proposed to terminate the relationship with the qualified entity. If after resubmission of documentation, CMS determined that the qualified entity did possess sufficient data, we proposed the qualified entity could resume all measurement and reporting activities.

Comment: Commenters requested two changes to our proposed process for addressing a decrease in the amount of other claims data. First, several commenters suggested that qualified entities only be required to stop measurement and reporting if the decrease in other claims data is significant. Second, commenters requested more time for qualified entities to acquire new data.

Response: While we recognize the interest in continuing measurement efforts during this review process, we believe it is important for CMS to make the determination as to whether the remaining claims data is adequate to ensure that the methodological concerns regarding sample size and reliability expressed by stakeholders regarding

calculation of performance measures from a single payer source. To ensure that the decrease does not materially affect the validity of measure results, we will maintain our proposal to require qualified entities to stop all activities while CMS reviews the documentation related to the decrease in other claims data; after the amount of claims data from other sources decreases, the qualified entity would no longer be able to create a report, use a measure, or share a report (either confidentially or publically) using Medicare data until CMS determines either that the remaining claims data is sufficient, or that the qualified entity has collected adequate additional data to address any deficiencies. That said, we recognize the request to extend the amount of time a qualified entity has to acquire new data, so we will extend this timeframe to 120 days.

We also proposed that if a qualified entity is not adhering to the requirements of the program, CMS may take several enforcement actions, such as providing a warning notice, requesting a corrective action plan, placing an entity on a special monitoring plan, or terminating the qualified entity. These enforcement actions are in addition to the actions CMS may take if a qualified entity violates the DUA, as discussed in more detail above in section II.D.1. The choice of enforcement action would depend on the seriousness of the deficiency. Any time a qualified entity is voluntarily or involuntarily terminated, we proposed requiring the destruction or return of Medicare data within 30 days.

Comment: We received some comments stating that the proposed penalties are not strict enough. Additionally, one commenter requested that CMS provide for termination for inaccurate reporting or for failing to make timely corrections upon providers' or suppliers' request.

Response: We are limited by the statute in the penalties we can impose on qualified entities who do not comply with the requirements of the program. We note, however, that CMS does have additional enforcement capabilities for violations of the DUA, including criminal penalties. As CMS will require the lead entity, as well as any contractors who have access to the Medicare claims data or beneficiary identifiable data, to sign the DUA before CMS releases any data, these penalties will apply to all organizations with access to the Medicare data.

While CMS reserves the right to terminate a qualified entity for inaccurate reporting, we believe that there are degrees of seriousness in inaccurate reporting, and some situations may not warrant termination, particularly if the inaccuracy was unintentional, CMS was promptly identified, and the inaccuracy was promptly resolved. We will therefore maintain our proposal to base our actions on the seriousness of the deficiency.

Comment: Several commenters requested clarification on how long qualified entities would be able to keep the Medicare data that they receive under this program. One commenter suggested placing an outer limit on retention of files.

Response: After carefully considering the beneficiary privacy and security implications of our policy, we do not believe that qualified entities must destroy or return Medicare data (including crosswalks) provided under the qualified entity program unless they voluntarily leave or are involuntarily terminated from the program. Qualified entities will need to retain the Medicare data, with appropriate privacy and security protections, in order to trend measure results over time or to calculate measures that require a number of years of data for measure calculation. We understand that this will mean that qualified entities will also retain beneficiary identifiable data (including that found in the crosswalks), but we believe that this information will also be necessary to calculate measures that require a number of years of claims data. We feel it is important to note that a beneficiary's encrypted identifier will not change from year to year, so unless a beneficiary dies or moves out of the geographic region, the qualified entity will continue to need the crosswalk linking the encrypted ID to the beneficiary HICN and name to carry out the activities outlined above in our crosswalk discussion. We have carefully considered the beneficiary privacy and security implications of our policy, and note that the DUA remains in effect so long as the qualified entity participates in the program. Furthermore, the monitoring requirements described herein, as well as the requirement that qualified entities reapply every three years as described below in section II.G., should assist in ensuring that this data remains secure and private. We would like to reiterate, however, that once an entity voluntarily leaves or is involuntarily terminated from the program it must destroy or return all CMS data provided under this subsection within 30 days.

G. Qualified Entity Application Content

We proposed to develop an application process for organizations interested in becoming qualified entities in which they would provide certain specified information. We proposed applications and related materials would be collected and reviewed once a year, at the close of the first quarter of the calendar year. We proposed approval periods of three years, followed by an opportunity to reapply.

Comment: We received comments containing suggestions for how CMS could improve the application content and process. Specifically, one commenter suggested using a standard electronic application. Additionally, a commenter suggested that CMS accept applications on a rolling basis. Another commenter preferred that CMS not require re-application after three years.

Response: CMS appreciates and acknowledges the benefits of accepting qualified entity applications on a rolling basis instead of once annually. This would allow organizations to apply to be a qualified entity as soon as they believe they meet all the eligibility requirements, instead of requiring the organization to wait a year until the next application cycle. We are therefore changing to a rolling application process. We will also use an electronic application.

While we understand the burdens that re-application will impose, we also need to ensure that Medicare data are being used appropriately and handled securely. While we believe the monitoring program described above will help ensure qualified entities continue to meet the requirements of the program, the application process covers significantly more aspects of an organization's continuing ability to serve as a qualified entity. Therefore, CMS believes that requiring re-application every three years balances the burden on qualified entities with the need to ensure Medicare data is being handled appropriately.

H. Other Comments

We received several additional suggestions for improvements to the program regarding topics that were not specifically discussed in the preamble to the proposed rule.

Comment: A few commenters advised that CMS require knowledge sharing among qualified entities, rather than merely suggesting it.

Response: CMS agrees with commenters that performance improvement will occur most rapidly in an open collaborative environment where ideas and knowledge are shared

freely and openly. CMS will strongly encourage and facilitate, where possible, collaborative knowledge sharing, but will not require it as a condition of program participation.

Comment: Several commenters expressed concern about CMS conducting performance analysis of providers and suppliers. Commenters also expressed concern about performance measurement generally, and had specific concerns about performance measurement based solely on claims data.

Response: This program is not a CMS measurement program and, therefore, CMS will not be conducting performance analysis of providers and suppliers in this program. Rather qualified entities will combine Medicare claims data supplied by CMS with other claims data to calculate performance measures for providers and suppliers. We recognize commenters' concerns about the limitations of performance measurement based on claims data alone. Therefore, as discussed above in section II.B.1, we will allow qualified entities to use measures that incorporate clinical data, as long as the measure can be calculated in part from Medicare and other claims data.

Comment: Commenters suggested CMS should undertake a public education and outreach program to inform consumers about the qualified entity program and explain the limitations of provider and supplier performance measurement.

Response: We agree that CMS should inform consumers about the qualified entity program. We also believe it is essential for CMS to be transparent to beneficiaries and the general public about our plans for sharing identifiable information, with appropriate privacy and security protections, with qualified entities. CMS will publish educational materials on the CMS Web site regarding the qualified entity program, including a description of the beneficiary information that is being shared with qualified entities and an explanation of the privacy and security requirements, as well as the qualified entity monitoring program and termination policies.

We also hope that qualified entities will engage in public education and outreach in the communities where they serve. However, we are not requiring qualified entities to do public outreach beyond making the performance reports, with an understandable description of the measures, available to the public after confidential review by providers and suppliers.

Comment: One commenter requested that we clarify how performance measurement information will be published.

Response: The statute requires that qualified entities allow confidential review of the reports, that they be provided to the public, and that the reports contain understandable descriptions of the methodologies used. Qualified entities must receive approval of report formats before they can be published, but each qualified entity has the discretion to design reports and publish using the approved formats.

Comment: One commenter suggested that CMS make available the full data set at no charge to recognized provider organizations such as the American Medical Association and allow providers and suppliers to analyze their data there.

Response: The statute does not permit CMS to release the data to any entity other than those approved as qualified entities. However, as stated in the preamble to the proposed rule, we are not placing any restrictions on the types of organizations that can apply to be a qualified entity. If a recognized provider organization meets the eligibility criteria, it can become a qualified entity and receive Medicare data. Additionally, the statute does not permit CMS to release data at no charge. Section 1874(e)(4)(A) states that the data ''shall be made available * * * at a fee equal to the cost of making such data available.'' That said, as discussed in section II.C.3. above, we have revised our method for pricing this data and we believe the data will be significantly more affordable than originally proposed.

Comment: One commenter requested that CMS clarify that the data released to qualified entities will not be subject to discovery or admissible as evidence in judicial or administrative proceedings.

Response: The statute, at 1874(e)(4)(D), explicitly states, ''[d]ata released to a qualified entity under this subsection shall not be subject to discovery or admission as evidence in judicial or administrative proceedings without consent of the applicable provider of services or supplier.'' We acknowledge that we did not address this specific statement in the preamble to the proposed rule, but we believe this statement is self-implementing in that it requires no further explanation, and the data will not be subject to discovery or admission as evidence absent the described consent(s).

Comment: One commenter asked CMS to clarify that these regulations have no effect on any other programs in which Medicare claims data are released. A second commenter requested that we ensure the program can accommodate the transition to ICD–10.

Response: We clarify that this program will not have any effect on other CMS programs in which Medicare claims data are released. CMS is working to ensure that the transition to ICD–10 happens smoothly.

Comment: One commenter requested that CMS only allow measurement and rating of providers and suppliers in situations where CMS pays for the item or services.

Response: Medicare only pays claims for covered services and supplies; if a service or supply is not covered, a claim will not appear in the Medicare data. While a qualified entity could decide to produce a measurement report based solely on its other claims data, such reporting would be outside of the qualified entity program and the reports would be outside of the reach of these regulations.

III. Provisions of the Final Regulations

For the most part, this final rule incorporates the provisions of the proposed rule. Those provisions of this final rule that differ from the proposed rule are as follows:

- We have made technical changes to the definition of a qualified entity, provider, and supplier to reflect regulatory interpretation of the statutory provisions cited in the proposed rule. We have also added a definition of claims data from other sources at § 401.703(h) and a definition of clinical data at § 401.703(i).
- We clarify that qualified entities do not need to be a single organization. Applicants may contract with others to achieve the ability to meet the eligibility criteria. Specifically, at § 401.705(b) we allow entities to demonstrate expertise and experience through activities it has conducted directly or through (a) contract(s) with other public or private entities.
- We changed our eligibility requirements at § 401.705(a)(1) to only require that entities demonstrate expertise in quality measurement and in the other three areas of measurement (efficiency, effectiveness, and resource use) to the extent that they propose to use such measures.
- At § 401.705(a)(1)(ii) we clarify that we only expect applicants to submit a plan for a business model that is projected to cover the costs of performing the required functions. We realize that qualified entities may need to adapt this plan once they are approved and do not intend to limit an entity's ability to adapt or change its

business plan once approved as a qualified entity.

• We added language at § 401.705(a)(1)(vii) that would require qualified entities to also disclose any violations of applicable federal and State privacy and security laws and regulations for the preceding 10-year period, in addition to requiring qualified entities to disclose any inappropriate disclosures of beneficiary identifiable information for the preceding 10-year period. We also clarified that for those entities that have not been in existence for 10 years, we will require a breach history for the length of time the organization has been in existence.

• We have revised the selection criteria to allow applicants to apply and receive a conditional acceptance as a qualified entity if they do not have adequate claims data from other sources at the time of their application, but meet all the other selection requirements.

• Since standard measure specifications are available to the public at this time, we removed the requirement that qualified entities submit measure specifications for standard measures the qualified entity plans to calculate.

• We clarified that these regulations do not place any added limitations on the qualified entity's ability to copyright the content of the publicly released reports. We noted, however that the qualified entity must provide confidential reports to the subject providers and suppliers free of charge and must provide the final reports to the public free of change in a manner consistent with the requirements in the qualified entity program statute.

• At § 401.711(a) we allow qualified entities to change their list of proposed measures, proposed prototype report, and plans for sharing reports with the public with 30 days notice to CMS, instead of 90 days notice to CMS. We provide for a possible 30-day extension of the review period where necessary. If a CMS decision on approval or disapproval for a change or modification is not forthcoming within 30 days or CMS does not request an additional 30 days for review, the change or modification shall be deemed to be approved.

• We will allow qualified entities to use standard and alternative measures calculated in full or in part from Medicare Parts A and B claims, and Part D prescription drug event data and claims from other sources. This means that qualified entities will be allowed to calculate measures that include clinical data. As noted above, we have added a definition of clinical data at § 401.703(i).

• We have added measures endorsed by a CMS-approved consensus-based entity to the list of standard measures. CMS will approve organizations as consensus-based entities based on review of documentation of the consensus-based entity's measure approval process.

• We have added a second process by which qualified entities may seek approval to use alternative measures. Organizations and individuals will still be able to submit alternative measures for approval through the notice and comment rulemaking process. However, at § 401.715(b)(1)(ii), we also allow an entity to submit measures for approval by the Secretary by submitting: (1) A description of the process by which the qualified entity notified stakeholders (defined as a valid cross representation of providers, suppliers, employers, payers, and consumers) in the geographic region the qualified entity serves of its intent to seek approval of an alternative measures; (2) a list of stakeholders from whom feedback was solicited, including the stakeholder names and each stakeholder's role in the community; (3) a description of the discussion about the proposed alternative measure, including a summary of all pertinent arguments for and against the measure; and (4) unless CMS has already approved the same measure for use by another qualified entity, an explanation backed by scientific evidence that demonstrates why the measure meets the requirements for alternative measures at Section 1874(e)(4)(B)(i)(II) of the Act. If a qualified entity is seeking to use an alternative measure that CMS has already approved for use by another qualified entity, the qualified entity submitting the measure for approval must submit any additional or new scientific evidence, if it is available. If a CMS decision on approval or disapproval of measures submitted via the process at 401.715(b)(1)(ii) is not forthcoming 60 days after the submission of the measure, the measure will be deemed approved. However, CMS retains the right, even after 60 days, to direct the qualified entity to stop using the measure if we subsequently find the measure does not meet the requirements at Section 1874(e)(4)(B)(i)(II) of the Act.

• We have identified efficiencies that will reduce the cost of Medicare claims data under the qualified entity program, and we have altered the dates of data that will be made available through this program, thereby increasing the timeliness of that data.

• We will allow qualified entities to purchase a 5 percent national sample of Medicare claims data for the purpose of calculating national benchmarks.

• Using appropriate privacy and security protections, we will provide qualified entities (that sign the DUA and meet all the privacy and security requirements) with a crosswalk file linking encrypted beneficiary ID to the beneficiary name and beneficiary Health Insurance Claim Number.

• At § 401.717(a), we extended the time period between a qualified entity sending a confidential report to a provider or supplier and public reporting of measure results to at least 60 calendar days.

• We will allow qualified entities 120 days to acquire new data if the amount of other claims data they have decreases and CMS determines the remaining amount of other claims data is not sufficient.

• We changed our application process and will accept applications on a rolling basis as discussed at § 401.709(a).

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

• The need for the information collection and its usefulness in carrying out the proper functions of our agency.

• The accuracy of our estimate of the information collection burden.

• The quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

If finalized, these regulations would require an organization seeking to receive data as a qualified entity to submit an application. Specifically, an applicant must submit the information listed in §§ 401.705–401.709. The burden associated with this requirement is the time and effort necessary to gather, process, and submit the required information to CMS. We estimate that 35 organizations would submit applications to receive data as qualified

entities. We further estimate that it would take each applicant 500 hours to gather, process and submit the required information. The total estimated burden associated with this requirement is 500 hours per applicant at an estimated cost of $795,641.

Section 401.713(a) states that as part of the application review and approval process, a qualified entity would be required to execute a Data Use Agreement (DUA) with CMS, that among other things, reaffirms the statutory bar on the use of Medicare data for purposes other than those referenced above. The burden associated with executing this DUA is currently approved under OMB control number 0938–0734.

Section 401.709(f) would require qualified entities in good standing to re-apply for qualified entity status 6 months before the end of their three-year approval period. We estimate that 25 entities would be required to comply with this requirement. We estimate that it would take 120 hours to reapply to CMS. The total estimated burden associated with this requirement is 120 hours at an estimated cost of $136,396.

Section 410.719(b) requires qualified entities to submit annual reports to CMS as part of CMS' ongoing monitoring of qualified entity activities. We estimate that the 25 entities in the program will be required to comply with this requirement. We estimate that it will take 150 hours to complete an annual monitoring report. The total estimated burden associated with this requirement is 150 hours at $170,475.

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING AND REPORTING BURDEN

Regulation section(s)	OMB control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($) *	Total capital/ maintenance costs ($)	Total cost ($)
§ 401.705(a)	0938–New	35	35	500	17,500	**	795,641	0	795,641
§ 401.709(f)	0938–New	25	25	120	3,000	**	136,396	0	136,396
§ 401.719(b)	0938–New	25	25	150	3,750	**	170,475	0	170,475
Total		35	35		24,250				1,102,512

* Total labor cost assuming 92% of total hours are professional and technical and 8% are legal.
** Wage rates vary by level of staff involved in complying with the information collection request (ICR).

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site at *http://www.cms.gov/PaperworkReductionActof1995/PRAL/list.asp#TopOfPage* or email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office at 410–786–1326.

If you comment on these information collection and recordkeeping requirements, please submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, CMS–5059–F.

Fax: (202) 395–6974; or

Email: *OIRA_submission@omb.eop.gov.*

V. Regulatory Impact Analysis

A. Response to Comments

We received several comments on the anticipated effects of the program.

Comment: Several commenters argued that the cost of the data is too high. As stated above, these commenters often recommended CMS remove the data application costs or provide a sliding scale fee for the data, charging non-profits and government organizations a lower fee.

Response: While we do not feel we were being too broad in our interpretation of the statute, we recognize commenters' concerns and, as discussed above, have removed the program management costs from the fee we will charge for the data. As further addressed above, we have also identified several efficiencies in the creation of the data files which will further lower the cost of the data. However, we would like to reiterate that these estimates are based on a qualified entity program with 25 approved qualified entities. The cost of the data will increase if fewer organizations are approved as qualified entities and decrease if more organizations are approved as qualified entities because the fixed costs of providing the data would be spread across the total number of qualified entities.

Comment: We received a handful of comments stating that the application process for qualified entities is too burdensome.

Response: As discussed above, we believe ensuring that organizations approved as qualified entities are experienced in performance measurement and reporting and have the necessary plans to serve as a qualified entity is essential for the success of the qualified entity program. Thus, we do not believe the application is too burdensome.

Comment: We received several comments on the impact on providers and suppliers. A number of commenters stated that the number of hours estimated for a provider or supplier to review performance reports or submit correction requests is too low. Many commenters also argued that the hourly wage rate for physicians' offices is too low. Finally, a number of comments suggested that providers and suppliers might hire contractors to help with reviewing draft reports and requesting corrections.

Response: While we understand that some providers and suppliers may spend many hours reviewing reports and submitting correction requests, we believe 5 hours reviewing reports is appropriate as an average. For example, some providers and suppliers will spend less than an hour reviewing their reports, but others may spend 10 hours. The same situation applies for error correction requests. Some providers and suppliers may only have concerns about one measure, and after seeing the data may realize that their concerns were unfounded. However, others may engage in a longer discourse with the qualified entity. On average, we believe that providers and suppliers will spend approximately 10 hours preparing and submitting error correction requests. We do recognize that some providers and suppliers may choose to hire contractors to assist in preparing and submitting a correction request and have added this to the impact on providers and suppliers discussed below.

Additionally, while we understand physicians' hourly wage exceeds $30.90, we believe physicians are not the only ones in their offices who will be reviewing the performance reports and

submitting correction requests. Some of this work may be done by other physician office staff such as administrative staff, nurses, physician assistants, and case workers. Therefore, we believe our average hourly wage rate is appropriate to calculate the impact of this program on providers and suppliers. Changes described in our response are reflected in the remainder of the Regulatory Impact Analysis.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both cost and benefits, reducing costs, harmonizing rules, and promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This final rule is not economically significant as measured by the $100 million threshold, and hence not a major rule under the Congressional Review Act. We estimate the total impact of this final rule to be approximately $86 million. We provided a detailed assessment of the impacts associated with this final rule, as noted below.

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. We estimate that two types of entities may be affected by the program established by section 1874(e) of the Act: Organizations that desire to operate as qualified entities and the providers and suppliers who receive performance reports from qualified entities. We anticipate that most providers and suppliers receiving qualified entities' performance reports would be hospitals and physicians. Many hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration definition of a small business (having revenues of less than $34.5 million in any 1 year) (for details, see the Small Business Administration's Web site at *http://sba.gov/idc/groups/public/documents/sba_homepage/serv_sstd_tablepdf.pdf* (refer to the 620000 series). For purposes of the RFA, physicians are considered small businesses if they generate revenues of $10 million or less based on Small Business Administration size standards. Approximately 95 percent of physicians are considered to be small entities. We estimate that most hospitals and most other providers are small entities as that term is used in the RFA (including small businesses, nonprofit organizations, and small governmental jurisdictions). However, because the total estimated impact would be spread over a number of providers and suppliers, no one entity would face a significant impact. Additionally, as CMS has reduced the cost of the data for qualified entities, we do not anticipate that this rule will have a significant impact on qualified entities. Therefore, the Secretary has determined this final rule would not have a significant impact on a substantial number of small entities. We have voluntarily provided an analysis of the estimated impacts on qualified entities and providers and suppliers below in section V.C., as well as alternatives considered in section V.D.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis, if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. Any such regulatory impact analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this final rule has impact on significant operations of a substantial number of small rural hospitals because we anticipate that most qualified entities would focus their performance evaluation efforts on metropolitan areas where the majority of health services are provided. Therefore, the Secretary has determined that this final rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately $136 million. This rule would not mandate any requirements for State, local, or tribal governments in the aggregate, or by the private sector, of $136 million. Specifically, as explained below we anticipate the total impact of this final rule on all parties to be approximately $86 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have examined this final rule in accordance with Executive Order 13132 and have determined that this regulation would not have any substantial direct effect on State or local governments, preempt States, or otherwise have a Federalism implication.

C. Anticipated Effects

a. Impact on Qualified Entities

Because section 1874(e) of the Act establishes a new program, there is little quantitative information available to inform our estimates. However, we believe that many or most qualified entities are likely to resemble community quality collaborative programs such as participants in the CMS Better Quality Information for Medicare Beneficiaries pilot (*https://www.cms.gov/BQI/*) and the AHRQ Chartered Value Exchange (CVE) program (*http://www.ahrq.gov/qual/value/lncveover.htm*). Community quality collaboratives are community-based organizations of multiple stakeholders that work together to transform health care at the local level by promoting quality and efficiency of care, and by measuring and publishing quality information. Consequently, we have examined available information related to those programs to inform our assumptions, although there is only limited available data that is directly applicable to this analysis.

We estimate that 35 organizations would submit applications to participate as qualified entities. We anticipate that the majority of applicants would be nonprofit organizations such as existing community collaboratives. In estimating qualified entity impacts, we used hourly labor costs in several labor categories reported by the Bureau of Labor Statistics (BLS) at *http://*

data.bls.gov/pdq/querytool.jsp?survey=ce. We used the annual rates for 2010, an update from the proposed rule where we used rates from 2009, and added 33 percent for overhead and fringe benefit costs. These rates are displayed in Table 2.

TABLE 2—LABOR RATES FOR QUALIFIED ENTITY IMPACT ESTIMATES

	2010 hourly wage rate (BLS)	OH and fringe (33%)	Total hourly costs
Professional & technical services	$34.63	$11.43	$46.06
Legal review	35.98	11.87	47.85
Custom computer programming	40.50	13.37	53.87
Data processing & hosting	31.57	10.42	41.99
Other information services	33.55	11.07	44.62

We estimate that preparation of an application would require a total of 500 hours of effort, requiring a combination of staff in the professional and technical services and the legal labor categories.

We estimate that 25 of these applicants would be approved as participating qualified entities, and that each qualified entity would request Medicare claims data accompanied by payment for these data. Because of the eligibility criteria we are proposing for qualified entities, we believe that it is likely that all of these organizations would already be performing work related to calculation of quality measures and production of performance reports for health care providers and suppliers, so the impact of the program established by section 1874(e) of the Act would be an opportunity to add Medicare claims data to their existing function.

The statute directs that the fees for these data be equal to the government's cost to make the data available. We are proposing to initially provide ten quarters of data to qualified entities with quarterly updates thereafter. Based on CMS past experience providing Medicare data to research entities, we estimate that the total approximate costs to provide ten quarters (CY 2009, CY 2010, and Q1–Q2 CY2011) of data for 2.5 million beneficiaries to a qualified entity would be $24,000. Qualified entities would also get 2 quarterly updates, each for a fee of $8,000, during the year, bringing the total cost of data for the first year of the program to $40,000 as shown in Table 3.

We estimate that, on average, each qualified entity's activity to analyze the Medicare claims data, calculate performance measures and produce provider and supplier performance reports would require 5,500 hours of effort. We estimate that half of the qualified entities (13) would propose alternative performance measures, which would involve an additional 2,100 hours of effort for each entity.

We further estimate that, on average, each qualified entity would expend 5,000 hours of effort processing providers' and suppliers' appeals of their performance reports and producing revised reports, and 2,000 hours making information about the performance measures publicly available. These estimates assume that, as discussed below in the section on provider and supplier impacts, on average 25 percent of providers and suppliers would appeal their results from a qualified entity. These assumptions are based on a belief that in the first year of the program many providers or suppliers would want to appeal their results prior to performance reports being made available to the public. Responding to these appeals in an appropriate manner would require a significant investment of time on the part of qualified entities. This equates to an average of four hours per appeal for each qualified entity. We assume that the complexity of appeals would vary greatly, and as such, the time required to address them would also vary greatly. Many appeals may be able to be dealt with in an hour or less while some appeals may require multiple meetings between the qualified entity and the affected provider or supplier. On average however, we believe that this is a realistic and reasonable estimate of the burden of the appeals process on qualified entities. We discuss the burden of the appeals process on providers and suppliers below.

We anticipate that qualified entities would expend 2,000 hours of effort developing their proposed performance report. These estimated hours are separated into labor categories in Table 3 below, with the pertinent hourly labor rates and cost totals.

Finally, we estimate that each qualified entity would spend 255 hours of effort submitting information to CMS for monitoring purposes. This would include audits and site visits as discussed above. It would also include an annual report that contains measures of general program adherence, measures of the provider and suppliers data sharing, error correction, and appeals process, and measures of the success of the program with consumers. Finally, qualified entities would be required to notify CMS of inappropriate disclosures or use of beneficiary identifiable data pursuant to the requirements in the DUA. We believe that many of the required data elements in both the annual report and the report generated in response to an inappropriate disclosure or use of beneficiary identifiable data would be generated as a matter of course by the qualified entities and therefore, would not require significant additional effort. Based on the assumptions we have described, we estimate the total impact on qualified entities for the first year of the program to be a cost of $45,504,048.

TABLE 3—IMPACT ON QUALIFIED ENTITIES FOR THE FIRST YEAR OF THE PROGRAM

[Impact on qualified entities]

Activity	Hours				Labor hourly cost	Cost per applicant	Number of applicants	Total cost impact
	Professional and technical	Legal	Computer programming	Data processing and hosting				
APPLICATION COSTS								
Preparation of application by candidate qualified entities								
a. Prepare draft application	360				$46.06	$16,582		
b. Legal review		40			47.85	1,914		
c. Revisions to draft application	60				46.06	2,764		
d. Senior management review and signature	40				46.06	1,842		
Total: application preparation	460	40				23,102	35	$808,556
Medicare data purchase costs by approved qualified entities						40,000	25	1,000,000
Total: Applications								1,808,556
QE OPERATIONS COSTS								
Database administration				500	41.99	20,995	25	524,875
Data analysis/measure calculation/report preparation			2500		53.87	134,675	25	3,366,875
				2500	41.99	104,975	25	2,624,375
Development and submission of alternative measures	1000				46.06	46,060	13	598,780
			100	1000	53.87	5,387	13	70,031
					41.99	41,990	13	545,870
Qualified entity processing of provider or supplier appeals and report revision	4000				46.06	184,240	25	4,606,000
		1000			47.85	47,850	25	1,196,250
Development of proposed performance report formats	1000				46.06	46,060	25	1,151,500
			1000		53.87	53,870	25	1,346,750
Publication of performance reports			1000		53.87	53,870	25	1,346,750
				1000	41.99	41,990	25	1,049,750
Monitoring				255	41.99	10,707	25	267,686
Computer hardware and processing						1,000,000	25	25,000,000
Total: Operations								43,695,492
TOTAL QUALIFIED ENTITY IMPACTS (application plus operations)								45,504,048

b. Impact on Health Care Providers and Suppliers

Table 4 reflects the hourly labor rates used in our estimate of the impacts of the first year of section 1874(e) of the Act on health care providers and suppliers, as well as the professional and technical services of consultants. The rates in Table 4 are for 2010 and have been updated from the proposed rule where we used rates for 2009. We note that numerous health care payers, community quality collaboratives, States, and other organizations are producing performance measures for health care providers and suppliers using data from other sources, and that providers and suppliers are already receiving performance reports from these sources. We anticipate that the Medicare claims data would merely be added to those existing efforts to improve the statistical validity of the measure findings, and therefore the impact of including Medicare claims data in these existing performance reporting processes is likely to be marginal. Additionally, while we acknowledge that reviewing and appealing the reports will be a burden for providers and suppliers, we also note that there are many benefits of this program for providers and suppliers, as well as the Medicare program, consumers, and purchasers. As a result of this program, providers and suppliers will likely receive one report covering a majority of their patients, rather than a report from each payer. Furthermore, the transparency of performance results will help providers and suppliers improve quality and reduce costs.

TABLE 4—LABOR RATES FOR PROVIDER AND SUPPLIER IMPACT ESTIMATES

	2010 hourly wage rate (BLS)	Overhead and fringe benefits (33%)	Total hourly costs
Labor Rates for Provider and Supplier Impact Estimates			
Physicians' offices	$32.24	$10.64	$42.88
Hospitals	27.42	9.05	36.47
Professional and technical services	34.63	11.43	46.06

We anticipate that the impacts on providers and suppliers consist of costs to review the performance reports generated by qualified entities and, if they choose, appeal their performance calculations. Based on a review of available information from the Better Quality Information and the Charter Value Exchange programs, we estimate that, on average, each qualified entity would distribute performance reports to 5,000 health providers and suppliers. We anticipate that the largest proportion of providers and suppliers would be physicians because they comprise the largest group of providers and suppliers, and are a primary focus of many recent performance evaluation efforts. Based on our review of information from these existing programs, we assume that 95 percent of the recipients of performance reports (that is, an average of 4,750 per qualified entity) would be physicians, and 5 percent (that is, an average of 250 per qualified entity) would be hospitals and other suppliers. Providers and suppliers receive these reports with no obligation to review them, but we assume that most would do so to verify that their calculated performance measures reflect their actual patients and health events. We estimate that, on average, each provider or supplier would devote five hours to reviewing these reports. This average reflects that some providers and suppliers will spend less than half an hour reviewing reports, while others may spend 10 hours.

We estimate that 25 percent of the providers and suppliers would decide to appeal their performance calculations, and that preparing the appeal would involve an average of ten hours of effort on the part of a provider or supplier. We assume that 50 percent of the providers and suppliers who decide to appeal would hire consultants to assist with the appeals process. As with our assumptions regarding the level of effort required by qualified entities in operating the appeals process, we believe that this average covers a range of provider and supplier efforts from those who would need just one or two hours to clarify any questions or concerns regarding their performance reports to those who would devote significant time and resources to the appeals process.

Using the hourly costs displayed in Table 4, the impacts on providers and suppliers are calculated below in Table 5. Based on the assumptions we have described, we estimate the total impact on providers and suppliers for the first year of the program to be a cost of $40,458,400.

As stated above in Table 3, we estimate the total impact on qualified entities to be a cost of $45,504,048. Therefore, the total impact on qualified entities and on providers and suppliers for the first year of the program is estimated to be $85,962,448.

TABLE 5—IMPACT ON PROVIDERS AND SUPPLIERS FOR THE FIRST YEAR OF THE PROGRAM

Activity	Hours per provider			Labor hourly cost	Cost per applicant	Number of providers per qualified entity	Number of qualified entities	Total cost impact
	Physician offices	Hospitals	Professional and technical					
Impact on Providers and Suppliers								
Provider review of performance reports	5			$42.88	$214	4,750	25	$25,460,000
		5		36.47	182	250	25	1,139,688
Preparing and submitting appeal request to qualified entities	10			42.88	429	594	25	6,367,680
		10		36.47	365	31	25	282,643
			10	46.06	461	626	25	7,208,390
Total provider impacts								40,458,400

D. Alternatives Considered

The statutory provisions that were added by section 1874(e) of the Act are detailed and prescriptive about the eligibility for, and requirements of the qualified entity program. Consequently, we believe there are limited alternative approaches that would ensure program success and statutory compliance. We considered proposing a less comprehensive set of eligibility criteria for qualified entities (for example, eliminating requirements that applicants demonstrate capabilities related to calculation of measures, developing performance reports, combining Medicare claims data with other claims, and data privacy and security protection). While such an approach might have reduced certain application and operating costs for these entities, we did not adopt such an approach for several reasons. An important consideration is the protection of beneficiary identifiable data. We believe if we do not require qualified entities to provide sufficient

evidence of data privacy and security protection capabilities, there would be increased risks related to the protection of beneficiary identifiable data.

Additionally, we believe that requiring less stringent requirements regarding the production and reporting of measures would lead to increases in the number of provider and supplier appeals, and consequently in appeals-related costs for providers, suppliers and qualified entities. We expect that such a scenario would not support the development of a cooperative relationship between qualified entities and providers and suppliers.

E. Conclusion

As explained above, we estimate the total impact for the first year of the program on qualified entities, providers and suppliers to be a cost of $85,962,448. Based on these estimates, we conclude this final rule does not reach the threshold for economically significant effects and thus is not considered a major rule.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 401

Claims, Freedom of information, Health facilities, Medicare, Privacy.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 401—GENERAL ADMINISTRATIVE REQUIREMENTS

■ 1. The authority citation for part 401 is revised to read as follows:

Authority: Secs. 1102, 1871, and 1874(e) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395w–5).

■ 2. A new subpart G is added to part 401 to read as follows:

Subpart G—Availability of Medicare Data for Performance Measurement

Sec.

401.701 Purpose and scope.
401.703 Definitions.
401.705 Eligibility criteria for qualified entities.
401.707 Operating and governance requirements for qualified entities.
401.709 The application process and requirements.
401.711 Updates to plans submitted as part of the application process.
401.713 Ensuring the privacy and security of data.
401.715 Selection and use of performance measures.
401.717 Provider and supplier requests for error correction.
401.719 Monitoring and sanctioning of qualified entities.
401.721 Terminating an agreement with a qualified entity.

Subpart G—Availability of Medicare Data for Performance Measurement

§ 401.701 Purpose and scope.

The regulations in this subpart implement section 1874(e) of the Social Security Act as it applies to Medicare data made available to qualified entities for the evaluation of the performance of providers and suppliers.

§ 401.703 Definitions.

For purposes of this subpart:

(a) *Qualified entity* means either a single public or private entity, or a lead entity and its contractors, that meets the following requirements:

(1) Is qualified, as determined by the Secretary, to use claims data to evaluate the performance of providers and suppliers on measures of quality, efficiency, effectiveness, and resource use.

(2) Agrees to meet the requirements described in this subpart at §§ 401.705 through 401.721.

(b) *Provider of services (referred to as a provider)* has the same meaning as the term ''provider'' in § 400.202 of this chapter.

(c) *Supplier* has the same meaning as the term ''supplier'' at § 400.202 of this chapter.

(d) *Claim* means an itemized billing statement from a provider or supplier that, except in the context of Part D prescription drug event data, requests payment for a list of services and supplies that were furnished to a Medicare beneficiary in the Medicare fee-for-service context, or to a participant in other insurance or entitlement program contexts. In the Medicare program, claims files are available for each institutional (inpatient, outpatient, skilled nursing facility, hospice, or home health agency) and non-institutional (physician and durable medical equipment providers and suppliers) claim type as well as Medicare Part D Prescription Drug Event (PDE) data.

(e) *Standardized data extract* is a subset of Medicare claims data that the Secretary would make available to qualified entities under this subpart.

(f) *Beneficiary identifiable data* is any data that contains the beneficiary's name, Medicare Health Insurance Claim Number (HICN), or any other direct identifying factors, including, but not limited to postal address or telephone number.

(g) *Encrypted data* is any data that does not contain the beneficiary's name or any other direct identifying factors, but does include a unique CMS-assigned beneficiary identifier that allows for the linking of claims without divulging any direct identifier of the beneficiary.

(h) *Claims data from other sources* means provider- or supplier-identifiable claims data that an applicant or qualified entity has full data usage right to due to its own operations or disclosures from providers, suppliers, private payers, multi-payer databases, or other sources.

(i) *Clinical data* is registry data, chart-abstracted data, laboratory results, electronic health record information, or other information relating to the care or services furnished to patients that is not included in administrative claims data, but is available in electronic form.

§ 401.705 Eligibility criteria for qualified entities.

(a) *Eligibility criteria:* To be eligible to apply to receive data as a qualified entity under this subpart, an applicant generally must demonstrate expertise and sustained experience, defined as 3 or more years, in the following three areas, as applicable and appropriate to the proposed use:

(1) Organizational and governance criteria, including:

(i) Expertise in the areas of measurement that they propose to use in accurately calculating quality, and efficiency, effectiveness, or resource use measures from claims data, including the following:

(A) Identifying an appropriate method to attribute a particular patient's services to specific providers and suppliers.

(B) Ensuring the use of approaches to ensure statistical validity such as a minimum number of observations or minimum denominator for each measure.

(C) Using methods for risk-adjustment to account for variations in both case-mix and severity among providers and suppliers.

(D) Identifying methods for handling outliers.

(E) Correcting measurement errors and assessing measure reliability.

(F) Identifying appropriate peer groups of providers and suppliers for meaningful comparisons.

(ii) A plan for a business model that is projected to cover the costs of performing the required functions, including the fee for the data.

(iii) Successfully combining claims data from different payers to calculate performance reports.

(iv) Designing, and continuously improving the format of performance reports on providers and suppliers.

(v) Preparing an understandable description of the measures used to evaluate the performance of providers and suppliers so that consumers, providers and suppliers, health plans, researchers, and other stakeholders can assess performance reports.

(vi) Implementing and maintaining a process for providers and suppliers identified in a report to review the report prior to publication and providing a timely response to provider and supplier inquiries regarding requests for data, error correction, and appeals.

(vii) Establishing, maintaining, and monitoring a rigorous data privacy and security program, including disclosing to CMS any inappropriate disclosures of beneficiary identifiable information, violations of applicable federal and State privacy and security laws and regulations for the preceding 10-year period (or, if the applicant has not been in existence for 10 years, the length of time the applicant has been an organization), and any corrective actions taken to address the issues.

(viii) Accurately preparing performance reports on providers and suppliers and making performance report information available to the public in aggregate form, that is, at the provider or supplier level.

(2) Expertise in combining Medicare claims data with claims data from other sources, including demonstrating to the Secretary's satisfaction that the claims data from other sources that it intends to combine with the Medicare data received under this subpart address the methodological concerns regarding sample size and reliability that have been expressed by stakeholders regarding the calculation of performance measures from a single payer source.

(3) Expertise in establishing, documenting and implementing rigorous data privacy and security policies including enforcement mechanisms.

(b) *Source of expertise and experience:* An applicant may demonstrate expertise and experience in any or all of the areas described in paragraph (a) of this section through one of the following:

(1) Activities it has conducted directly through its own staff.

(2) Contracts with other entities if the applicant is the lead entity and includes documentation in its application of the contractual arrangements that exist between it and any other entity whose expertise and experience is relied upon in submitting the application.

§ 401.707 Operating and governance requirements for qualified entities.

A qualified entity must meet the following operating and governance requirements:

(a) Submit to CMS a list of all measures it intends to calculate and report, the geographic areas it intends to serve, and the methods of creating and disseminating reports. This list must include the following information, as applicable and appropriate to the proposed use:

(1) Name of the measure, and whether it is a standard or alternative measure.

(2) Name of the measure developer/owner.

(3) If it is an alternative measure, measure specifications, including numerator and denominator.

(4) The rationale for selecting each measure, including the relationship to existing measurement efforts and the relevancy to the population in the geographic area(s) the entity would serve, including the following:

(i) A specific description of the geographic area or areas it intends to serve.

(ii) A specific description of how each measure evaluates providers and suppliers on quality, efficiency, effectiveness, and/or resource use.

(5) A description of the methodologies it intends to use in creating reports with respect to all of the following topics:

(i) Attribution of beneficiaries to providers and/or suppliers.

(ii) Benchmarking performance data, including the following:

(A) Methods for creating peer groups.

(B) Justification of any minimum sample size determinations made.

(C) Methods for handling statistical outliers.

(iii) Risk adjustment, where appropriate.

(iv) Payment standardization, where appropriate.

(b) Submit to CMS a description of the process it would establish to allow providers and suppliers to view reports confidentially, request data, and ask for the correction of errors before the reports are made public.

(c) Submit to CMS a prototype report and a description of its plans for making the reports available to the public.

(d) Submit to CMS information about the claims data it possesses from other sources, as defined at § 401.703(h), and documentation of adequate rights to use the other claims data for the purposes of this subpart.

(e) If requesting a 5 percent national sample to calculate benchmarks for the specific measures it is using, submit to CMS a justification for needing the file to calculate benchmarks.

§ 401.709 The application process and requirements.

(a) *Application deadline.* CMS accepts qualified entity applications on a rolling basis after an application is made available on the CMS Web site. CMS reviews applications in the order in which they are received.

(b) *Selection criteria.* To be approved as a qualified entity under this subpart, the applicant must meet one of the following:

(1) *Standard approval process:* Meet the eligibility and operational and governance requirements, fulfill all of the application requirements to CMS' satisfaction, and agree to pay a fee equal to the cost of CMS making the data available. The applicant and each of its contractors that are anticipated to have access to the Medicare data must also execute a Data Use Agreement with CMS, that among other things, reaffirms the statutory ban on the use of Medicare data provided to the qualified entity by CMS under this subpart for purposes other than those referenced in this subpart.

(2) *Conditional approval process:* Meet the eligibility and operational and governance requirements, and fulfill all of the application requirements to CMS' satisfaction, with the exception of possession of sufficient claims data from other sources. Meeting these requirements will result in a conditional approval as a qualified entity. Entities gaining a conditional approval as a qualified entity must meet the eligibility requirements related to claims data from other sources the entity intends to combine with the Medicare data, agree to pay a fee equal to the cost of CMS making the data available, and execute a Data Use Agreement with CMS, that among other things, reaffirms the statutory ban on the use of Medicare data provided to the qualified entity by CMS under this subpart for purposes other than those referenced in this subpart before receiving any Medicare data. If the qualified entity is composed of lead entity with contractors, any contractors that are anticipated to have access to the Medicare data must also execute a Data Use Agreement with CMS.

(c) *Duration of approval.* CMS permits an entity to participate as a qualified entity for a period of 3 years from the date of notification of the application approval by CMS. The qualified entity must abide by all CMS regulations and instructions. If the qualified entity wishes to continue performing the tasks after the 3-year approval period, the entity may re-apply for qualified entity status following the procedures in paragraph (f) of this section.

(d) *Reporting period.* A qualified entity must produce reports on the performance of providers and suppliers at least annually, beginning in the calendar year after they are approved by CMS.

(e) *The distribution of data.*—(1) *Initial data release.* Once CMS fully approves a qualified entity under this subpart, the qualified entity must pay a fee equal to the cost of CMS making data available. After the qualified entity pays the fee, CMS will release the applicable encrypted claims data, as well as a file that crosswalks the encrypted beneficiary ID to the beneficiary name and the Medicare HICN. The data will be the most recent data available, and will be limited to the geographic spread of the qualified entity's other claims data, as determined by CMS.

(2) *Subsequent data releases.* After the first quarter of participation, CMS will provide a qualified entity with the most recent additional quarter of currently available data, as well as a table that crosswalks the encrypted beneficiary ID to the beneficiary's name and the Medicare HICN. Qualified entities are required to pay CMS a fee equal to the cost of making data available before CMS will release the most recent quarter of additional data to the qualified entity.

(f) *Re-application.* A qualified entity that is in good standing may re-apply for qualified entity status. A qualified entity is considered to be in good standing if it has had no violations of the requirements in this subpart or if the qualified entity is addressing any past deficiencies either on its own or through the implementation of a corrective action plan. To re-apply a qualified entity must submit to CMS documentation of any changes to what was included in its previously-approved application. A re-applicant must submit this documentation at least 6 months before the end of its 3-year approval period and will be able to continue to serve as a qualified entity until the re-application is either approved or denied by CMS. If the re-application is denied, CMS will terminate its relationship with the qualified entity and the qualified entity will be subject to the requirements for return or destruction of data at § 401.721(b).

§ 401.711 Updates to plans submitted as part of the application process.

(a) If a qualified entity wishes to make changes to the following parts of its previously-approved application:

(1) Its list of proposed measures—the qualified entity must send all the information referenced in § 401.707(a) for the new measures to CMS at least 30 days before its intended confidential release to providers and suppliers.

(2) Its proposed prototype report—the qualified entity must send the new prototype report to CMS at least 30 days before its intended confidential release to providers and suppliers.

(3) Its plans for sharing the reports with the public—the qualified entity must send the new plans to CMS at least 30 days before its intended confidential release to providers and suppliers.

(b) CMS will notify the qualified entity when the entity's proposed changes are approved or denied for use, generally within 30 days of the qualified entity submitting the changes to CMS. If a CMS decision on approval or disapproval for a change is not forthcoming within 30 days and CMS does not request an additional 30 days for review, the change or modification shall be deemed to be approved.

(c) If the amount of claims data from other sources available to a qualified entity decreases, the qualified entity must immediately inform CMS and submit documentation that the remaining claims data from other sources is sufficient to address the methodological concerns regarding sample size and reliability. Under no circumstances may a qualified entity use Medicare data to create a report, use a measure, or share a report after the amount of claims data from other sources available to a qualified entity decreases until CMS determines either that the remaining claims data is sufficient or that the qualified entity has collected adequate additional data to address any deficiencies.

(1) If the qualified entity cannot submit the documentation required in paragraph (c) of this section, or if CMS determines that the remaining claims data is not sufficient, CMS will afford the qualified entity up to 120 days to obtain additional claims to address any deficiencies. If the qualified entity does not have access to sufficient new data after that time, CMS will terminate its relationship with the qualified entity.

(2) If CMS determines that the remaining claims data is sufficient, the qualified entity may continue issuing reports, using measures, and sharing reports.

§ 401.713 Ensuring the privacy and security of data.

(a) A qualified entity must comply with the data requirements in its data use agreement (DUA) with CMS. Contractors of qualified entities that are anticipated to have access to the Medicare claims data or beneficiary identifiable data in the context of this program are also required to execute and comply with the DUA. The DUA will require the qualified entity to maintain privacy and security protocols throughout the duration of the agreement with CMS and will ban the use of data for purposes other than those set out in this subpart. The DUA will also prohibit the use of unsecured telecommunications to transmit CMS data and will specify the circumstances under which CMS data must be stored and transmitted.

(b) A qualified entity must inform each beneficiary whose beneficiary identifiable data has been (or is reasonably believed to have been) inappropriately accessed, acquired, or disclosed in accordance with the DUA.

(c) Contractor(s) must report to the qualified entity whenever there is an incident where beneficiary identifiable data has been (or is reasonably believed to have been) inappropriately accessed, acquired, or disclosed.

§ 401.715 Selection and use of performance measures.

(a) *Standard measures.* A standard measure is a measure that can be calculated in full or in part from claims data from other sources and the standardized extracts of Medicare Parts A and B claims, and Part D prescription drug event data and meets the following requirements:

(1) Meets one of the following criteria:

(i) Is endorsed by the entity with a contract under section 1890(a) of the Social Security Act.

(ii) Is time-limited endorsed by the entity with a contract under section 1890(a) of the Social Security Act until such time as the full endorsement status is determined.

(iii) Is developed under section 931 of the Public Health Service Act.

(iv) Can be calculated from standardized extracts of Medicare Parts A or B claims or Part D prescription drug event data, was adopted through notice-and-comment rulemaking, and is currently being used in CMS programs that include quality measurement.

(v) Is endorsed by a CMS-approved consensus-based entity. CMS will approve organizations as consensus-based entities based on review of documentation of the consensus-based entity's measure approval process. To receive approval as a consensus-based entity, an organization must submit information to CMS documenting its processes for stakeholder consultation and measures approval; an organization will only receive approval as a consensus-based entity if all measure specifications are publically available. An organization will retain CMS acceptance as a consensus-based entity

for 3 years after the approval date, at which time CMS will review new documentation of the consensus-based entity's measure approval process for a new 3-year approval.

(2) Is used in a manner that follows the measure specifications as written (or as adopted through notice-and-comment rulemaking), including all numerator and denominator inclusions and exclusions, measured time periods, and specified data sources.

(b) *Alternative measure.* (1) An alternative measure is a measure that is not a standard measure, but that can be calculated in full, or in part, from claims data from other sources and the standardized extracts of Medicare Parts A and B claims, and Part D prescription drug event data, and that meets one of the following criteria:

(i) *Rulemaking process:* Has been found by the Secretary, through a notice-and comment-rulemaking process, to be more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by standard measures, and is used by a qualified entity in a manner that follows the measure specifications as adopted through notice-and-comment rulemaking, including all numerator and denominator inclusions and exclusions, measured time periods, and specified data sources.

(ii) *Stakeholder consultation approval process:* Has been found by the Secretary, using documentation submitted by a qualified entity that outlines its consultation and agreement with stakeholders in its community, to be more valid, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by standard measures, and is used by a qualified entity in a manner that follows the measure specifications as submitted, including all numerator and denominator inclusions and exclusions, measured time periods, and specified data sources. If a CMS decision on approval or disapproval of alternative measures submitted using the stakeholder consultation approval process is not forthcoming within 60 days of submission of the measure by the qualified entity, the measure will be deemed approved. However, CMS retains the right to disapprove a measure if, even after 60 days, we find it to not be ''more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource'' than a standard measure.

(2) An alternative measure approved under the process at paragraph (b)(1)(i) of this section may be used by any qualified entity. An alternative measure approved under the process at paragraph (b)(1)(ii) of this section may only be used by the qualified entity that submitted the measure for consideration by the Secretary. A qualified entity may use an alternative measure up until the point that an equivalent standard measure for the particular clinical area or condition becomes available at which point the qualified entity must switch to the standard measure within 6 months or submit additional scientific justification and receive approval, via either paragraphs (b)(1)(i) or (b)(1)(ii) of this section, from the Secretary to continue using the alternative measure.

(3) To submit an alternative measure for consideration under the notice-and-comment-rulemaking process, for use in the calendar year following the submission, an entity must submit the following information by May 31st:

(i) The name of the alternative measure.

(ii) The name of the developer or owner of the alternative measure.

(iii) Detailed specifications for the alternative measure.

(iv) Evidence that use of the alternative measure would be more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by standard measures.

(4) To submit an alternative measure for consideration under the documentation of stakeholder consultation approval process described in paragraph (b)(1)(ii) of this section, for use once the measure is approved by the Secretary, an entity must submit the following information to CMS:

(i) The name of the alternative measure.

(ii) The name of the developer or owner of the alternative measure.

(iii) Detailed specifications for the alternative measure.

(iv) A description of the process by which the qualified entity notified stakeholders in the geographic region it serves of its intent to seek approval of an alternative measure. Stakeholders must include a valid cross representation of providers, suppliers, payers, employers, and consumers.

(v) A list of stakeholders from whom feedback was solicited, including the stakeholders' names and roles in the community.

(vi) A description of the discussion about the proposed alternative measure, including a summary of all pertinent arguments supporting and opposing the measure.

(vii) Unless CMS has already approved the same measure for use by another qualified entity, no new scientific evidence on the measure is available, and the subsequent qualified entity wishes to rely upon the scientific evidence submitted by the previously approved applicant, an explanation backed by scientific evidence that demonstrates why the measure is more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by a standard measure.

§ 401.717 Provider and supplier requests for error correction.

(a) A qualified entity must confidentially share measures, measurement methodologies, and measure results with providers and suppliers at least 60 calendar days before making reports public. The 60 calendar days begin on the date on which qualified entities send the confidential reports to providers and suppliers. A qualified entity must inform providers and suppliers of the date the reports will be made public at least 60 calendar days before making the reports public.

(b) Before making the reports public, a qualified entity must allow providers and suppliers the opportunity to make a request for the data, or to make a request for error correction, within 60 calendar days after sending the confidential reports to providers or suppliers.

(c) During the 60 calendar days between sending a confidential report on measure results and releasing the report to the public, the qualified entity must, at the request of a provider or supplier and with appropriate privacy and security protections, release the Medicare claims data and beneficiary names to the provider or supplier. Qualified entities may only provide the Medicare claims and/or beneficiary names relevant to the particular measure or measure result the provider or supplier is appealing.

(d) A qualified entity must inform providers and suppliers that reports will be made public, including information related to the status of any data or error correction requests, after the date specified to the provider or supplier when the report is sent for review and, if necessary, error correction requests (at least 60 calendar days after the report was originally sent to the providers and suppliers), regardless of the status of any requests for error correction.

(e) If a provider or supplier has a data or error correction request outstanding at the time the reports become public, the qualified entity must, if feasible, post publicly the name of the appealing

provider or supplier and the category of the appeal request.

§ 401.719 Monitoring and sanctioning of qualified entities.

(a) CMS will monitor and assess the performance of qualified entities and their contractors using the following methods:

(1) Audits.

(2) Submission of documentation of data sources and quantities of data upon the request of CMS and/or site visits.

(3) Analysis of specific data reported to CMS by qualified entities through annual reports (as described in paragraph (b) of this section) and reports on inappropriate disclosures or uses of beneficiary identifiable data (as described in paragraph (c) of this section).

(4) Analysis of complaints from beneficiaries and/or providers or suppliers.

(b) A qualified entity must provide annual reports to CMS containing information related to the following:

(1) General program adherence, including the following information:

(i) The number of Medicare and private claims combined.

(ii) The percent of the overall market share the number of claims represent in the qualified entity's geographic area.

(iii) The number of measures calculated.

(iv) The number of providers and suppliers profiled by type of provider and supplier.

(v) A measure of public use of the reports.

(2) The provider and supplier data sharing, error correction, and appeals process, including the following information:

(i) The number of providers and suppliers requesting claims data.

(ii) The number of requests for claims data fulfilled.

(iii) The number of error corrections.

(iv) The type(s) of problem(s) leading to the request for error correction.

(v) The amount of time to acknowledge the request for data or error correction.

(vi) The amount of time to respond to the request for error correction.

(vii) The number of requests for error correction resolved.

(c) A qualified entity must inform CMS of inappropriate disclosures or uses of beneficiary identifiable data under the DUA.

(d) CMS may take the following actions against a qualified entity if CMS determines that the qualified entity violated any of the requirements of this subpart, regardless of how CMS learns of a violation:

(1) Provide a warning notice to the qualified entity of the specific concern, which indicates that future deficiencies could lead to termination.

(2) Request a corrective action plan (CAP) from the qualified entity.

(3) Place the qualified entity on a special monitoring plan.

(4) Terminate the qualified entity.

§ 401.721 Terminating an agreement with a qualified entity.

(a) *Grounds for terminating a qualified entity agreement.* CMS may terminate an agreement with a qualified entity if CMS determines the qualified entity or its contractor meets any of the following:

(1) Engages in one or more serious violations of the requirements of this subpart.

(2) Fails to completely and accurately report information to CMS or fails to make appropriate corrections in response to confidential reviews by providers and suppliers in a timely manner.

(3) Fails to submit an approvable corrective action plan (CAP) as prescribed by CMS, fails to implement an approved CAP, or fails to demonstrate improved performance after the implementation of a CAP.

(4) Improperly uses or discloses claims information received from CMS in violation of the requirements in this subpart.

(5) Based on its re-application, no longer meets the requirements in this subpart.

(6) Fails to maintain adequate data from other sources in accordance with § 401.711(c).

(b) *Return or destruction of CMS data upon voluntary or involuntary termination from the qualified entity program:*

(1) If CMS terminates a qualified entity's agreement, the qualified entity and its contractors must immediately upon receipt of notification of the termination commence returning or destroying any and all CMS data (and any derivative files). In no instance can this process exceed 30 days.

(2) If a qualified entity voluntarily terminates participation under this subpart, it and its contractors must return to CMS, or destroy, any and all CMS data in its possession within 30 days of notifying CMS of its intent to end its participation.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 1, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: November 29, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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Part IV

Department of Health and Human Services

45 CFR Part 158

Medical Loss Ratio Requirements Under the Patient Protection and Affordable Care Act; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 158

[CMS–9998–FC]

RIN 0938–AQ71

Medical Loss Ratio Requirements Under the Patient Protection and Affordable Care Act

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period revises the regulations implementing medical loss ratio (MLR) requirements for health insurance issuers under the Public Health Service Act in order to address the treatment of ''mini-med'' and expatriate policies under these regulations for years after 2011; modify the way the regulations treat ICD–10 conversion costs; change the rules on deducting community benefit expenditures; and revise the rules governing the distribution of rebates by issuers in group markets.

DATES: *Effective date.* This rule is effective on January 3, 2012.

Comment date. We will consider comments on § 158.150(b)(2)(i)(A)(*6*) and (c)(5) regarding the treatment of ICD–10 conversion costs, and § 158.242(b) and § 158.260 regarding the process for providing rebates to group enrollees and reporting of rebates that are received at one of the addresses provided in the **ADDRESSES** section of this rule no later than 5 p.m. EST on January 6, 2012.

Applicability Date. The amendments to Part 158 generally apply beginning January 1, 2012, to health insurance issuers offering group or individual health insurance coverage.

ADDRESSES: In commenting please refer to file code CMS–9998–FC. Because of staff and resource limitations, we cannot accept comments by email or facsimile (Fax) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the ''More Search Options'' tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–9998–FC, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–9998–FC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments only to the following addresses prior to the close of comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (800) 743–3591.

FOR FURTHER INFORMATION CONTACT: Carol Jimenez, (301) 492–4457.

SUPPLEMENTARY INFORMATION:

Comment Subject Areas: We will consider comments on the treatment of ICD–10 conversion costs, and the process for providing rebates to group enrollees, as discussed in this final rule with comment period that are received by the date and time indicated in the **DATES** section of this final rule with comment period.

I. Background

The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010; the Health Care and Education Reconciliation Act (Pub. L. 111–152) was enacted on March 30, 2010. In this preamble, we refer to the two statutes collectively as the Affordable Care Act. The Affordable Care Act reorganizes, amends, and adds to the provisions of Part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets.

A request for information relating to the medical loss ratio (MLR) provisions of PHS Act section 2718 was published in the **Federal Register** on April 14, 2010 (75 FR 19297). On December 1, 2010, HHS published an interim final rule (75 FR 74864) with 60 day public comment period, entitled ''Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act,'' that added a new 45 CFR Part 158. A technical correction to the interim final rule was issued on December 30, 2010 (75 FR 82277).

II. Provisions of the Interim Final Rule and Responses to Comments

We received approximately 90 public comments on the December 1, 2010 interim final rule with comment period. Commenters included consumer and patient organizations, insurance regulators, health insurance issuers, provider groups, actuarial professional group, and others. In this final rule, we do not address all of the comments we received on the interim final rule, but only those comments that pertain to the provisions in this final rule: (1) Rules regarding the treatment of ''mini-med'' and expatriate policies; (2) rules governing how ICD–10 conversion costs, fraud reduction expenses, and community benefit expenditures are accounted for; and (3) rules regarding

the distribution of rebates in group markets. In this section of the preamble, we summarize the provisions of the interim final rule and respond to the public comments received on these subjects.

A. ''Mini-med'' Policies (45 CFR 158.110(b)(2), 158.120(d)(3), and 158.221(b)(3))

For purposes of the MLR requirements, the interim final rule provided separate treatment for mini-med policies with total annual benefit limits of $250,000 or less by requiring issuers to report mini-med experience separately from other experience, by State and by market, for the 2011 MLR reporting year. Issuers of mini-med policies with total annual benefit limits of $250,000 or less were also directed to use a special methodology for calculating the MLR numerator for calendar year 2011 reporting and rebate purposes. Specifically, incurred claims and activities that improve health care quality are multiplied by 2.00 in calculating the MLR for mini-med policies. Issuers of mini-med policies were directed to submit a report for each of the first three quarters of the 2011 MLR reporting year as provided under § 158.110(b), in addition to the annual report required of all issuers subject to MLR standards. The authority for this treatment of special circumstances is provided under section 2718(c) of the PHS Act, which directs HHS to ''take into account the special circumstances of smaller plans, different types of plans, and newer plans.''

The preamble to the interim final rule notes that, after reviewing the quarterly filings of the mini-med policies' 2011 experience, CMS would make a determination as to whether this treatment of special circumstances should continue and, if so, whether it should be modified beyond the 2011 MLR reporting year.

Comment: We received comments that both support and oppose an adjustment for issuers of mini-med policies. Commenters that supported a special methodology for mini-med experience generally claimed that the unique cost structure of mini-med policies make issuers unable to meet the statutory MLR without an adjustment to the reporting methodology. Specifically, issuers of mini-med policies asserted that such plans have higher administrative costs relative to benefits paid, as compared to other more comprehensive coverage, as a result of—(1) Higher enrollee turnover; (2) shorter enrollment periods; and (3) lower incurred claims due to high deductibles and limited coverage. Two commenters asserted that an adjustment is necessary to preserve access to mini-med policies for employers and participants.

Three commenters requested that HHS extend until 2014 the 2011 special circumstances methodology of a multiplier of 2.00 for mini-med policies. These commenters stated that the unique structure of these plans would remain consistent between 2011 and 2014, after which a total prohibition on annual dollar limits under PHS Act section 2711 will be in effect, other than for grandfathered plans in the individual market. These commenters asserted that without this MLR treatment for the interim years, before new coverage options and premium tax credits are available through the Affordable Insurance Exchanges, issuers may withdraw from the market. This withdrawal could leave employers unable to afford other health care coverage for their employees, leaving some consumers without affordable health care coverage that will be available to them in 2014.

Many commenters, however, opposed any continuation of this methodology for issuers of mini-med policies. Consumer advocates, healthcare organizations, and a labor organization asserted that mini-med policies do not need a special circumstances adjustment. They noted that issuers did not request such an adjustment during the public comment period of the National Association of Insurance Commissioners (NAIC) model rule making process and that the NAIC did not recommend such an adjustment. They also asserted that issuers of mini-med policies should be required to operate with the same efficiency as more robust policies and to meet the statutory MLR standard. Two commenters did not support extending the adjustment for mini-med policies any longer than 2014.

Response: In determining the appropriate treatment for mini-med policies with total annual benefit limits of $250,000 or less with respect to MLR, we considered commenters' concerns about loss of coverage if issuers of mini-med policies exit the market absent separate MLR treatment. We also considered commenters' concerns about the need for issuers to operate efficiently and provide valuable coverage.

In the interim final rule, we requested three quarters of data, including amount of premium spent on claims, quality improving activities, non-claims costs, and taxes. This final rule is being issued after receiving and analyzing two quarters of this data. We believe it is necessary to determine the final MLR policy as to the treatment of mini-med policies, despite the fact that we have not yet analyzed the third quarter data, because otherwise we could not issue rules in time for the special circumstances adjustment to be effective for 2012 and to minimize the chance that issuers may withdraw these policies due to uncertainty about MLR requirements. After analyzing the first and second quarter data, seeking to strike a balance that ensures continued access for consumers while ensuring that they receive value for their premium dollar, we have determined that in 2012, the appropriate multiplier for mini-med policy experience is 1.75, in 2013, the appropriate multiplier is 1.50, and in 2014, the appropriate multiplier is 1.25.

The Department only addresses mini-med policy experience for the 2012, 2013, and 2014 MLR reporting years. Section 2711 of the PHS Act provides that for policy years beginning on and after January 1, 2014, when the Affordable Insurance Exchanges will be in place to provide consumers with better, more affordable coverage options, non-grandfathered plans in all markets and grandfathered plans in the large and small group markets will no longer be permitted to have annual dollar limits. Thus, policies with annual limits under § 158.110(d)(3) will no longer exist in those markets. We have applied a multiplier through the 2014 MLR reporting year to account for mini-med policies with a plan year that begins after January 1, 2013 and ends sometime in 2014.

Based upon the data we received from the first and second quarterly reports of 2011, without any multiplier, in 2011, seven of the 12 issuers in the individual market, and six of the 15 issuers in the large group market would not meet the MLR of 80 and 85 percent, respectively. With the multiplier of 2.00, three of the 12 issuers in the individual market would not meet the MLR standard [1], and all issuers in the small group or large group market would meet the MLR standard.

A graduated allowance for an adjustment of 1.75 in 2012, 1.50 in 2013 and 1.25 in 2014 will incentivize issuers to reduce their administrative expenses and operate more efficiently to ensure that they meet the MLR standard while minimizing issuer market withdrawal, maintaining access to coverage for consumers and ensuring that they receive greater value from these policies

[1] This analysis takes into consideration issuers that operate in States which have been granted an adjustment to the MLR standard for the individual market, pursuant to § 158.301.

until 2014. We plan on publishing the data used in this analysis in the spring of 2012.

B. ''Expatriate'' Policies (45 CFR 158.110(b)(2), 158.120(d)(4), and 158.221(b)(4))

The interim final rule defines expatriate policies as ''group policies that provide coverage for employees working outside their country of citizenship, employees working outside of their country of citizenship and outside the employer's country of domicile, and non-U.S. citizens working in their home country * * *'' (45 CFR 158.120(d)(4)). Several public comments were received regarding the definition of expatriate policies. In this final rule, we are amending the definition of expatriate policies to read ''group policies that provide coverage to employees, substantially all of whom are: Working outside their country of citizenship; working outside of their country of citizenship and outside the employer's country of domicile; or non-U.S. citizens working in their home country * * *.'' We add the phrase ''substantially all of whom are'' to ensure that issuers do not classify a policy as an expatriate policy when expatriates account for only a limited proportion of the covered population.

The preamble to the interim final rule states that expatriate policies issued by non-U.S. issuers for services rendered outside the United States are not subject to the MLR regulation, nor are expatriate policies written on a form not filed with and approved by a State insurance department. Issuers must report expatriate policy experience separately from other experience for the 2011 MLR reporting year and must aggregate that experience on a national level for the large group market and the small group market. The definition of expatriate policies does not include policies issued in the individual market.

Section 158.221(b)(4) directs issuers of expatriate policies to use a separate methodology for calculating the MLR numerator for reporting and rebate purposes for the 2011 MLR reporting year. Specifically, incurred claims and activities that improve health care quality are to be multiplied by a factor of 2.00 in calculating the MLR. The interim final rule directs issuers to submit a report for each of the first three quarters of the 2011 MLR reporting year. The preamble to the interim final rule notes that, after reviewing the quarterly filings of the expatriate policies based on 2011 experience, we will make a determination as to whether this treatment should continue or be modified beyond the 2011 MLR reporting year.

Comment: CMS received six comments regarding the treatment of expatriate policies in the interim final rule. The majority of the commenters supported the interim final rule's treatment of expatriate policies for the 2011 MLR reporting year. Specifically, issuers and trade associations supported the special methodology for calculating the MLR numerator for expatriate policies, noting that these policies have higher administrative costs as a result of (1) Providing international access to providers; (2) maintaining emergency evacuation services; and (3) navigating health care and legal systems in different countries. These policies may also have unpredictable experience depending on the location of the enrollees. One issuer stated that a large portion of international policies are sold through brokers, and high broker fees contribute to the increased administrative cost. We received no comments opposing a special circumstances adjustment for expatriate policies.

Other issuers and commenters suggested that the interim final rule's adjustment to the MLR numerator does not do enough to relieve expatriate issuers from the MLR standards provided in the Affordable Care Act. One issuer claimed that the MLR reporting requirement creates an unlevel playing field because U.S. issuers must disclose proprietary cost structure information under the MLR reporting requirements, while foreign issuers would not be required to do so. Two commenters specifically suggested that the adjustment for expatriate policies should extend beyond the 2011 MLR reporting year, either temporarily or permanently.

Response: We recognize the unique administrative costs associated with expatriate policies as evidenced from the public comments and the first two quarterly reports of 2011.[2] Commenters asserted that the costs of: (1) Identifying and credentialing providers worldwide in countries with different licensing and other requirements; (2) processing claims submitted in various languages; (3) standardizing billing procedures; (4) providing translation and other services to enrollees; and (5) helping subscribers locate qualified providers internationally justify a separate methodology that takes into account these special circumstances. After reviewing the first and second quarter data, we have determined that continuing a special circumstances adjustment of a multiplier of 2.00 to the numerator of the MLR is appropriate for expatriate policies.

According to the year-to-date second quarter data provided by issuers of expatriate policies, without applying the special circumstances adjustment provided in the interim final rule, the majority of issuers in the large group market[3] reported credibility-adjusted MLRs significantly below 85 percent MLR standard. However, with the multiplier of 2.00, we estimate that issuers' credibility-adjusted MLRs will meet the MLR standards, thus ensuring that Americans working abroad will still have access to U.S.-based coverage.

Based on the reported data and on information from stakeholders concerning this unique market, we believe that a multiplier of two is appropriate to ensure that issuers remain in the expatriate market. As discussed previously, expatriate policies have significantly different and additional administrative costs than do policies that provide primarily domestic coverage. In addition, the experience of expatriate policies is subject to more variability than other types of policies, due to the fact that they primarily cover care in all parts of the world in a wide variety of health care systems, which also makes pricing to a particular MLR standard much more difficult. Due to this inherent uncertainty in pricing and their unique administrative costs, we have determined that it is appropriate to provide this special circumstances multiplier to expatriate policies. We understand that the experience of expatriate policies is significantly more variable than the experience of other types of policies, warranting a larger adjustment to account for this. This multiplier of two applies to expatriate policies beginning in the 2012 MLR reporting year, and applies indefinitely.

We believe that the MLR standards do not materially affect U.S. issuers' ability to compete with foreign issuers, in part because U.S. employers want to provide their employees who are working abroad and their dependents with comprehensive health insurance that meets the unique needs of expatriates and provides benefits that are comparable to the coverage of their U.S.-based employees. Also, U.S.-based issuers generally will not be required to disclose any proprietary financial structure information that is not already

[2] CMS is basing its determination on two quarters of data for the same reasons set forth above with respect to mini-med policies.

[3] No issuers of expatriate policies in the small group market had credible experience in 2011. However, they may become credible in 2012, when issuers' MLRs will generally be calculated based on multiple years of experience and data.

being provided to the States through the NAIC's Supplemental Health Care Exhibit (SHCE).

C. Fraud Reduction Expenses (45 CFR 158.140(b)(2)(iv) and 158.150(c)(8))

The interim final rule describes the types of expenses that are adjustments to claims under the MLR disclosure and reporting requirements. Specifically, under § 158.140(b)(2)(iv), the amount of claim payments recovered through fraud reduction efforts, not to exceed the amount of fraud reduction expenses, can be included in incurred claims. Fraud reduction efforts include fraud prevention as well as fraud recovery. In addition, the interim final rule provides that fraud prevention activities are excluded from quality improvement activities (QIA).

Comment: We received 12 comments on the treatment of fraud prevention activities in the interim final rule. Eleven of the commenters supported the inclusion of fraud prevention activities as QIA. Specifically on this point, issuers argued that fraud prevention activities improve patient safety, and deter the use of medically unnecessary services, thus providing a higher level of health care quality. Commenters asserted that, by not including all fraud reduction efforts as QIA, issuers would reduce their fraud reduction efforts, which would decrease patient safety and quality of care. Two commenters added that by prohibiting plans from including the costs they incur for fraud prevention activities as QIA, the rule likens the costs to wages, overhead, and advertising expenses. Two trade associations asserted that HHS should be consistent with the Administration's efforts to prevent fraud in government programs, stating that excluding fraud prevention as QIA undermines the federal government's efforts to prevent, detect, and prosecute fraud. Two commenters provided information regarding the savings that fraud prevention programs can provide issuers. This information suggested that among large issuers surveyed, the net savings from anti-fraud operations were more than $3 per enrollee in 2008, that medium sized issuers reported $1 savings per enrollee, and that small issuers estimated $2.70 savings per enrollee.

Not all commenters supported characterizing fraud prevention activities as QIA. A provider association expressed concerns that Pharmacy Benefit Managers may improperly try to categorize certain activities as fraud detection due to the lack of a clear definition for fraud detection and recovery. This commenter asserted that excluding fraud prevention activities from QIA is an appropriate way to apportion medical costs versus administrative costs, and urged HHS to allow only those efforts to reduce fraud, as defined by Medicare, to be allowed to be deducted from an issuer's administrative costs.

Response: We considered the comments regarding fraud reduction expenses, and are maintaining the MLR treatment of fraud reduction expenses provided in the interim final rule. We will continue to exclude fraud prevention activities from QIA. The current treatment of fraud reduction efforts under the MLR rule is consistent with the NAIC's position and adequately addresses the concerns of issuers, while still recognizing that many fraud prevention efforts are not directly targeted towards quality improvement. We recognize the importance of fraud reduction expenses and the disincentive it could create if these expenses were treated solely as non-claims and non-quality improving expenses. Thus, allowing payments recovered through fraud reduction efforts as adjustments to incurred claims gives issuers the opportunity to recoup monies invested to deter fraud. Modifying the interim final rule to allow an unlimited adjustment would undermine the purpose of requiring issuers to meet the MLR standard in the Affordable Care Act.

We believe that issuers will continue to invest in fraud reduction, including fraud prevention, regardless of the MLR treatment and encourage issuers to do so. Issuers have incentives to reduce fraud regardless of how this expense is classified within the MLR, as demonstrated from the comments and data provided by issuers. By allowing fraud reduction expenses as an adjustment to incurred claims, up to the amount of fraudulent claims recovered, the interim final rule mitigates any disincentive issuers may have to invest in these programs. We appreciate the comments from the industry regarding the savings that result from fraud reduction efforts, which support the MLR policy in the interim final rule that the amount of claims payments recovered through fraud reduction efforts, not to exceed the amount of fraud reduction expenses, should be included in incurred claims.

D. ICD–10 Conversion Expenses (45 CFR 158.150(b)(2)(i)(A)(6) and (c)(5))

Under § 158.150(a), health insurance issuers are required to submit an annual report to the Secretary documenting their expenditures for activities that improve health care quality. As provided by § 158.150(b), in order for an activity to be considered a QIA, it must be designed, among other things, to improve health quality and increase the likelihood of desired health outcomes in ways that are capable of being objectively measured and of producing verifiable results and achievements. In addition, the activity must be primarily designed to—(1) Improve health outcomes; (2) prevent hospital readmissions; (3) improve patient safety; or (4) implement, promote and increase wellness and health activities. Health Information Technology (HIT) expenditures that meet the requirements under § 158.150 are considered QIA. The list of activities excluded as QIA includes—(1) Those activities designed primarily to control or contain costs; and (2) those that establish or maintain a claims adjudication system, including costs directly related to upgrades in HIT that are designed primarily or solely to improve claims payment capabilities or to meet regulatory requirements for processing claims (for example, costs of implementing new administrative simplification standards and code sets adopted pursuant to the Health Insurance Portability and Accountability Act (HIPAA), 42 U.S.C. 1320d–2, as amended, including ICD–10 requirements). The preamble to the interim final rule stated that CMS would examine the reported conversion costs of ICD–10 to determine whether the policy to exclude these costs from QIA should be revisited. In addition, the interim final rule specifically requested comments on whether ICD–10 should be included as a QIA.

Comment: Provider associations and advocacy groups supported the interim final rule's treatment of ICD–10. Specifically, provider associations contended that ICD–10 does not have any bearing on the treatment that an enrollee receives, and that there is no direct impact on patient outcomes, even if it benefits the medical community as a whole. Commenters also noted that issuers will achieve greater administrative efficiency with ICD–10's more detailed coding, allowing claims to be paid more efficiently. For these reasons, such commenters asserted that these costs are administrative in nature and should be excluded from QIA. A consumer advocate further suggested that excluding ICD–10 costs from QIA would prevent issuers from reclassifying administrative tasks as QIAs.

Issuers opposed the interim final rule's treatment of ICD–10 conversion costs, asserting that ICD–10 costs are a QIA because they are meant to improve data collection for diagnoses and medical procedure coordination, patient

safety, health outcomes, and medical research. They also stated that ICD–10 conversion allows for alignment of quality and wellness programs, which are QIA. In support of classifying ICD–10 expenses as QIA, a health insurance issuer stated that ICD–10 coding can improve health plans' ability to share data among clinicians for the purpose of quality improvement and care coordination activities, thereby allowing for a better understanding of diagnoses and better treatment. An issuer and an industry association asserted that because ICD–10 implementation is a legal requirement, the burden of cost should not be on the issuers.

Finally, issuers acknowledged that conversion costs can be tracked and separated from maintenance costs through current accounting processes, and most supported excluding ICD–10 maintenance costs occurring after October 1, 2013 from QIA.

Response: In response to the comments highlighting the dual nature of ICD–10, we considered the impact of ICD–10 on improving data collection for diagnoses and medical procedure coordination, patient safety, health outcomes, and medical research. In addition, we consulted with the Office of E-Health Standards and Services (OESS) within CMS. OESS oversees ICD–10 and considers some of the impact of ICD–10 to be QIA, and supports the treatment of ICD–10 set forth in this final rule.

We also recognize that ICD–10 has some claims processing functions as well. This final rule recognizes the dual nature of ICD–10 and includes as QIA ICD–10 conversion costs incurred in 2012 and 2013 up to 0.3 percent of an issuer's earned premium in the relevant State market in each of those years. Analysis of the 2010 SHCE filings reveals that ICD–10 expenses, as a percent of earned premium, account for less than 0.02 percent of issuer spending in each market (individual, small group and large group). However, significant ICD–10 conversion efforts will be made in 2012 and 2013, as issuers cannot convert to ICD–10 until after January 1, 2012, when the new version 5010 standards for electronic health care transactions will be upgraded. Federal HIPAA regulations direct that the ICD–10 transition must be completed by October 2013. The industry provided a range of percentages using their projected expenditures of ICD–10 conversion costs on their MLRs, if allowed as a QIA. After reviewing the data provided by issuers and 2010 SHCE filings, we chose a cap that allows as QIA amounts that issuers projected spending on ICD–10 conversion, without permitting issuers to include claims adjudication systems costs in QIA.

In addition, ICD–10 maintenance costs are excluded from QIA in this final rule, based on the industry's collective comments stating that separating conversion costs from maintenance costs is feasible, and based on their support for excluding ICD–10 maintenance costs from QIA.

We request further comment on the treatment of ICD–10 conversion costs adopted in this final rule. Specifically, we are soliciting comments on whether including as QIA ICD–10 conversion costs as a QIA is appropriate, and if the cap set at up to 0.3 percent of an issuer's earned premium is an appropriate amount based on past and future ICD–10 conversion expenses.

E. Community Benefit Expenditures (45 CFR 158.160(b)(2)(vi) and 158.162(b)(1)(vii), (c)(1))

In the interim final rule, we requested comment on the treatment of community benefit expenditures. The interim final rule allows a not-for-profit, tax-exempt issuer to deduct from earned premium the amount of its community benefit expenditures, limited to the State premium tax rate applicable to for-profit issuers. The interim final rule also requires a not-for-profit issuer to report community benefit expenditures ''in lieu of taxes * * * but not to exceed the amount of taxes [it] would otherwise be required to pay.'' (45 CFR 158.162(c)(1)).

Comment: CMS received nine comments on the treatment of community benefit expenditures, including from six issuers, a labor union, a law firm, and an issuer coalition organization. Seven commenters agreed that the MLR rule should not discourage not-for-profit issuers from providing services and financial support to the community. Three commenters expressed concern that limiting community benefit expenditures deductibility would discourage community benefit expenditures and community investment. Two commenters suggested that the definition of community benefit expenditures be expanded to include expenses not specifically targeted at increasing access to health care. Another commenter suggested that community benefit expenditures be considered QIA.

Some commenters expressed concern that the treatment of community benefit expenditures in the interim final rule would result in unequal treatment among not-for-profit issuers, and between not-for-profit and for-profit issuers, for several reasons. Five commenters noted that the community benefit expenditures deduction would not be uniformly available to a not-for-profit issuer because State premium tax rates vary by State, and within some States, vary by issuer type (for example, PPO or HMO). They also suggested that the varying premium tax rates by type of issuer within a State would result in confusion when determining which premium tax rate to apply to the community benefit expenditures limit. The commenters asserted that in States without a premium tax, a not-for-profit issuer's community benefit expenditures would not be deductible and therefore its MLR would be relatively lower than an issuer in a State with a premium tax.

Six commenters suggested that a flat national community benefit expenditures deduction limit would result in a more even playing field, as well as simplify the administrative burden in determining community benefit expenditures deduction limits. Five commenters proposed a flat deduction limit ranging from three to five percent of earned premium. Another commenter proposed allowing not-for-profit issuers to deduct all community benefit expenditures from earned premium.

Four commenters asserted that because of the different corporate structures, business plans, missions, and tax liabilities of not-for-profit and for-profit issuers, it would be speculative and burdensome to determine what a not-for-profit issuer's hypothetical tax liability would be if it were a for-profit issuer. Finally, issuers expressed concern that not-for-profit issuers have fundamentally different missions than for-profit issuers, that tax liability is determined based on a series of credits and adjustments built into a taxable issuer's business plan, and that it would be too burdensome and speculative for a tax-exempt or not-for-profit issuer to estimate its ''but for'' tax liability.

Response: Although we share the concern that the MLR standard should not discourage a not-for-profit issuer from spending on community benefit expenditures, we are not persuaded that the definition of community benefit expenditures should generally be expanded and maintain the definition currently in § 158.160(c)(2). We note that existing laws pertaining to not-for-profit issuer status and the benefits associated with this status continue to apply. However, based on the comments regarding the variance of State premium tax rates by type of issuer, in this final rule the community benefit expenditures deduction is revised to

help ameliorate such disparate effects. Currently, 48 States have premium taxes, but tax rates in many States differ for different kinds of plans and in some States they differ for not-for-profit and for-profit issuers. Several States do not tax HMOs or not-for-profit issuers at all. In this final rule, we modify § 158.162(b)(1)(vii) to allow an issuer to deduct either the amount it paid in State premium taxes, or the amount of its community benefit expenditures up to a maximum of the highest State premium tax rate in the State, whichever is greater. This treatment does not create a disincentive against community benefit expenditures, while equalizing some of the disparities that were identified in comments to the interim final rule.

We also considered the comments regarding a hypothetical tax reporting requirement in § 158.162(c)(1) and agree that it is not necessary. Because of the modification to the community benefit expenditures deduction limit, it is no longer necessary for an issuer to report community benefit expenditures limited by its hypothetical tax liability, and thus this final rule removes that requirement. By removing § 158.162(c)(1) of the interim final rule, this final rule simplifies the reporting requirement.

Section 158.160(b)(2)(vi) of the interim final rule directs issuers to report non-claims costs by type, including all community benefit expenditures. This reporting standard applies regardless of whether an issuer elects to adjust earned premium for community benefit expenditures, as permitted by § 158.162(b)(1)(vii) in this final rule.

F. Rebates to Enrollees in Group Markets (45 CFR 158.241(b), 158.242(b), 158.243(a)(1), 158.250, and 158.260(c))

In § 158.242(b), the interim final rule directs issuers in the large and small group markets that have not met the applicable MLR standard to provide any owed rebate to the policyholder and each subscriber, ''in amounts proportionate to the amount of premium each paid.'' The interim final rule also allows an issuer to enter into an agreement with the group policyholder to distribute the rebates on behalf of the issuer if the policyholder agrees to distribute it proportionately as directed and provide detailed documentation regarding the distribution to each subscriber. However, under the interim final rule, the issuer remains liable for complying with all of its obligations under the statute and for maintaining records that demonstrate rebates were provided accurately to individual enrollees.

Comment: CMS received several comments regarding rebate distribution in the group market. Generally, commenters supported the pro rata distribution of rebates to the policyholder and each subscriber. Many commenters, however, expressed significant concern about the logistical and tax problems inherent in the interim final rule's mechanism for providing rebates in the group markets. For example, several issuers expressed concern that the issuer lacks access to the information needed to distribute rebates to individual enrollees covered under a group policy, asserting that the policyholder (and not the issuer) has information regarding the premium contribution amount from the employer and the employee. A few commenters expressed their concern that it is unfair for issuers to remain liable under the interim final rule, even when the issuer enters into an agreement with a policyholder, since issuers are unable to monitor or control the actions of the policyholder.

Issuers, trade associations, and a State regulator recommended that issuers be allowed to distribute rebates to policyholders, and that the policyholder should become responsible for distributing rebates to enrollees. Two commenters noted that the proposed distribution treatment should be governed by the Employee Retirement Income Security Act of 1974, as amended (ERISA). However, one commenter asserted that rebates should not be considered plan assets under ERISA for which plan administrators owe a fiduciary duty.

A few commenters also recommended allowing issuers to rely on the representations made by policyholders that they calculated and disbursed rebates as required and that making a good faith effort to obtain the information from policyholders should fulfill issuers' reporting obligations under the interim final rule.

Subsequent to the closing of the public comment period on the interim final rule, CMS received several inquiries to our public email address asking about the tax implications to issuers, employers, and consumers, as a result of the mechanism for providing rebates established in the interim final rule.

Response: In response to the comments we received and the inquiries to our public email address, we examined the issue in consultation with the Departments of Labor and Treasury. Requiring issuers to apportion and pay rebates directly to policyholders and each of their subscribers (who are generally employees) in the group health plan context, as provided by the interim final rule, has unintended administrative consequences as well as potential tax consequences for issuers, employers, and consumers. For the portion of the premiums that were paid with pre-tax dollars (that is, through an Internal Revenue Code section 125 cafeteria plan), which is the case for a significant proportion of group enrollees, rebates paid to enrollees may be treated as wages, raising issues as to the application of employment taxes and the potential that an issuer may have to administer any applicable withholding obligations.

While the above burdens and logistical problems could be avoided by simply providing for rebates to be paid to the policyholder (for example, employer), the statute directs that enrollees receive the benefit of rebates and we are committed to ensuring that this is the case. Having considered the tax and other logistical implications of providing rebates to enrollees in a group health plan, the effect on consumers, and the burden on issuers and employers, this final rule directs issuers in the group markets to provide rebates to the group policyholder but, as discussed below, includes protections designed to satisfy, in a practical way, the objective of benefitting subscribers and their related enrollees. In providing rebates to the group policyholder, the final rule maintains the definition of enrollee for purposes of the rebate provisions, found in § 158.240(b), which states that ''enrollee'' means the subscriber, policyholder, and/or government entity that paid the premium for health care coverage received by an individual during the relevant MLR reporting year. Issuers must provide rebates, if any, to policyholders covered during the MLR reporting year on which the rebate is based.

The final rule establishes separate standards for ERISA-covered group health plans and plans that are neither covered by ERISA nor are governmental plans (for example, church plans). The handling of rebates by ERISA-covered plans and church plans are not subject to direct CMS regulation. Thus, the separate standards for such plans in the final rule are designed to acknowledge the different legal and regulatory frameworks that apply to those plans while still establishing, either directly or through reliance on other applicable legal standards, such as ERISA, a requirement that is consistent with the statutory directive that MLR rebates benefit enrollees. Non-Federal governmental plans are subject to direct regulation by CMS and we are issuing

an interim final rule contemporaneous with this final rule that addresses rebates to such plans.

Many group health plans are employee benefit plans that are subject to ERISA. Through consultation regarding this final rule, the Department of Labor has advised CMS that, in the context of ERISA-covered group health plan coverage, rebates paid to the policyholder in accordance with § 158.242(b) of this final rule may have plan asset, fiduciary responsibility, and prohibited transaction implications under Title I of ERISA. Distributions from insurance companies to their policyholders, including employee benefit plans, take a variety of forms, including refunds, dividends, demutualization payments and excess surplus distributions. ERISA, Department of Labor rulings, and other authority currently provide guidance on the proper handling of such distributions to employee benefit plans covered under Title I of ERISA. To the extent MLR rebates constitute plan assets of an ERISA-covered group health plan, decisions regarding the handling and allocation of the rebate would have to be made by a plan fiduciary consistent with ERISA. The Department of Labor has also advised that it is publishing guidance on its Web site at *http://www.dol.gov/ebsa/healthreform,* contemporaneously with this final rule, regarding the duties of employers/plan sponsors and other fiduciaries responsible under sections 403, 404 and 406 of ERISA for decisions relating to MLR rebates. Accordingly, rebates paid in connection with policies for ERISA-covered employee benefit plans may constitute plan assets that are required to be handled in accordance with the requirements of ERISA.

With respect to non-Federal governmental plans, there currently is no similar legal framework set forth in Federal law governing distributions from issuers to their plan policyholders. Accordingly, under the authority in section 2792 of the PHS Act to promulgate regulations determined ''appropriate'' to ''carry out'' the provisions of part A of title XXVII of the PHS Act, which include PHS Act section 2718, we are, in a separate interim final rule being published contemporaneously with this final rule, directing that the portion of rebates attributable to the amount of premium paid by subscribers of non-Federal governmental plans be used for the benefit of subscribers, which ensures that enrollees in such plans similarly receive the benefit of rebates.

With respect to rebates paid to a policyholder that is a group health plan but is not a governmental plan and not subject to ERISA, for example a church plan, this final rule provides that an issuer may make rebate payment to the policyholder if the issuer receives written assurance from the policyholder that the rebate will be used for the benefit of current subscribers using one of the options prescribed for non-Federal governmental plans. Without such written assurance, the issuer must pay directly the policyholder's subscribers covered by the policy during the MLR reporting year on which the rebate is based.

The purpose of the MLR is to provide enrollees value for their premium dollar, and issuers must meet the applicable MLR standard or pay rebates based upon aggregated market data in each State. The law does not provide for a group health plan MLR or an individual enrollee MLR. Thus, rebates are not based upon a particular group health plan's experience or a particular subscriber's experience. We believe that distributing rebates to subscribers in the manner prescribed by this final rule and the interim final rule published contemporaneously with this final rule accomplishes the purpose of the MLR requirement, while streamlining the rebate process for consumers, employers, and issuers. Because the final rule and the interim final rule published contemporaneously with this final rule provide that rebates are to be distributed to the policyholder for subscribers of group health plans, the final rule modifies § 158.241(b) regarding rebates to former enrollees, so that § 158.241(b) now applies only to former enrollees in the individual market.

The final rule also provides that issuers must provide notice of rebates, if any, to current group health plan subscribers as well as group policyholders, and to subscribers in the individual market. The notice of rebates to policyholders and subscribers of group health plans will be prescribed by the Secretary of Health and Human Services, in consultation with the Secretary of Labor.

The notice must include information about the MLR and its purpose, the MLR standard, the issuer's MLR, and the rebate being provided. In addition, the notice to policyholders and current subscribers in plans that are not subject to ERISA must contain an explanation as to how the rebate will be handled. If the plan is subject to ERISA, the notice to policyholders and subscribers must contain an explanation that the policyholder may have obligations under ERISA's fiduciary responsibility provisions with respect to the handling and allocation of the rebate and contact information for questions concerning the handling and allocation of the rebate under their plan. As noted above, the Department of Labor is publishing guidance on its Web site contemporaneously with the publication of this final rule that provides guidance on the duties of policyholders under ERISA with respect to the handling and allocation of rebates in the case of policies that cover an employee benefit plan subject to ERISA.

If the policyholder is a non-Federal governmental plan, the notice to the policyholder and subscribers must contain an explanation that the policyholder must use the portion of the rebate attributable to subscribers' contribution to premium in certain ways for the benefit of current subscribers. If the policyholder is not a governmental plan and not subject to ERISA, the notice must contain an explanation that the policyholder must agree to use the portion of the rebate attributable to subscribers' contribution to premium for the benefit of current subscribers or the issuer will pay the rebate directly to the policyholder's subscribers.

We believe that the above notice requirement will not only provide policyholders and subscribers with information on rebates to be paid, and how they will benefit from them, but greater transparency on how premium dollars are used by issuers, and how the issuer's MLR compares to the standard set by Congress. We believe that these latter two purposes would also be served by a notice to policyholders and subscribers with MLR information from issuers that do not owe rebates. In addition to providing policyholders and subscribers with material information on how their premium dollars are used, the provision of such a notice would create an incentive to spend as high a percentage of premium dollars on care and quality improvement as possible, rather than just enough to avoid paying rebates.

Because the interim final rule did not discuss the possibility of a notice requirement for issuers that do not owe rebates, and the public has not had an opportunity to comment on such a requirement, we have not included it in this final rule but intend to amend this rule pursuant to comments. We invite comment on the fact that the current notice requirement only applies to issuers that owe rebates, and that as a result, policyholders and subscribers of issuers not owing rebates would not receive MLR information. We also invite comment on the idea of the provision of notices to subscribers and policyholders not receiving rebates at the same time

that subscribers and policyholders receiving notices of rebates get theirs in 2012 and beyond.

We also are considering whether it would be useful to include information in notices about the issuer's prior year MLR, so that enrollees could see whether the issuer is doing a better or worse job than the year before of efficiently using premium revenue. Information showing a less favorable MLR in the current year than that from the year before could be useful to policyholders and subscribers in predicting what might be expected to happen the next year, and thus in making plan choices. Again, because we did not discuss or seek comment on such a requirement in the interim final rule, we invite public comment on whether we should impose a requirement that it be included for all MLR notices in 2012 and/or subsequent years.

Under § 158.242(b)(4) of the final rule, if a group health plan, regardless of whether it is subject to ERISA, has been terminated at the time of rebate payment and the issuer cannot, despite reasonable efforts, locate the policyholder or employer whose employees were enrolled in the group health plan, the issuer must distribute the entire rebate (both the policyholder and subscriber's portions of the rebate) to the subscribers of the group health plan enrolled during the MLR reporting year on which the rebate was calculated by dividing the rebate equally among all subscribers entitled to a rebate. Since issuers do not know how much of a group health plan premium was paid by the policyholder and how much each subscriber contributed, issuers would not be able to divide rebates based upon each subscriber's contribution.

The final rule also modifies the minimum threshold for issuer payments of rebates in the group market from $5.00 per subscriber to a total of $20.00 for the policyholder portion and subscriber portion of the rebate combined when the rebate is paid directly to the policyholder. When an issuer pays the rebate directly to each subscriber in a group health plan, as provided in § 158.242(b)(3) and (4), or pays rebates in the individual market, the minimum rebate threshold remains at $5.00 per subscriber. Finally, in § 158.260(c), the final rule modifies issuers' rebate reporting requirements to conform to changes in how rebates are provided in group markets, which we believe also simplifies the reporting requirements.

We request comment on the treatment of rebates in group markets. We request comments specifically on whether the mechanism provided in this final rule solves or meaningfully reduces the logistical challenges of providing rebates to group health plans and their subscribers and on other potential solutions to these challenges while ensuring that enrollees benefit when rebates are paid.

III. Provisions of the Final Rule

Those provisions of this final rule that differ from the interim final rule are:

- *Mini-med Plans.* Issuers of policies with total annual benefit limits of $250,000 or less must continue for 2012, 2013 and 2014 to report mini-med experience separately from other experience and must continue to aggregate it by State and by (individual, small group, or large group) market. Issuers of mini-med policies must apply a special circumstances adjustment to the numerator of their MLR by multiplying the total of the incurred claims plus expenditures for activities that improve health care quality by a factor of 1.75 for the 2012 MLR reporting year, 1.50 for the 2013 MLR reporting year and 1.25 for the 2014 MLR reporting year. For the 2012, 2013 and 2014 MLR reporting years, mini-med experience will be reported annually, but not quarterly.
- *Expatriate Plans.* Issuers of expatriate plans must continue to aggregate and report the experience from these policies on a national basis, separately for the large group market and small group market, and separately from other policies. Issuers of expatriate policies must apply a special circumstances adjustment to the numerator of their MLR by multiplying the total of the incurred claims plus expenditures for activities that improve health care quality by a factor of 2.0 beginning with the 2012 MLR reporting year. This applies indefinitely. Expatriate experience will be reported annually, but not quarterly. The definition of expatriate policies is amended to read ''group policies that provide coverage to employees, substantially all of whom are: Working outside their country of citizenship; working outside of their country of citizenship and outside the employer's country of domicile; or non-U.S. citizens working in their home country.''
- *ICD–10 Conversion Expenses.* Activities that are considered quality improvement activities (QIA) include, for each of the 2012 and 2013 MLR reporting years, ICD–10 conversion costs up to 0.3 percent of an issuer's earned premium in the relevant State market. Comments are solicited on this issue.
- *Community Benefit Expenditures.* The amount an issuer may deduct from earned premium is the higher of either the total amount paid in State premium tax, or actual community benefit expenditures up to the highest premium tax rate in the State. In addition, not-for-profit issuers are no longer required to estimate the amount of taxes they would have paid if they were for-profit.
- *Recipients of Rebates.* The rebate distribution process for group markets provides that issuers generally distribute rebates to group policyholders. Comments are solicited on this issue. With respect to policyholders that are a group health plan but not a governmental plan or subject to ERISA, issuers must obtain written assurance from the policyholder that rebates will be used for the benefit of current subscribers or otherwise must pay the rebates directly to subscribers covered by the policy during the MLR reporting year on which the rebate is based. Issuers must distribute the entire rebate directly to subscribers if the group health plan has been terminated. In addition, the amount for a *de minimis* rebate in the group market is less than $20.00 per group health plan for rebates that are distributed to the policyholder. There are conforming changes made to the reporting requirements. Enrollees are required to receive a rebate notification.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency;
- The accuracy of our estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

ICRs Regarding MLR and Rebate Reporting and Notice Requirement (§ 158.101 Through § 158.170, and § 158.250)

For purposes of MLR and rebate reporting under Part 158, this final rule does not impose any new reporting requirements and generally conforms to the requirements under the interim final regulation. However, CMS plans to publish for public comment, in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the annual MLR reporting form that issuers will be required to submit to CMS starting in June 2012 for the 2011 reporting year as well as the notice of rebates that issuers will be required to send to policyholders and subscribers starting in August 2012 for the 2011 report year, in the near future.

One exception is that mini-med and expatriate issuers are no longer required to submit quarterly reports, beginning in MLR reporting year 2012. The quarterly report information collection requirements are currently approved under OMB control number 0938–1132. Due to the elimination of the quarterly reporting requirement for mini-med and expatriate issuers, it is estimated that annual reporting costs for such issuers will be reduced by a total of approximately $2.8 million.

CMS has submitted a copy of these final regulations to OMB in accordance with 44 U.S.C. 3507(d) for review of the information collections. If you comment on this information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this final rule with comment period; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, *Attention:* CMS Desk Officer, 9998–FC, *Fax:* (202) 395–6974; or *Email: OIRA_submission@omb.eop.gov*.

V. Response to Comments

Because of the large number of public comments CMS receives on **Federal Register** documents, CMS is not able to acknowledge or respond to them individually. A discussion of the comments CMS received is included in the preamble of this document.

VI. Regulatory Impact Statement

A. Summary

This final rule is designed to address several specific issues that have arisen regarding section 2718 of the PHS Act, which sets forth standards for reporting of certain medical loss ratio (MLR) related data to the Secretary on an annual basis by issuers offering coverage in the individual and group markets, and calculating and providing rebates to policyholders in the event that an issuer's MLR fails to meet or exceed the statutory standard. This final rule establishes standardized methodologies designed to take into account the special circumstances of mini-med policies and expatriate policies in the methodologies for calculating measures of the activities that are used to calculate an issuer's MLR. This final rule also addresses ICD–10 conversion costs, expenses related to fraud reduction activities, community benefit expenditures and the distribution of rebates in the group market. These provisions are generally effective beginning January 1, 2012.

CMS is publishing this final rule to implement the protections intended by Congress in the most economically efficient manner possible. CMS has examined the effects of this rule as required by Executive Order 12866 (58 FR 51735, September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)). In accordance with OMB Circular A–4, CMS has quantified the benefits, costs and transfers where possible, and has also provided a qualitative discussion of some of the benefits, costs and transfers that may stem from this final rule.

B. Executive Orders 12866 and 13563

Executive Order 12866 (58 FR 51735) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 (76 FR 3821, January 21, 2011) is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866.

Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule (1) Having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or Tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year); and a ''significant'' regulatory action is subject to review by the Office of Management and Budget (OMB). As discussed below, CMS has concluded that this rule is not likely to have economic impacts of $100 million or more in any one year, and therefore does not meet the definition of ''economically significant rule'' under Executive Order 12866. Nevertheless, CMS has provided an assessment of the potential costs, benefits, and transfers associated with this final regulation.

1. Need for Regulatory Action

Consistent with the provisions in Section 2718 of the PHS Act, this final rule establishes methodologies for calculating the MLR to accommodate the special circumstances of two different types of plans, mini-med policies and expatriate policies, and a mechanism for providing rebates to enrollees in group health plans when the MLR standard is not met by an issuer. This final rule also addresses ICD–10 conversion costs, expenses related to fraud reduction activities and community benefit expenditures. Section 2718(b) of the PHS Act (captioned ''ensuring that consumers receive value for their premium payments'') requires issuers to provide an annual rebate to each enrollee if the ratio of the amount of premium revenue expended on reimbursement for clinical services and activities that improve quality is less than the applicable minimum standard and specifies how the rebate is to be calculated.

2. Summary of Impacts

In accordance with OMB Circular A–4, Table VI.1 below depicts an accounting statement summarizing CMS's assessment of the benefits, costs, and transfers associated with this regulatory action. Tables VI.1.1–VI.1.5 list benefits, costs and transfers for each individual provision. For purposes of this regulatory impact analysis, CMS has updated relevant information that

was presented in the December 1, 2010 MLR interim final rule (75 FR 74892) based on the provisions of this final rule. CMS has limited the period covered by this regulatory impact analysis (RIA) to 2012–2013. Estimates are not provided for subsequent years because there will be significant changes in the marketplace in 2014 related to the offering of new individual and small group plans through the Affordable Insurance Exchanges. In addition, this RIA focuses only on the modifications to the provisions in the interim final rule and estimates the effects of those modifications relative to a baseline of no modifications. As discussed earlier, CMS anticipates that the adjustments to the MLR methodology in this final regulation will help ensure that consumers receive value for their premium dollars, have continued access to insurance coverage options, and encourage efficiency in the disbursement of rebates to group health plan enrollees. Additionally, CMS believes that allowing issuers of group health plans to distribute all rebates to the policyholder for the benefit of subscribers will avoid any increase in tax and administrative burdens for consumers and issuers. Elimination of quarterly reporting requirements for mini-med and expatriate policies will reduce related reporting costs for issuers of those policies. Allowing for inclusion of community benefit expenditures in the MLR calculation for issuers without requiring not-for-profit issuers to calculate hypothetical tax liability will also reduce reporting costs for issuers. Executive Order 12866 also requires consideration of the ''distributive impacts'' and ''equity'' of a regulation. As described in this RIA, the adjustment in the MLR methodology for mini-med policies will result in an increase in rebate payments to enrollees in those policies, while the adjustments in MLR methodology to account for costs related to ICD–10 conversion and community benefit expenditures in some States will result in reduced rebate payments to affected enrollees. Distributing group health plan rebates to the policyholders for the benefit of subscribers will also transfer the benefits of those rebates from enrollees who leave the plan to new enrollees in the plan. In accordance with Executive Order 12866, CMS believes that the benefits of this regulatory action justify the costs. The regulatory impact analysis does not include estimates related to fraud reduction activities since this final rule does not change the policy or treatment of fraud reduction expenses.

TABLE VI.1—ACCOUNTING TABLE: SUMMARY

Benefits:

Qualitative:
* Increase in quality of medical care as a result of increased spending on quality improving activities by issuers of mini-med policies.
* Improved health as a result of increased spending on medical care by issuers of mini-med policies.
* Continued access to mini-med and expatriate health policies for consumers.
* Benefits to consumers by encouraging issuers to undertake community benefit expenditures.

Costs:	Estimate	Year dollar	Discount rate percent	Period covered
Annualized Monetized ($millions/year)	($4.2 million)	2011	7	2012–2013
	($4.4 million)	2011	3	2012–2013

Annual reduction in costs for issuers of mini-med and expatriate policies due to elimination of requirement to file quarterly reports and change in method of disbursement of rebates for group health plans.

Qualitative:
* Increased spending on quality-improving activities by issuers of mini-med policies.
* Increased spending on medical care by issuers of mini-med policies.
* Reduced administrative burden for not-for-profit issuers since they will no longer need to calculate and report hypothetical tax liabilities.
* Reduced tax burden for group health plan enrollees relating to the change in the method of disbursement of rebate payments.
* Increased administrative costs for policyholders that disburse rebates to group health plan subscribers.

Transfers:	Estimate	Year dollar	Discount rate percent	Period covered
Annualized Monetized ($millions/year)	$2.4 million	2011	7	2012–2013
	$2.6 million	2011	3	2012–2013

Annual transfer of rebate dollars to enrollees from shareholders or nonprofit stakeholders of mini-med policies, resulting from adjustment in MLR methodology for mini-med policies.

Qualitative:
* Savings for consumers and reduced profit for issuers of mini-med policies.
* Transfer from enrollees to shareholders or nonprofit stakeholders in individual, small and large group markets, resulting from adjustment in MLR methodology to account for community benefit expenditures and ICD–10 conversion costs.
* Transfer of benefits of rebate dollars disbursed to the group health plan from enrollees who leave the group health plan to enrollees new to the group health plan.

TABLE VI.1.1—ACCOUNTING TABLE: MINI-MED POLICIES

Benefits:

Qualitative:
* Increase in quality of medical care as a result of increased spending on quality improving activities by issuers of mini-med policies.
* Improved health as a result of increased spending on medical care by issuers of mini-med policies.

TABLE VI.1.1—ACCOUNTING TABLE: MINI-MED POLICIES—Continued

* Continued access to mini-med health policies for consumers.

Costs:	Estimate	Year dollar	Discount rate percent	Period covered
Annualized Monetized ($millions/year)	($2.5 million)	2011	7	2012–2013
	($2.6 million)	2011	3	2012–2013

Annual reduction in costs for issuers of mini-med policies due to elimination of requirement to file quarterly reports.

Qualitative:
* Increased spending on quality-improving activities by issuers of mini-med policies.
* Increased spending on medical care by issuers of mini-med policies.

Transfers:	Estimate	Year dollar	Discount rate percent	Period covered
Annualized Monetized ($millions/year)	$2.4 million	2011	7	2012–2013
	$2.6 million	2011	3	2012–2013

Annual transfer of rebate dollars to enrollees from shareholders or nonprofit stakeholders of mini-med policies, resulting from adjustment in MLR methodology for mini-med policies.

Qualitative:
* Savings for consumers and reduced profit for issuers of mini-med policies.

TABLE VI.1.2—ACCOUNTING TABLE: EXPATRIATE POLICIES

Benefits:

Qualitative:
* Continued access to expatriate health policies for consumers.

Costs:	Estimate	Year dollar	Discount rate percent	Period covered
Annualized Monetized ($millions/year)	($80,000)	2011	7	2012–2013
	($85,000)	2011	3	2012–2013

Annual reduction in costs for issuers of expatriate policies due to elimination of requirement to file quarterly reports.

TABLE VI.1.3—ACCOUNTING TABLE: ICD–10 COSTS

Transfers:

Qualitative:
* Transfer from enrollees to shareholders or nonprofit stakeholders in individual, small and large group markets, resulting from adjustment in MLR methodology to account for ICD–10 conversion costs.

TABLE VI.1.4—ACCOUNTING TABLE: COMMUNITY BENEFIT EXPENDITURES

Benefits:

Qualitative:
* Benefits to consumers by encouraging issuers to undertake community benefit expenditures.

Costs:

* Reduced administrative burden for not-for-profit issuers since they will no longer need to calculate and report hypothetical tax liabilities.

Transfers:

Qualitative:
* Transfer from enrollees to shareholders or nonprofit stakeholders in individual, small and large group markets resulting from adjustment in MLR methodology to account for community benefit expenditures.

TABLE VI.1.5—ACCOUNTING TABLE: DISTRIBUTION OF REBATES IN GROUP MARKETS

Costs:	Estimate	Year dollar	Discount rate percent	Period covered
Annualized Monetized ($millions/year)	($1.6 million) ($1.7 million)	2011 2011	7 3	2012–2013 2012–2013
Annual reduction in costs due to change in method of disbursement of rebates for group health plans.				
Qualitative: * Reduced tax burden for group health plan subscribers relating to the change in the method of disbursement of rebate payments. * Increased administrative costs for policyholders that disburse rebates to group health plan enrollees.				
Transfers:				
Qualitative: * Transfer of benefits of rebate dollars disbursed to the group health plan from subscribers who leave the group health plan to subscribers new to the group health plan.				

3. Qualitative Discussion of Anticipated Benefits, Costs and Transfers

The medical loss ratio (MLR) is a measurement that, stated simply, measures the percentage of total premiums that insurance companies spend on health care and quality initiatives, versus what they spend on administration, marketing and profit. The MLR interim final rule (75 FR 74892) provided an overall discussion of the anticipated benefits, costs and transfers associated with the MLR provisions. In the following sections, we discuss some of the anticipated benefits, costs and transfers associated with the adjustment of the MLR methodology for mini-med and expatriate policies, accounting of ICD–10 conversion costs and community benefit expenditures in the MLR, and change in the process for disbursement of rebates for enrollees in group health plans.

a. Benefits

In developing this final rule, CMS carefully considered its potential effects including both costs and benefits. Because of data limitations, CMS did not attempt to quantify all of the benefits of this rule. Nonetheless, CMS was able to identify several potential qualitative benefits which are discussed below.

Mini-med and expatriate policies tend to have relatively higher administrative costs compared to other types of policies due to their special circumstances. As discussed earlier in the preamble, commenters claimed that mini-med issuers have a unique cost structure—low premiums, high administrative costs (for example, as a result of high turnover) and low incurred claims (because of high deductibles and limited coverage)—that make some issuers unable to meet the statutory MLR without any adjustment to the claim reporting methodology. Under the interim final rule, for the MLR reporting year 2011, the total of the incurred claims and expenditures for activities that improve healthcare quality for mini-med issuers with total annual benefit limits of $250,000 or less is multiplied by a factor of 2.00. The level of the adjustment is changed from a multiplier of 2.00 under the interim final rule to a multiplier of 1.75 for the 2012 MLR reporting year, 1.50 for the 2013 MLR reporting year and 1.25 for the 2014 MLR reporting year under the final rule. We have applied a multiplier through the 2014 MLR reporting year to account for mini-med policies with a plan year that begins after January 1, 2013 and ends sometime in 2014. Based on analysis of 2011 quarterly data submitted by mini-med issuers, CMS anticipates that with the adjustment to MLR methodology provided in this final rule, a majority of issuers in this market would reach the applicable MLR standard, and that all issuers who would be subject to rebates will remain profitable in the markets in which they would be paying rebates. The adjustment minimizes potential market withdrawal by issuers and preserves access to benefits for individuals served by these policies. Issuers that do not otherwise meet the MLR standard may attempt to do so by increasing quality promoting activities, expanding covered benefits or reducing cost sharing, and reducing administrative costs. Increased spending on quality improving activities and medical care would result in better quality of medical care and better health for enrollees in these plans. There are 25 issuers of mini-med policies with approximately 932,000 enrollees collectively and we expect that this rule should not have an effect on mini-med issuers' participation in the market.

As discussed earlier in the preamble, expatriate policies have unique administrative costs, as evidenced from public comments and the first two quarterly reports submitted by issuers of expatriate policies. These unique costs arise from factors such as identifying and credentialing international providers, processing claims in different languages, standardizing billing procedures and providing translation and other services to enrollees. Under the interim final rule, for the MLR reporting year 2011, the total of the incurred claims and expenditures for activities that improve healthcare quality for expatriate experience is multiplied by a factor of 2.00. The level of the adjustment remains at a multiplier of 2.00 under this final rule. The reasons for this level of adjustment are discussed earlier in Section II.B., which include the volatility of the expatriate experience. Based on analysis of 2011 quarterly data submitted by issuers of expatriate policies, CMS anticipates that with the adjustments to MLR methodology provided in this final rule, all issuers in this market would reach the applicable MLR standard. Maintaining the multiplier of 2.00 would not result in any change in rebates being paid to enrollees, but should help ensure that issuers of expatriate policies generally are able to meet the requirements of section 2718 as well as help ensure that the MLR standard does not cause issuers to leave the market. There are eight issuers of expatriate policies that submitted quarterly reports, with approximately 288,000 enrollees.

Under the interim final rule, a not-for-profit issuer could deduct from earned premium community benefit expenditures, limited to the amount of State premium taxes the issuer would otherwise pay if it were a for-profit issuer. A not-for-profit issuer was also required to report community benefit expenditures up to the amount of taxes it would have paid if it were a for-profit

issuer. As discussed earlier in the preamble, commenters expressed concern that variations in State premium tax rates, by State and by type of issuer and the fact that some States do not have a premium tax, created an uneven playing field. Commenters also expressed concern about the difficulties and burden in calculating hypothetical tax liability. The final rule provides that an issuer will be able to deduct from earned premium the greater of the amount actually spent on community benefit expenditures limited to the State's highest premium tax rate, or the amount it pays in State premium tax. Issuers that otherwise do not meet the MLR standard may increase community benefit expenditures if their current expenditure levels or premium taxes are lower than the maximum amount they would be able to deduct under the final rule. CMS anticipates that this may encourage community benefit expenditures and allow for more equitable treatment of issuers and eliminate the reporting burden inherent in not-for-profit issuers calculating a hypothetical tax liability.

b. Costs

Under the final rule, the multiplier for the numerator of the MLR for mini-med policies has been lowered from 2.00 to 1.75 for the 2012 MLR reporting year, 1.50 for the 2013 MLR reporting year and 1.25 for the 2014 MLR reporting year. Based on analysis of 2011 quarterly data submitted by mini-med issuers, CMS anticipates that most issuers in this market would reach the applicable MLR standard. Issuers that do not otherwise meet the MLR standard may attempt to do so by increasing spending on quality improving activities and by increasing covered benefits or lowering consumers' cost-sharing, which would increase issuer spending on medical care.

There are some cost savings as a result of this final rule.

Issuers of mini-med and expatriate policies were directed to submit a report for each of the first three quarters of the 2011 MLR reporting year as provided under § 158.110(b), in addition to the annual report required of all issuers. Beginning in MLR reporting year 2012, these issuers will no longer submit quarterly reports. The elimination of this requirement will reduce these issuers' administrative burden related to reporting, approximately $2.8 million dollars annually.

This final rule also provides standardized ways to account for community benefit expenditures in the MLR methodology. Not-for-profit issuers will no longer need to calculate and report hypothetical tax liability and this will reduce administrative burdens related to reporting for these issuers.

Finally, this rule provides for a more efficient and cost effective way for issuers in group markets to disburse rebate payments to enrollees by allowing issuers in group markets to provide rebates to the policyholders for distribution. This provision will lower administrative costs related to rebate disbursement for issuers of group health plans by approximately $1.8 million annually, and will largely eliminate the tax burden on employers and consumers inherent in the prior rebate mechanism. Policyholders will experience an increase in administrative costs related to the disbursement of rebates, although these administrative costs will be offset by eliminating the administrative burden and tax consequences inherent in the prior rebate mechanism.

c. Transfers

To the extent that issuers' MLR experience falls short of the minimum MLR standard, they must provide rebates to enrollees. These rebates would reflect transfer of income from the issuers or their shareholders to the policyholders.

Under the interim final rule, for the 2011 MLR reporting year, the total of the incurred claims and expenditures for activities that improve healthcare quality for mini-med experience is multiplied by a factor of 2.00. The level of the adjustment is changed from a multiplier of 2.00 under the interim final rule to a multiplier of 1.75 for the 2012 MLR reporting year, 1.50 for the 2013 MLR reporting year and 1.25 for the 2014 MLR reporting year under the final rule. The adjustment of the MLR methodology for mini-med policies will result in higher rebate payments to enrollees, estimated to be approximately $1.3 million in 2012 and $4.1 million in 2013, assuming the spending patterns included in the 2011 quarterly data do not change. However, the final rule also allows issuers to account for ICD–10 conversion costs and community benefit expenditures in the MLR, both up to a specified cap, which will lower rebate payments. In addition, issuers of mini-med policies that do not otherwise meet the MLR standard may attempt to do so by increasing spending on quality promoting activities and medical care, which would result in savings for consumers and reduced profits for issuers.

In addition, this final rule allows issuers in group markets to disburse rebate payments to enrollees by allowing issuers to provide rebates to the policyholder for distribution. This change in the process for disbursement of rebate payments for enrollees in group health plans may result in a transfer of benefits from enrollees who have left the group health plan to enrollees new to the group health plan.

4. Overview of Data Sources, Methods, and Limitations

As discussed in the MLR interim final regulation, the most complete source of data on the number of licensed entities offering fully insured, private comprehensive major medical coverage in the individual and group markets is the National Association of Insurance Commissioners' (NAIC) Annual Financial Statements and Policy Experience Exhibits database. These data contain multiple years of information on issuers' revenues, expenses, and enrollment, collected on various NAIC financial exhibits (commonly referred to as ''Blanks'') including Supplemental Health Care Exhibits (SHCEs) that issuers submit to State insurance regulators through the NAIC. The NAIC has four different Blanks for different types of issuers: Health; Life; Property & Casualty; and Fraternal issuers.[4]

In the interim final rule, our analysis relied on 2009 data from the NAIC database. A total of 618 issuers offering comprehensive major medical coverage filed annual financial statements in 2009, with the Health and Life Blank filers accounting for approximately 99 percent of all comprehensive major medical premiums earned. For this reason we restricted our analysis to Health and Life Blank companies. Comprehensive major medical coverage[5]—including coverage offered in the individual and group markets that is subject to this final regulation—accounted for approximately 47.8 percent of all Accident and Health (A&H) premiums in 2009. Although the NAIC data represent the best available data source with which to estimate impacts of the MLR regulation, the data

[4] If a company's premiums and reserve ratios for its health insurance products equals 95 percent or more of their total business for both the current and prior reporting years, a company files its annual statement using the Health Blank. Otherwise, a company files the annual statement associated with the type of license held in its domiciliary State, for example, the Life, Property & Casualty, or Fraternal Blank.

[5] Comprehensive major medical coverage sold to associations and trusts has been included in individual comprehensive major medical coverage for purposes of the RIA. CMS's estimates exclude Medigap coverage, which in the NAIC data is reported separately from comprehensive major medical coverage offered in the individual and group markets. The 2009 NAIC data does not allow us to identify mini-med policies or expatriate policies separately.

contain certain limitations; we developed imputation methods to account for these limitations and we made several additional data edits that led us to exclude 176 companies from the analysis. We used the remaining 442 companies to estimate the regulatory impacts that were discussed in the interim final rule, as well as the regulatory impacts that are discussed below. Please see the regulatory impact analysis of the interim final rule (75 FR 74892) for additional methodological information.

Although the 2009 NAIC data do not allow us to identify mini-med policies or expatriate policies separately, under the interim final rule, for the 2011 MLR reporting year issuers of mini-med and expatriate policies were required to report MLR data on a quarterly schedule under § 158.110(b). CMS has received, to date, two quarterly reports from these issuers. These quarterly reports are the best source of data for the experience of these policies.

In addition, data from NAIC's 2010 SHCE has recently become available, and we are in the process of reviewing this information.[6] We have reported some preliminary estimates from this data in this impact analysis.

5. MLR and Rebate Estimation Methodology

Consistent with the methodology that was used in the RIA for the interim final rule, the following formula has been used for estimating companies' adjusted MLRs for the mini-med, expatriate markets, rounded to the nearest thousandth decimal place as dictated in the regulation:

$$\text{Adjusted MLR} = (i + q/p - t - f) + c + u$$

Where i = incurred claims

q = expenditures on quality improving activities

p = earned premiums

t = Federal and State taxes

f = licensing and regulatory fees

c = credibility adjustment, if any

u = low, medium, or high assumptions to account for quality improving activities, unknown behavioral changes and data measurement error.

We then calculate rebates for a company whose adjusted MLR value in a State (or on a national basis for expatriate policies) falls below the minimum MLR standard in a given market using the following formulas:

$$\text{Rebates} = [(m - a) * (p - t - f)]$$

Where m = the applicable minimum MLR standard for a particular market

a = an issuer's adjusted MLR for a particular State and market.

Finally, to estimate impacts under the final rule, for each year, we assume that the number of issuers, enrollment, and experience are stable over time.

6. ''Mini-med'' Policies

The term ''mini-med'' policy is used here to generally refer to policies that often cover the same types of medical services as comprehensive medical policies, but have annual benefit limits at or below $250,000. We therefore have been using this figure as a proxy for capturing this type of policy. Under the interim final rule, for the 2011 MLR reporting year, HHS allowed a methodological change to address the special circumstances of mini-med policies. Mini-med policy issuers applied an adjustment to their reported experience to address the unusual expense and premium structure of these policies. Specifically, in the case of a policy with a total of $250,000 or less in annual limits, the total of the incurred claims and expenditures for activities that improve health care quality reported was multiplied by a factor of 2.00. Under this final rule, this factor will be 1.75 for the 2012 MLR reporting year, 1.50 for the 2013 MLR reporting year and 1.25 for the 2014 MLR reporting year. A graduated allowance for the adjustment of 1.75 in 2012, 1.50 in 2013 and 1.25 in 2014 will incentivize issuers to reduce their administrative expenses and operate more efficiently to ensure that they meet the MLR standard while minimizing issuer market withdrawal, maintaining access to coverage for consumers and ensuring that they receive greater value from these policies until 2014. We have applied a multiplier through the 2014 MLR reporting year to account for mini-med policies with a plan year that begins after January 1, 2013 and ends sometime in 2014.

Under the interim final rule, for the 2011 MLR reporting year, issuers of mini-med policies were required to report three quarters of MLR data on a schedule specified under § 158.110(b), in addition to the annual report required of all issuers. Issuers of mini-med policies have submitted two quarterly reports thus far based on 2011 data. Table VI.2 shows the estimated distribution of issuers offering coverage in the mini-med market. Based on the reports that have been submitted, there are 25 issuers offering mini-med policies in 2011, including 12 issuers in the individual market, four issuers in the small group market and 15 issuers in the large group market, which cover more than 300 life-years each in a given State.[7] Only five mini-med issuers offer policies in multiple markets, and of those five only one issuer offers such policies in all three markets. In addition, 11 issuers offer mini-med policies in only one State, while 14 offer policies in multiple States. There are 277 issuer/State/market combinations.

TABLE VI.2—ESTIMATED NUMBER OF MINI-MED POLICY ISSUERS SUBJECT TO MEDICAL LOSS RATIOS BY MARKET

Description	Number of issuers		Enrollment	
	Number	Percentage of total	Number	Percent of total
Total # of Issuers	25	100	931,866	100
By Market:				
Individual	12	48	234,859	25
Small Group	4	16	18,770	2
Large Group	15	60	678,237	73

Notes: (1) Source: CMS analysis of annualized 2011 quarterly data submitted by issuers of mini-med policies, each with more than 300 life-years of experience. (2) Enrollment represents ''life-years'' (life-years are the total number of months of enrollees' coverage during the MLR reporting year, divided by 12 if based upon a full year of reporting).

[6] The 2010 SHCE data includes data for each issuer by market (individual, small and large group) and by State. It also includes data such as QIA expenses, ICD–10 implementation costs, underwriting gain/loss and taxes and fees.

[7] Not all issuers have 1,000 or more life-years and thus are not credible in each State in which they have mini-med business, but may become partially credible in the 2012 or 2013 reporting year when issuers combine two or three years of experience, respectively.

Analysis of data shows that in the absence of any recognition of special circumstances, the 2011 credibility-adjusted MLRs for issuers of mini-med policies range from six[8] percent to 134 percent in the individual market, with a mean of 67 percent and a median of 66 percent; 62 percent to 96 percent in the small group market, with a mean of 70 percent and a median of 73 percent; and 62 percent to 105 percent in the large group market, with a mean of 75 percent and a median of 71 percent. The large variations in the MLRs may be explained by variations in products, deductibles and premiums. For example, a plan with a low premium but a very high deductible will have very few claims, resulting in a very low MLR, while a plan with a higher premium but lower deductible would have more claims and would have a higher MLR. For the 2011 MLR reporting year, based on multiplying total incurred claims and expenditures for activities that improve health care quality by a factor of 2.00 (consistent with the provisions in the interim final rule), it is estimated that three issuers of mini-med policies will pay rebates of approximately $1.1 million in the individual market while no mini-med issuers will pay rebates in the small or large group markets.[9]

We use 2011 data to estimate the effects of the change in MLR methodology and assume no changes in issuers' behavior or quality improvement activities beyond what was reported in the quarterly filing. As shown in Table VI.3, it is estimated that with a multiplier of 1.75, four of the 25 issuers will pay rebates of $2.4 million to 45,838 enrollees. With a multiplier of 1.50, six of the 25 issuers would pay rebates of $5.2 million to 73,427 enrollees. Therefore, a reduction in the multiplier from 2.00 to 1.75 in the 2012 MLR reporting year and a further reduction to 1.50 in the 2013 MLR reporting year will result in higher rebates being paid to enrollees, with more issuers affected and more enrollees receiving rebates. It is important to note, however, that issuers can change their spending targets to adjust to meet MLR targets moving forward.

TABLE VI.3—ESTIMATED ANNUAL REBATE PAYMENTS BY MINI-MED POLICY ISSUERS BY MARKET, 2011

Market	Multiplier = 1 (no adjustment)			Multiplier = 2			Multiplier = 1.75			Multiplier = 1.50		
	Number of affected issuers	Number of enrollees receiving rebates	Estimated rebate ($ million)	Number of affected issuers	Number of enrollees receiving rebates	Estimated rebate ($ million)	Number of affected issuers	Number of enrollees receiving rebates	Estimated rebate ($ million)	Number of affected issuers	Number of enrollees receiving rebates	Estimated rebate ($ million)
Individual Market	7	176,204	$53.0	3	43,463	$1.1	4	45,838	$2.4	5	62,699	$5.0
Small Group Market	0	0	0.0	0	0	0	0	0	0.0	0	0	0.0
Large Group Market	6	575,786	120.4	0	0	0.0	0	0	0.0	1	10,728	0.2
Total	13	751,990	173.4	3	43,463	1.1	4	45,838	2.4	6	73,427	5.2

Source: CMS analysis of annualized 2011 quarterly data submitted by issuers of mini-med policies with more than 300 life-years of experience in at least one State.

Beginning in MLR reporting year 2012, issuers of mini-med policies will only submit an annual report and will no longer be required to submit quarterly reports. Therefore, this will significantly reduce the annual costs related to MLR reporting for issuers. Issuers of mini-med policies were required to submit a report for each of the first three quarters of the 2011 MLR reporting year as provided under § 158.110(b) for each large group market, small group market, and individual market within each State in which the issuer conducts business. Therefore, in addition to the annual report which is required of all issuers, mini-med issuers were required to submit a total of 277 reports three times a year. The burden estimates included in the information collection requirement for the quarterly reports estimated that each quarterly report would require 62.4 hours with an hourly labor cost of $52.46; therefore the estimated total annual administrative cost for all mini-med issuers for all quarterly reports would be approximately $2.7 million. Each year, the cost reduction associated with eliminating the quarterly reporting requirement will be approximately $2.7 million for all issuers of mini-med policies. CMS anticipates that the adjustment in MLR methodology and reduction in reporting costs will allow issuers to remain profitable and ensure continued access to coverage for enrollees in this market, while bringing increased value to consumers.

7. Expatriate Policies

Expatriate policies provide coverage for employees, substantially all of whom are: working outside of their country of citizenship; working outside of their country of citizenship and outside the employer's country of domicile; or non-U.S. citizens working in their home country. As discussed earlier in the preamble, based on public comments and review of data submitted by expatriate policy issuers, the unique nature of these policies results in a higher percentage of administrative costs in relation to premiums than policies that provide coverage primarily within the United States. Under the interim final rule, for the 2011 MLR reporting year, issuers were required to report the experience of these expatriate policies separately from other coverage, as provided in § 158.120(d)(4), and the calculation of claims and quality improving activities for these policies was to be multiplied by a factor of 2.00, as provided in § 158.221(b). Under this final rule, beginning in MLR reporting year 2012, this factor will remain 2.00.

Issuers of expatriate policies were required in 2011 to report three quarters of MLR data on a quarterly schedule specified under § 158.110(b), in addition to the annual report required of all issuers. Issuers of expatriate policies have submitted two quarterly reports thus far based on 2011 data. Table VI.4 shows the estimated distribution of issuers offering coverage in the

[8] This six percent MLR is for an issuer that sells a policy with a $50,000 deductible and thus has very low claims.

[9] In the absence of any recognition of any special circumstances adjustment, CMS estimates that seven mini-med issuers would have paid rebates of approximately $53 million in the individual market and six mini-med issuers would have paid rebates of approximately $120 million in the large group market.

expatriate market. Based on the reports that have been submitted, there are eight issuers in offering expatriate coverage in 2011—two issuers in the small group market and seven issuers in the large group market. Only one issuer offers policies in both markets. There are nine issuer/market combinations.

TABLE: VI.4—ESTIMATED NUMBER OF EXPATRIATE POLICY ISSUERS SUBJECT TO MEDICAL LOSS RATIOS BY MARKET

Description	Number of issuers		Enrollment	
	Number	Percentage of total	Number	Percent of total
Total # of Issuers	8	100	287,789	100
By Market:				
Small Group	2	25	903	0.3
Large Group	7	87.5	286,887	99.7

Notes: (1) Source: CMS analysis of annualized 2011 quarterly data submitted by issuers of expatriate policies, each with more than 300 life-years of experience. (2) Enrollment represents ''life-years''.

Analysis of data shows that in the 2011 MLR reporting year, in the absence of any recognition of special circumstances, issuers of expatriate policies had adjusted MLRs that range from 32 percent to 61 percent in the small group market and from 49 percent to 85 percent, with a mean of 69 percent and median of 72 percent, in the large group market. For 2011, based on multiplying total incurred claims and expenditures for activities that improve health care quality by a factor of 2.00 (consistent with the provisions in the interim final rule), it is estimated that no issuer of expatriate policies will pay any rebates.[10]

We use 2011 data to estimate the effects of maintaining the multiplier of 2.00 and assume no changes in issuers' behavior and quality improvement activities beyond what was reported in the quarterly filing. It is estimated that with a multiplier of 2.00, no issuer will likely have an MLR below the threshold in 2012 and 2013, consistent with the policy in the first year. This should help ensure that the MLR standard does not cause issuers to leave the market.

Beginning in MLR reporting year 2012, expatriate policy issuers will submit only an annual report and will no longer be required to submit quarterly reports. The interim final rule required issuers of mini-med policies to submit a report for each of the first three quarters of the 2011 MLR reporting year as provided under § 158.110(b) for each large group market, small group market, and individual market, combining data from all states in which the issuer conducts business. Therefore, in addition to the annual report required of all issuers, expatriate issuers were required to submit a total of nine reports three times a year. The burden estimates included in the information collection requirement for the quarterly reports estimated that each quarterly report would require 62.4 hours with an hourly labor cost of $52.46. Therefore, estimated total annual cost for all expatriate policy issuers for all quarterly reports would be approximately $88,000. The provisions in this final rule will reduce the annual costs related to MLR reporting for issuers. This cost reduction will be approximately $88,000 for all expatriate policy issuers per year. CMS anticipates that the adjustment in MLR methodology and reduction in reporting costs will allow issuers to remain viable and ensure continued access to coverage for enrollees in this market.

8. ICD–10 Conversion Costs

In the interim final rule, HHS adopted the NAIC's recommendation to exclude the conversion of International Classification of Disease (ICD) code sets from ICD–9 to ICD–10 as a quality improvement activity. However, there is general recognition that the conversion to ICD–10 will enhance the provision of quality care through the collection of better and more refined data. As discussed earlier in the preamble, some believe that ICD–10 coding can improve health plans' ability to share data among clinicians for quality improvement and care coordination activities, thereby allowing for a better understanding of diagnoses and better treatment. This final rule provides that for each of the MLR reporting years 2012 and 2013, issuers may account for ICD–10 conversion costs of up to 0.3 percent of earned premiums in the relevant State market as a quality improving activity in their MLR calculation. In addition, ICD–10 maintenance costs will continue to be excluded from QIA in the final rule, based on the industry's comments that separating conversion costs from maintenance costs is feasible. The industry provided a range of percentages using their projected expenditures of ICD–10 conversion costs on their MLRs, if allowed as a QIA. After reviewing the data provided by issuers and 2010 SHCE filings, CMS chose a cap that allows as QIA amounts that issuers projected spending on ICD–10 conversion, without permitting issuers to include claims adjudication systems costs in QIA.

Preliminary analysis of 2010 SHCE data indicates that issuers reported ICD–10 conversion costs as representing less than 0.02 percent of earned premiums for individual, small group and large group comprehensive major medical coverage. However, ICD–10 conversion costs are expected to be higher for 2011 through 2013 since implementation efforts had only begun in 2010 but conversion to ICD–10 must be completed by October 2013. As stated earlier in the preamble, one issuer estimated that ICD–10 implementation will cost the entire industry between $50–70 million each year for 2011 through 2013. Another issuer anticipated spending $9.4 million in 2011 on ICD–10 implementation. An industry association commented that a study of 20 health insurance plans found that the costs averaged about $12 per member, with small health plans paying around $38 per member and large health plans paying around $11 per member. However, none of these comments indicate whether these estimates apply to issuers subject to the MLR requirements, Medicare, Medicaid, self-insured, or other types of plans or the time frame spanned by these estimates. In the absence of data on actual costs related to ICD–10 conversion that will be included in the 2012 and 2013 MLR calculations, it is difficult to estimate the effect of this provision on issuers and rebates. Even so, we expect that accounting for these costs in MLR calculation will only have a small effect on MLRs and rebates.

[10] In the absence of any recognition of any special circumstances adjustment, CMS estimates that four issuers in the large group market would have paid rebates of approximately $145 million, while no issuer would have paid rebates in the small group market.

9. Community Benefit Expenditures

In the interim final rule, HHS adopted the NAIC's recommendation to allow community benefit expenditures (as defined in § 158.162(c)(2)) by not-for-profit plans to be excluded from premium revenue up to the State premium tax rate, and requiring that not-for-profit issuers report their actual community benefit expenditures up to the amount they would have paid in Federal and State taxes if they had been for-profit. As discussed elsewhere in the preamble, this final rule provides that issuers will be able to deduct either the amount it paid in State premium taxes or the amount of its community benefit expenditures up to a maximum of the highest State premium tax rate in the State, whichever is greater. This creates a level playing field among issuers in States that have different premium tax rates for different types of plans, for example, PPOs and HMOs.

In the absence of reliable data on the total number of not-for-profit issuers offering major medical coverage and on community benefit expenditures, we are unable to quantify the effect of this provision. Five commenters proposed a flat deduction limit ranging between 3 to 5 percent of earned premium. Currently, 48 States have premium taxes, but tax rates in many States differ for different kinds of plans and in some States they differ for not-for-profit and for-profit issuers. Several States do not tax HMOs or not-for-profit issuers at all. State premium taxes range between 0.4 percent and 4.265 percent, according to data provided by the NAIC, and these taxes have been accounted for in the MLR and rebate calculations in the interim final rule. It is not known how many issuers will include community benefit expenditures or State premium tax liability in their MLR calculation, or how much community benefit expenditures will be included in the MLR calculation. Rebates may be reduced for issuers in States with a higher maximum premium tax rate than they are required to pay (for example, an issuer is an HMO and the State has a higher premium tax rate for PPOs) and who have higher community benefit expenditures than the applicable premium tax rate.

As discussed earlier in the preamble, CMS anticipates that this treatment will encourage community benefit expenditures. Issuers that otherwise do not meet the MLR standard may increase community benefit expenditures if their current expenditure levels or premium taxes are lower than the maximum amount they would be able to deduct under the final rule. This provision will also allow more equitable treatment of issuers, and reduce significantly the reporting burden related to community benefit expenditures, as not-for-profit issuers no longer need to calculate and report hypothetical tax liabilities.

10. Distribution of Rebates to Enrollees in Group Markets

Section 2718(b)(1)(A) of the PHS Act requires an issuer to provide ''an annual rebate to each enrollee'' if the issuer does not meet the applicable MLR standard. The interim final rule directs issuers of group coverage to provide rebates to the policyholder and each subscriber in amounts proportionate to the amount of premium each paid. The interim final rule also allows an issuer to delegate its rebate disbursement obligation to group policyholders, though the issuer remains liable for complying with all its obligations under the statute and for maintaining records that demonstrated rebates were provided accurately. As discussed elsewhere in this preamble, commenters expressed concern that the issuer lacks access to the information needed to distribute rebates, asserting that the policyholder, and not the issuer, has information regarding the premium contribution amount from the employer and the employee.

This final rule provides that issuers will distribute rebates to the policyholder to be used for the benefit of subscribers. For policyholders that are a group health plan but are not a governmental plan or subject to ERISA, an issuer must obtain written assurance from the policyholder that rebates will be used for the benefit of current subscribers using one of the options permitted for non-Federal governmental plans as described in the interim final rule issued contemporaneously with this final rule; otherwise, the issuer must evenly distribute the rebate directly to the policyholder's subscribers covered by the policy during the MLR reporting year on which the rebate is based.

Disbursing rebates directly to subscribers would result in a tax burden for consumers and also a tax-administration burden for the issuers making the payment, as most premiums are paid with pre-tax dollars and thus the rebates may be wages subject to withholding obligations. Because issuers would not otherwise be paying wages to these individuals, the administrative burden of administering any applicable withholding obligations could be significant in total. If the rebates are disbursed to the policyholder (generally the employer) for the benefit of subscribers (generally the employees), they must be used in a way that benefits subscribers (in the case of ERISA plans, consistent with their fiduciary obligations) but minimizes any tax administration issues for employers and enrollees, while consumers would still receive the benefit of the rebates. Subscribers who no longer are covered under the group health plan, however, generally would not receive the benefits from the rebates distributed through the policyholder. Therefore, there would be a transfer of benefits from enrollees who leave the plan to new enrollees in the same plan. We expect this transfer to be small since persistence rates in group health plans tend to be high.

Group health plan issuers will also experience savings due to the fact that rebate payments will no longer be required to be sent to a large number of individuals. In the interim final rule, the average cost of sending rebate payments was estimated to be $1 per check. For the years 2012 and 2013, it was estimated that each year 0.8 million enrollees in the small group market and 1 million enrollees in the large group market would receive rebates and 50 percent of these enrollees would receive rebate checks. Assuming that all issuers of group coverage distribute rebates to policyholders, we estimate that this will lead to an annual reduction in administrative costs of approximately $1.8 million for these issuers. However, policyholders will experience an increase in administrative costs related to the disbursement of rebates. The actual cost would depend on whether the policyholders send rebate checks or whether the rebates are disbursed through future premium reductions or through payroll. These costs will also be offset by eliminating the administrative burden and tax consequences inherent in the prior rebate mechanism.

C. Regulatory Alternatives

Under the Executive Order, CMS is required to consider alternatives to issuing regulations and alternative regulatory approaches. CMS considers a variety of regulatory alternatives below.

1. Mini-Med and Expatriate Policies

One alternative to the MLR methodology set forth in this final rule is to provide no adjustments in the MLR calculation for the experience of these policies. Without any adjustments to the MLR methodology for issuers of mini-med policies with total annual benefit limits of $250,000 or less, CMS estimates that in 2011, seven issuers would have paid rebates of approximately $53 million in the

individual market and six issuers would pay approximately $120 million in the large group market. Without any adjustments to MLR methodology for issuers of expatriate policies, CMS estimates that in 2011, four issuers in the large group market would have paid rebates of approximately $145 million.

Another alternative was to maintain the multiplier of 2.00 provided in the interim final rule, for mini-med policies with total annual benefit limits of $250,000 or less. Based on 2011 data, with a multiplier of 2.00, three issuers of mini-med policies in the individual market would have paid an estimated $1.1 million in rebates while no issuers in the small or large group markets would have paid rebates. As described elsewhere in this preamble, CMS has concluded that the MLR methodology set forth in the final rule will best balance the goals of providing value to consumers and ensuring that consumers have continued access to coverage in these markets.

2. Distribution of Rebates in the Group Market

One alternative to the MLR methodology set forth in this final rule is to require issuers to send rebate payments directly to subscribers in group health plans. As described previously, this would result in increased tax burden for consumers with group coverage and for their employers, as well as increased administrative costs for issuers associated with rebate payments. As discussed earlier, the average annual cost per issuer of sending rebate checks was estimated to be between $43,962 and $71,467 in the interim final rule.

3. ICD–10 Conversion Expenses and Community Benefit Expenditures

With respect to ICD–10 conversion costs, one alternative to the MLR methodology set forth in this final rule was to exclude these costs from QIA. As discussed previously, this would result in slightly lower MLRs for issuers and therefore higher rebate payments for issuers that fail to meet the MLR standard.

With respect to community benefit expenditures, one alternative to the MLR methodology set forth in this final rule was to allow only a not-for-profit, tax-exempt issuer to deduct from earned premium the amount of its community benefit expenditures, limited to the State premium tax rate applicable to for-profit issuers and also require a not-for-profit issuer to report community benefit expenditures ''in lieu of taxes * * * but not to exceed the amount of taxes [it] would otherwise be required to pay.'' As discussed previously, this would result in lower MLRs for some issuers and therefore higher rebate payments for issuers that fail to meet the MLR standard.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires agencies that issue a regulation to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. The RFA generally defines a ''small entity'' as: (1) A proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a nonprofit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000 (States and individuals are not included in the definition of ''small entity''). HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

The Regulatory Flexibility Act only requires an analysis to be conducted for those final rules for which a Notice of Proposed Rule Making was required. Accordingly, we have determined that a regulatory flexibility analysis is not required for this final rule. However, CMS has considered the likely impact of this final rule on small entities.

As discussed in the Web Portal final rule published on May 5, 2010 (75 FR 24481), HHS examined the health insurance industry in depth in the Regulatory Impact Analysis we prepared for the proposed rule on establishment of the Medicare Advantage program (69 FR 46866, August 3, 2004). In that analysis the Department determined that there were few if any insurance firms underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) that fell below the size thresholds for ''small'' business established by the SBA (currently $7 million in annual receipts for health issuers).[11]

For the MLR interim final rule, the Department used the data set created from 2009 NAIC Health and Life Blank annual financial statement data to develop an updated estimate of the number of small entities that offer comprehensive major medical coverage in the individual and small group markets, and are therefore subject to the MLR reporting requirements. For purposes of this analysis, the Department used total Accident and Health (A&H) earned premiums as a proxy for annual receipts. These estimates may overstate the actual number of small health insurance issuers that would be affected, since they do not include receipts from these companies' other lines of business.

In the MLR interim final rule (75 FR 74892), the Department estimated that there are 28 small entities with less than $7 million in A&H earned premiums that offer individual or group comprehensive major medical coverage, and would therefore be subject to the requirements of this final regulation. These small entities accounted for 6 percent of the estimated 442 total issuers that the Department estimated would be affected by the MLR requirements. The Department estimated that 86 percent of these small issuers are subsidiaries of larger carriers, 75 percent only offer coverage in a single State, 68 percent only offer individual or group comprehensive coverage in a single market, 46 percent also offer other types of A&H coverage, and 29 percent are Life Blank filers.

CMS has estimated that the provisions of the final rule do not impose any additional costs on small entities. There are, however, some cost savings as a result of this final rule. There will be an increase in rebates for some issuers of mini-med policies with total annual benefit limits of $250,000 or less, though no small entities are affected. The changes in MLR methodology to account for inclusion of ICD–10 costs and community benefit expenditures will also lead to reduction in rebates and will therefore, not affect any small entities adversely.

CMS believes that these estimates overstate the number of small entities that will be affected by the requirements in this final regulation, as well as the relative impact of these requirements on these entities because the Department has based its analysis on issuers' total A&H earned premiums (rather than their total annual receipts). Therefore, the Secretary certifies that these final regulations will not have significant impact on a substantial number of small entities. In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant economic impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. This final rule would not affect small rural hospitals. Therefore, the Secretary has determined that this rule would not have a significant impact on the

[11] ''Table of Size Standards Matched to North American Industry Classification System Codes,'' effective November 5, 2010, U.S. Small Business Administration, available at *http://www.sba.gov.*

operations of a substantial number of small rural hospitals.

E. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule that includes a Federal mandate that could result in expenditure in any one year by State, local or Tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold level is approximately $136 million.

UMRA does not address the total cost of a rule. Rather, it focuses on certain categories of cost, mainly those ''Federal mandate'' costs resulting from: (1) Imposing enforceable duties on State, local, or Tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, State, local, or Tribal governments under entitlement programs.

Consistent with policy embodied in UMRA, this final regulation has been designed to be the least burdensome alternative for State, local and Tribal governments, and the private sector while achieving the objectives of the Affordable Care Act.

This final regulation contains MLR methodology adjustments and rebate payment requirements for private sector firms (for example, health insurance issuers offering coverage in the mini-med, expatriate, individual and group markets). CMS estimates that none of these provisions impose additional costs on consumers or private sector firms, and will lead to reduced administrative costs to issuers. There will be a reduction in rebates paid by issuers in individual, small and group markets due to inclusion of ICD–10 conversion costs and community benefit expenditures. Rebates paid by issuers of mini-med policies will increase by an estimated $59 million annually. It includes no mandates on State, local, or Tribal governments.

F. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. In CMS's view, while this final rule does not impose substantial direct requirement costs on State and local governments, this final regulation has Federalism implications due to direct effects on the distribution of power and responsibilities among the State and Federal governments relating to determining and enforcing minimum MLR standards and rebate requirements relating to coverage that State-licensed health insurance issuers offer in the individual and group markets.

However, CMS anticipates that the Federalism implications (if any) are substantially mitigated because the Affordable Care Act does not provide any role for the States in terms of receiving or analyzing the data or enforcing the requirements of Section 2718 of the PHS Act.

As discussed in the MLR interim final rule, States may continue to apply State law requirements except to the extent that such requirements prevent the application of the Affordable Care Act requirements that are the subject of this rulemaking. State insurance laws that are more stringent than the Federal requirements are unlikely to ''prevent the application of'' the Affordable Care Act and to be preempted.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have Federalism implications or limit the policy making discretion of the States, the Department has engaged in efforts to consult with and work cooperatively with affected States, including participating in conference calls with and attending conferences of the National Association of Insurance Commissioners, and consulting with State insurance officials on an individual basis.

Throughout the process of developing this final regulation, to the extent feasible within the specific preemption provisions of HIPAA as it applies to the Affordable Care Act, the Department has attempted to balance the States' interests in regulating health insurance issuers, and Congress' intent to provide uniform minimum protections to consumers in every State. By doing so, it is the Department's view that we have complied with the requirements of Executive Order 13132. Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to this regulation, the Department certifies that the Centers for Medicare & Medicaid Services has complied with the requirements of Executive Order 13132 for the attached final regulation in a meaningful and timely manner.

G. Congressional Review Act

This final regulation is not subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*).

List of Subjects in 45 CFR Part 158

Administrative practice and procedure, Claims, Health care, Health insurance, Health plans, Penalties, Reporting and recordkeeping requirements.

Accordingly, the interim final rule amending 45 CFR part 158, which was published at 75 FR 74864 on December 1, 2010, and further amended by a correction on December 30, 2010, is adopted as final with the following changes:

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

■ 1. The authority citation for part 158 continues to read as follows:

Authority: Section 2718 of the Public Health Service Act (42 U.S.C. 300gg–18), as amended.

§ 158.110 [Amended]

■ 2. Section 158.110 is amended by—

■ a. Removing in paragraph (b)(1) the phrase ''Except as provided in paragraph (b)(2) of this section, the'' and adding ''The'' in its place.

■ b. Removing paragraph (b)(2).

■ c. Removing the paragraph designation for paragraph (b)(1).

■ 3. Section 158.120 is amended by revising paragraphs (d)(3) and (4) to read as follows:

§ 158.120 Aggregate reporting.

* * * * *

(d) * * *

(3) An issuer with policies that have a total annual limit of $250,000 or less must report the experience from such policies separately from other policies.

(4) An issuer with group policies that provide coverage to employees, substantially all of whom are: Working outside their country of citizenship; working outside of their country of citizenship and outside the employer's country of domicile; or non-U.S. citizens working in their home country, must aggregate and report the experience from these policies on a national basis, separately for the large group market and small group market, and separately from other policies.

■ 4. Section 158.150 is amended by—

■ a. Adding paragraph (b)(2)(i)(A)(*6*).

■ b. Revising paragraph (c)(5).

The addition and revision read as follows:

§ 158.150 Activities that improve health care quality.

* * * * *

(b) * * *
(2) * * *
(i) * * *
(A) * * *
(*6*) For each of the 2012 and 2013 MLR reporting years, implementing ICD–10 code sets that are designed to improve quality and are adopted pursuant to the Health Insurance Portability and Accountability Act (HIPAA), 42 U.S.C. 1320d–2, as amended, limited to 0.3 percent of an issuer's earned premium as defined in § 158.130 of this subpart.
* * * * *
(c) * * *
(5) Establishing or maintaining a claims adjudication system, including costs directly related to upgrades in health information technology that are designed primarily or solely to improve claims payment capabilities or to meet regulatory requirements for processing claims, including maintenance of ICD–10 code sets adopted pursuant to the Health Insurance Portability and Accountability Act (HIPAA), 42 U.S.C. 1320d–2, as amended.
* * * * *

■ 5. Section 158.162 is amended by—
■ a. Revising paragraph (b)(1)(vii).
■ b. Revising paragraph (c).
The revisions read as follows:

§ 158.162 Reporting of Federal and State taxes.

* * * * *
(b) * * *
(1) * * *
(vii) In lieu of reporting amounts described in paragraph (b)(1)(vi) of this section, an issuer may choose to report payment for community benefit expenditures as described in paragraph (c) of this section, limited to the highest premium tax rate in the State for which the report is being submitted.
* * * * *
(c) *Community benefit expenditures.* Community benefit expenditures means expenditures for activities or programs that seek to achieve the objectives of improving access to health services, enhancing public health and relief of government burden. This includes any of the following activities that:
(1) Are available broadly to the public and serve low-income consumers;
(2) Reduce geographic, financial, or cultural barriers to accessing health services, and if ceased to exist would result in access problems (for example, longer wait times or increased travel distances);
(3) Address Federal, State or local public health priorities such as advancing health care knowledge through education or research that benefits the public;
(4) Leverage or enhance public health department activities such as childhood immunization efforts; and
(5) Otherwise would become the responsibility of government or another tax-exempt organization.

■ 6. Section 158.221 is amended by revising paragraphs (b)(3) and (4) to read as follows:

§ 158.221 Formula for calculating an issuer's medical loss ratio.

* * * * *
(b) * * *
(3) The numerator of the MLR for policies that are reported separately under § 158.120(d)(3) of this part must be the amount specified in paragraph (b) of this section, except that for the 2012 MLR reporting year, the total of the incurred claims and expenditures for activities that improve health care quality are then multiplied by a factor of 1.75, for the 2013 MLR reporting year, the total of the incurred claims and expenditures for activities that improve health care quality are then multiplied by a factor of 1.50, and for the 2014 MLR reporting year, the total of the incurred claims and expenditures for activities that improve health care quality are then multiplied by a factor of 1.25.
(4) The numerator of the MLR for policies that are reported separately under § 158.120(d)(4) of this part must be the amount specified in paragraph (b) of this section, except that the total of the incurred claims and expenditures for activities that improve health care quality are then multiplied by a factor of 2.00.
* * * * *

■ 7. Section 158.241 is amended by revising paragraph (b) to read as follows:

§ 158.241 Form of rebate.

* * * * *
(b) *Former enrollees in the individual market.* Rebates owing to former enrollees in the individual market must be paid in the form of lump-sum check or lump-sum reimbursement using the same method that was used for payment, such as credit card or direct debit.

■ 8. Section 158.242 is amended by revising paragraph (b) to read as follows:

§ 158.242 Recipients of rebates.

* * * * *
(b) *Large group and small group markets.* Except as provided in paragraphs (b)(3) and (4) of this section, an issuer must meet its obligation to provide any rebate to persons covered under a group health plan by providing it to the policyholder.
(1) [Reserved.]
(2) [Reserved.]
(3) If the policyholder is a group health plan that is not a governmental plan and not subject to the Employee Retirement Income Security Act of 1974, as amended (29 U.S.C. 1001 *et seq.*) (ERISA), rebates may only be paid to the policyholder if the issuer receives a written assurance from the policyholder that the rebates will be used to benefit enrollees; otherwise, the issuer must distribute the rebate directly to the subscribers of the group health plan covered by the policy during the MLR reporting year on which the rebate is based by dividing the entire rebate, including the amount proportionate to the amount of premium paid by the policyholder, in equal amounts to all subscribers entitled to a rebate without regard to how much each subscriber actually paid toward premiums.
(4) If the group health plan has been terminated at the time of rebate payment and the issuer cannot, despite reasonable efforts, locate the policyholder whose plan participants or employees were enrolled in the group health plan, the issuer must distribute the rebate directly to the subscribers of the terminated group health plan by dividing the entire rebate, including the amount proportionate to the amount of premium paid by the policyholder, in equal amounts to all subscribers entitled to a rebate without regard to how much each subscriber actually paid toward premiums.

■ 9. Section 158.243 is amended by revising paragraph (a)(1) to read as follows:

§ 158.243 De minimis rebates.

(a) * * *
(1) For a group policy for which the issuer distributes the rebate to the policyholder, if the total rebate owed to the policyholder and the subscribers combined is less than $20 for a given MLR reporting year; or for a group policy for which the issuer distributes the rebate directly to the subscribers, as provided in § 158.242(a)(3) and (4) of this subpart, if the total rebate owed to each subscriber is less than $5.
* * * * *

■ 10. Section 158.250 is revised to read as follows:

§ 158.250 Notice of rebates.

(a) *Notice of rebates to policyholders and subscribers of group health plans.* For each MLR reporting year, at the time any rebate of premium is provided to a policyholder of a group health plan in accordance with this part, an issuer must provide each policyholder who receives a rebate and subscribers whose

policyholder receives a rebate, or each subscriber who receives a rebate directly from an issuer, the following information in a form prescribed by the Secretary:

(1) A general description of the concept of an MLR;

(2) The purpose of setting an MLR standard;

(3) The applicable MLR standard;

(4) The issuer's MLR, adjusted in accordance with the provisions of this subpart;

(5) The issuer's aggregate premium revenue as reported in accordance with § 158.130 of this part, minus any Federal and State taxes and licensing and regulatory fees that may be excluded from premium revenue as described in § 158.162(a)(1) and (b)(1) of this part;

(6) The rebate percentage and the amount owed to enrollees, as defined in section 158.240(b), based upon the difference between the issuer's MLR and the applicable MLR standard; and

(7) The fact that, as provided by this subpart, the total aggregated rebate for the group health plan is being provided to the policyholder:

(i) If the policy provides benefits for a plan subject to ERISA, a statement that the policyholder may have additional obligations under ERISA's fiduciary responsibility provisions with respect to the handling of rebates and contact information for questions regarding the rebate;

(ii) If the policyholder is a non-Federal governmental plan, the proportion of the rebate attributable to subscribers' contribution to premium must be used for the benefit of subscribers, using one of the methods set forth in § 158.242(b)(1) of this subpart; and

(iii) If the policyholder is a group health plan that is not a governmental plan and is not subject to ERISA,

(A) The policyholder has provided written assurance that the proportion of the rebate attributable to subscribers' contribution to premium will be used for the benefit of current subscribers, using one of the methods set forth in § 158.242(b)(1) of this subpart, or

(B) If the policyholder did not provide such written assurance, the issuer must distribute the rebate evenly among the policyholder's subscribers covered by the policy during the MLR reporting year on which the rebate is based.

(b) *Notice of rebates to subscribers in the individual market.* For each MLR reporting year, at the time any rebate of premium is provided to a subscriber in the individual market in accordance with this part, an issuer must provide each subscriber that is receiving the rebate the following information in a form prescribed by the Secretary:

(1) A general description of the concept of an MLR;

(2) The purpose of setting an MLR standard;

(3) The applicable MLR standard;

(4) The issuer's MLR, adjusted in accordance with the provisions of this subpart;

(5) The issuer's aggregate premium revenue as reported in accordance with § 158.130 of this part, minus any Federal and State taxes and licensing and regulatory fees that may be excluded from premium revenue as described in § 158.162(a)(1) and (b)(1) of this part; and

(6) The rebate percentage and amount owed to enrollees based upon the difference between the issuer's MLR and the applicable MLR standard.

■ 11. Section 158.260 is amended by revising paragraphs (c)(1) through (5) to read as follows:

§ 158.260 Reporting of rebates.

* * * * *

(c) * * *

(1) Number of subscribers in the individual, small group and large group markets to whom the issuer paid a rebate directly, and number of small group and large group policyholders receiving a rebate on behalf of enrollees;

(2) Amount of rebates provided as premium credit;

(3) Amount of rebates provided as lump sum payment regardless of whether in cash, reimbursement to an enrollee's credit card, or direct payment to an enrollee's bank account;

(4) Amount of rebates that were de minimis as provided in § 158.243 of this subpart and the number of enrollees who did not receive a rebate because it was de minimis; and

(5) Amount of unclaimed rebates, a description of the methods used to locate the applicable enrollees, and a description of how the unclaimed rebates were disbursed.

Dated: November 2, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: November 29, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2011–31289 Filed 12–2–11; 11:15 am]

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Part V

Department of Health and Human Services

45 CFR Part 158

Medical Loss Ratio Rebate Requirements for Non-Federal Governmental Plans; Interim Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 158

[CMS–9998–IFC2]

RIN 0938–AR35

Medical Loss Ratio Rebate Requirements for Non-Federal Governmental Plans

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with request for comments.

SUMMARY: This interim final rule with comment period revises the regulations implementing medical loss ratio (MLR) requirements for health insurance issuers under the Public Health Service Act in order to establish rules governing the distribution of rebates by issuers in group markets for non-Federal governmental plans.

DATES: *Effective date.* This rule is effective on January 3, 2012.

Comment date. To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on February 6, 2012.

Applicability Date. The amendments to Part 158 generally apply beginning January 1, 2012, to health insurance issuers offering group health insurance coverage.

ADDRESSES: In commenting please refer to file code CMS–9998–IFC2. Because of staff and resource limitations, we cannot accept comments by email or facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the ''More Search Options'' tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–9998–IFC2, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–9998–IFC2, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments only to the following addresses prior to the close of comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (800) 743–3591.

FOR FURTHER INFORMATION CONTACT: Carol Jimenez, (301) 492–4457.

SUPPLEMENTARY INFORMATION: *Comment Subject Areas:* We will consider comments on the rules for providing rebates to group enrollees in non-Federal governmental plans, as discussed in this interim final rule with comment period, that are received by the date and time indicated in the **DATES** section of this interim final rule with comment period.

I. Background

The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010; the Health Care and Education Reconciliation Act (Pub. L. 111–152) was enacted on March 30, 2010. In this preamble, we refer to the two statutes collectively as the Affordable Care Act. The Affordable Care Act reorganizes, amends, and adds to the provisions of Part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets.

A request for information relating to the medical loss ratio (MLR) provisions of PHS Act section 2718 was published in the **Federal Register** on April 14, 2010 (75 FR 19297). On December 1, 2010, HHS published an interim final rule (75 FR 74864) with 60-day public comment period, entitled ''Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act,'' that added a new 45 CFR Part 158. A technical correction to the interim final rule was issued on December 30, 2010 (75 FR 82277). The Department of Health and Human Services (HHS) published a final rule entitled ''Medical Loss Ratio Requirements under the Patient Protection and Affordable Care Act,'' published elsewhere in this **Federal Register** (hereinafter referred to as the Medical Loss Ratio final rule).

II. Provisions of the Interim Final Rule

Rebates to Enrollees in Non-Federal Governmental Plans in Group Markets (45 CFR 158.242(b))

As stated in the Medical Loss Ratio final rule published elsewhere in this **Federal Register**, with respect to non-Federal governmental plans, there currently is no legal framework set forth in Federal law governing the use of rebates received from an issuer under the MLR regulations. However, CMS has direct authority over non-Federal governmental plans. Accordingly, for reasons discussed in the preamble of the Medical Loss Ratio final rule, under the authority in section 2792 of the PHS Act to promulgate regulations determined ''appropriate'' to ''carry out'' the provisions of part A of title XXVII of the PHS Act, which include PHS Act section 2718, this interim final rule with

comment period directs that issuers distribute the entire rebate to the group policyholder and the group policyholder is required to use the portion of rebates attributable to the amount of premium paid by subscribers of non-Federal governmental plans for the benefit of subscribers, ensuring that enrollees in such plans receive the benefit of rebates. For example, if an issuer whose MLR is lower than the applicable MLR standard owes a rebate of $20,000 to the policyholder and subscribers of a group health plan, the issuer would provide the $20,000 directly to the policyholder. If the non-Federal governmental plan's subscribers paid 40 percent of the total premium, then the policyholder must use 40 percent of the rebate, or $8,000, for the benefit of the subscribers.

With respect to rebates paid to non-Federal governmental plans, we direct in this interim final rule with comment period that the subscriber portion of the rebate be used, at the option of the policyholder, in one of the following ways—(1) To reduce subscribers' portion of the annual premium for the subsequent policy year for all subscribers covered under any group health policy offered by the plan; (2) to reduce subscribers' portion of the annual premium for the subsequent policy year for only those subscribers covered by the group health policy on which the rebate was based; or (3) to provide a cash refund only to subscribers that were covered by the group health policy on which the rebate is based. In all three options, the rebate is used to reduce premiums or is paid to subscribers enrolled during the year in which the rebate is actually paid, rather than the MLR reporting year on which the rebate was calculated. We believe that this results in administrative simplicity, as it does not require tracking former enrollees or determining who was covered by which issuer the prior year while maintaining the law's intent of benefitting enrollees.

These options were created to provide maximum flexibility to policyholders and employers while ensuring that enrollees receive the benefits of the rebate. No single option is preferred by CMS. The first option allows all subscribers who receive health care coverage through the plan, and not just those participants that were covered by the policy that produced the rebate, to receive reduced premiums in the subsequent policy year. While this option allows some employees to benefit from a rebate despite the fact that they did not contribute to the premium paid to the particular issuer providing the rebate, we believe that this option provides for ease of rebate calculation and administration, especially for large employers with enrollees in multiple states who offer multiple policy choices and may get rebates from several issuers.

We request comment on the treatment of rebates in the non-Federal governmental group market. Since we provide, in this interim final rule with comment period, three specific methods for non-Federal governmental plans to distribute to current subscribers rebates attributable to subscribers' aggregated contribution to premium, we request comments specifically on whether the mechanism provided in this interim final rule with comment period solves or meaningfully reduces the logistical challenges of providing rebates to non-Federal governmental plans and distributing them to their subscribers and on other potential solutions to these challenges while ensuring that enrollees benefit when rebates are paid.

III. Collection of Information Requirements

This interim final rule with comment period does not impose any new reporting requirements and generally conforms to the requirements under the interim final regulation published on December 1, 2010.

IV. Response to Comments

Because of the large number of public comments CMS receives on **Federal Register** documents, CMS is not able to acknowledge or respond to them individually. CMS will consider all comments CMS receives by the date and time specified in the **DATES** section of this preamble, and, when CMS proceeds with a subsequent document, CMS will respond to the comments in the preamble to that document.

V. Waiver of Proposed Rulemaking

This interim final rule with comment period includes in § 158.242(b) a provision governing how a non-Federal governmental plan is required to distribute rebates. A non-Federal governmental plan would not have had any reason to believe that the MLR regulations would impose any requirements on them, as this possibility was not discussed in the interim final rule published on December 1, 2010. Thus, ordinarily, before imposing such a requirement, the Administrative Procedure Act (APA) would require that they be provided with an opportunity for prior public comment.

Section 2792 of the PHS Act, however, authorizes the Secretary of HHS to promulgate interim final rules determined appropriate to carry out the provisions of part A of title XXVII of the PHS Act, which include PHS Act section 2718, without subjecting the rules to prior notice and comment. CMS accordingly is relying on the authority in section 2792 to implement this provision on an interim final basis without a prior opportunity for public comment. CMS will consider public comments received on this provision.

CMS notes that under the APA (5 U.S.C. 551 *et seq.*), while an opportunity for public comment is generally required before promulgation of regulations, this is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. The provisions of the APA that ordinarily require a notice of proposed rulemaking do not apply here because of the specific authority in section 2792 of the PHS Act cited above.

However, even if the APA requirements for notice and comment were applicable to the revisions to § 158.242(b), regarding permissible distribution of rebates by non-Federal governmental plans, these APA requirements have been satisfied. This is because the Secretary finds that providing an additional opportunity for public comment on this provision would be impractical and contrary to the public interest, for the reasons set forth below.

Specifically, the Department waives notice and comment for § 158.242(b)(1) and (2), regarding permissible distribution of rebates by non-Federal governmental group plan policyholders, due to the immediate problematic operational impact a failure to put these changes in place would have on issuers and non-Federal governmental group plan policyholders (that is, mostly employers).

As stated in the Medical Loss Ratio final rule published contemporaneously with this interim final rule with comment period, the Department received many comments expressing significant concern with the requirement that issuers in the group markets distribute the enrollee portion of the rebate directly to the subscriber. Additionally, there are tax implications to distributing rebates directly to subscribers. To address these concerns, both the Medical Loss Ratio final rule and this interim final rule with comment period require issuers to send group policyholders the entire rebate attributable to the group health plan.

However, as noted in the preamble to the separate Medical Loss Ratio final rule, a provision that simply permits issuers to pay rebates to a non-Federal

governmental plan would not ensure that enrollees in those plans would benefit from the rebate, as is ensured under Federal law in the case of plans governed by the Employee Retirement Income Security Act of 1974 (ERISA), as amended (29 CFR 1001 *et seq.*). The new provisions eliminating burdens for making rebate payments in 2012 put in place by the Medical Loss Ratio final rule published today thus could not effectively be implemented for non-Federal governmental plans without measures to ensure that rebates are used for the benefit of enrollees. CMS has authority to regulate non-Federal governmental plans and, therefore, is setting requirements that are necessary in order to combine the efficiencies of paying rebates to the non-Federal governmental plan with the assurance that enrollees of the plan will benefit from such payments.

Informing issuers and non-Federal governmental plans of these changes as soon as possible is necessary so that they may take them into account in negotiating their group health insurance contracts for the 2012 MLR reporting year, as those preparations are currently underway. In addition, issuers are pricing their insurance products and the regulatory requirement regarding disbursement of rebates is a component of their pricing structure.

The changes CMS makes in this interim final rule with comment period are necessary in order for the provisions of the Medical Loss Ratio final rule simplifying the procedures that issuers must follow to work effectively, and thus are necessary in order to reduce administrative burdens. Issuers and policyholders will welcome and support these changes, which need to be communicated immediately, providing just cause for waiving the notice of proposed rulemaking. Therefore, CMS finds good cause to waive prior notice and comment with respect to the new rules governing distribution of rebates by non-Federal governmental plans. CMS is providing a 30-day public comment period on provisions in this interim final rule.

VI. Regulatory Impact Statement

A. Summary

This interim final rule with comment period is designed to address a specific issue that has arisen regarding section 2718 of the PHS Act, which sets forth standards for reporting of certain medical loss ratio (MLR) related data to the Secretary on an annual basis by issuers offering coverage in the individual and group markets, and calculating and providing rebates to policyholders in the event that an issuer's MLR fails to meet or exceed the statutory standard. This interim final rule with comment period establishes rules for the distribution of rebates in non-Federal governmental plans in the group market. These provisions are generally effective beginning January 1, 2012.

CMS is publishing this interim final rule with comment period to implement the protections intended by the Congress in the most economically efficient manner possible. CMS has examined the effects of this rule as required by Executive Order 12866 (58 FR 51735, September 1993, Regulatory Planning and Review), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

B. Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule (1) Having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or Tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year); and a ''significant'' regulatory action is subject to review by the Office of Management and Budget (OMB). CMS has concluded that this interim final rule with comment period is not likely to have economic impacts of $100 million or more in any one year, and therefore does not meet the definition of ''economically significant rule'' under Executive Order 12866.

1. Need for Regulatory Action

Consistent with the provisions in Section 2718 of the PHS Act, this interim final rule with comment period establishes rules for providing rebates to enrollees in non-Federal governmental group health plans when the MLR standard is not met by an issuer. Section 2718(b) of the PHS Act (captioned ''ensuring that consumers receive value for their premium payments'') requires issuers to provide an annual rebate to each enrollee if the ratio of the amount of premium revenue expended on reimbursement for clinical services and activities that improve quality is less than the applicable minimum standard and specifies how the rebate is to be calculated. This interim final rule with comment period directs that issuers distribute the entire rebate to the group policyholder and the group policyholder is required to use the portion of rebates attributable to the amount of premium paid by subscribers of non-Federal governmental plans for the benefit of subscribers, ensuring that enrollees in such plans receive the benefit of rebates.

2. Summary of Impacts

This interim final rule with comment period provides for a more efficient and cost effective way for issuers to disburse rebate payments to subscribers of non-Federal governmental plans by allowing issuers in group markets to provide rebates to the policyholders for distribution. As stated in the Medical Loss Ratio final rule published contemporaneously with this interim final rule with comment period, it is estimated that for the years 2012 and 2013, 0.8 million enrollees in the small group market and 1 million enrollees in the large group market would receive rebates each year. Only a fraction of these enrollees will be in non-Federal governmental plans. This provision will lower administrative costs related to rebate disbursement for issuers of group health plans and will largely eliminate the tax burden on employers and consumers inherent in the prior rebate

mechanism as explained in the Medical Loss Ratio final rule published contemporaneously with this interim final rule with comment period. Policyholders will experience an increase in administrative costs related to the disbursement of rebates, although these administrative costs will be offset by eliminating the administrative burden and tax consequences inherent in the prior rebate mechanism that directed issuers to pay rebates directly to policyholders and each of their subscribers. As a result, CMS has concluded that the impacts are not economically significant.

An alternative to the rebate distribution methodology set forth in this interim final rule with comment period is to require issuers to send rebate payments directly to subscribers of non-Federal governmental group health plans. As described previously, this would result in increased tax burden for consumers and for their employers, as well as increased administrative costs for issuers associated with rebate payments.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires agencies that issue a regulation to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. The RFA generally defines a ''small entity'' as: (1) A proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a nonprofit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000 (States and individuals are not included in the definition of ''small entity''). HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

CMS has estimated that the provisions of the interim final rule with comment period do not impose any additional costs on small entities. Therefore, the Secretary has determined that this interim final rule with comment period will not have a significant impact on a substantial number of small entities. In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant economic impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. This interim final rule with comment period would not affect small rural hospitals. Therefore, the Secretary has determined that this interim final rule with comment period would not have a significant impact on the operations of a substantial number of small rural hospitals.

D. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule that includes a Federal mandate that could result in expenditure in any one year by State, local or Tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold level is approximately $136 million. This interim final rule with comment period has no consequential effect on State, local, or Tribal governments in the aggregate, or by the private sector.

UMRA does not address the total cost of a rule. Rather, it focuses on certain categories of cost, mainly those ''Federal mandate'' costs resulting from: (1) Imposing enforceable duties on State, local, or Tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, State, local, or Tribal governments under entitlement programs.

E. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This interim final rule with comment period does not impose substantial direct requirement costs on State and local governments, and also does not have effects on the distribution of power and responsibilities among the State and Federal governments.

Throughout the process of developing this interim final regulation the Department has attempted to balance the States' interests and Congress' intent to provide uniform minimum protections to consumers in every State. By doing so, it is the Department's view that we have complied with the requirements of Executive Order 13132. Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to this regulation, the Department certifies that the Centers for Medicare & Medicaid Services has complied with the requirements of Executive Order 13132 for the attached interim final regulation in a meaningful and timely manner.

F. Congressional Review Act

This interim final regulation is not subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*).

List of Subjects in 45 CFR Part 158

Administrative practice and procedure, Claims, Health care, Health insurance, Health plans, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 45 CFR part 158 as set forth below:

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

■ 1. The authority citation for part 158 continues to read as follows:

Authority: Section 2718 of the Public Health Service Act (42 U.S.C. 300gg–18), as amended.

■ 2. Section 158.242 is amended by—

■ a. Adding new paragraphs (b)(1) and (2).

■ b. Revising paragraph (b)(3).

The additions and revision read as follows:

§ 158.242 Recipients of rebates.

* * * * *

(b) * * *

(1) In the case of a policyholder that is a non-Federal governmental group health plan, the policyholder must use the amount of the rebate that is proportionate to the total amount of premium paid by all subscribers under the policy, for the benefit of subscribers in one of the following ways, at the option of the policyholder:

(i) For all subscribers covered under any option offered under the policyholder's group health plan at the time the rebate is received by the policyholder, to reduce the subscribers' portion of premium for the subsequent policy year;

(ii) For subscribers covered, at the time the rebate is received by the policyholder, under the group health plan option for which the issuer is providing a rebate, to reduce the subscribers' portion of premium for the subsequent policy year;

(iii) A cash refund to subscribers enrolled in the group health plan option, at the time the rebate is received by the policyholder, for which the issuer is providing a rebate; and

(iv) The reduction in future premium or the cash refund provided under paragraphs (b)(1)(i), (ii), or (iii) of this

section may, at the option of the policyholder, be: Divided evenly among such subscribers; divided based on each subscriber's actual contributions to premium; or apportioned in a manner that reasonably reflects each subscriber's contributions to premium.

(2) In the case of a policyholder that is a non-Federal governmental group health plan, the portion of a rebate based upon former subscribers' contributions to premium must be aggregated and used for the benefit of current subscribers in the group health plan in any manner permitted by paragraph (b)(1) of this section.

(3) If the policyholder is a group health plan that is not a governmental plan and not subject to the Employee Retirement Income Security Act of 1974, as amended (29 U.S.C. 1001 *et seq.*) (ERISA), rebates may only be paid to the policyholder if the issuer receives a written assurance from the policyholder that the rebates will be used as provided in paragraphs (b)(1) and (2) of this section; otherwise, the issuer must distribute the rebate directly to the subscribers of the group health plan covered by the policy during the MLR reporting year on which the rebate is based by dividing the entire rebate, including the amount proportionate to the amount of premium paid by the policyholder, in equal amounts to all subscribers entitled to a rebate without regard to how much each subscriber actually paid toward premiums.

* * * * *

Dated: December 1, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: December 1, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2011–31291 Filed 12–2–11; 11:15 am]

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