FEDERAL REGISTER

Vol. 79 Thursday,

No. 233 December 4, 2014

Pages 71955–72106

OFFICE OF THE FEDERAL REGISTER

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see *www.ofr.gov.*

The seal of the National Archives and Records Administration authenticates the Federal Register as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge at *www.fdsys.gov*, a service of the U.S. Government Printing Office.

The online edition of the **Federal Register** is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 59, 1 (January 2, 1994) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Printing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, *gpocusthelp.com.*

The annual subscription price for the **Federal Register** paper edition is $749 plus postage, or $808, plus postage, for a combined **Federal Register, Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is $165, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register,** including postage, is based on the number of pages: $11 for an issue containing less than 200 pages; $22 for an issue containing 200 to 400 pages; and $33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for $3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: U.S. Government Printing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see *bookstore.gpo.gov.*

There are no restrictions on the republication of material appearing in the **Federal Register.**

How To Cite This Publication: Use the volume number and the page number. Example: 77 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Printing Office, Washington, DC 20402, along with the entire mailing label from the last issue received.

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	**202–512–1800**
Assistance with public subscriptions	**202–512–1806**
General online information	**202–512–1530; 1–888–293–6498**

Single copies/back copies:

Paper or fiche	**202–512–1800**
Assistance with public single copies	**1–866–512–1800 (Toll-Free)**

FEDERAL AGENCIES

Subscriptions:

Assistance with Federal agency subscriptions:

Email	*FRSubscriptions@nara.gov*
Phone	**202–741–6000**

Contents

Federal Register

Vol. 79, No. 233

Thursday, December 4, 2014

Agriculture Department
See Animal and Plant Health Inspection Service

Animal and Plant Health Inspection Service
PROPOSED RULES
Establishing a Performance Standard for Authorizing the Importation and Interstate Movement of Fruits and Vegetables, 71973

Bonneville Power Administration
NOTICES
Meetings:
Power and Transmission Rate Adjustments, Fiscal Year 2016–2017; Public Hearing, 71984–71990

Bureau of Consumer Financial Protection
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 71984

Children and Families Administration
NOTICES
Delegations of Authority:
Statement of Organization, Functions, and Delegations of Authority, 72002–72003

Commerce Department
See International Trade Administration
See National Oceanic and Atmospheric Administration

Commodity Futures Trading Commission
PROPOSED RULES
Position Limits for Derivatives and Aggregation of Positions, 71973–71975

Defense Department
PROPOSED RULES
Federal Acquisition Regulations:
Information on Corporate Contractor Performance and Integrity, 71975–71979

Education Department
RULES
Program Integrity:
Gainful Employment; Correction, 71957–71959

Energy Department
See Bonneville Power Administration
See Federal Energy Regulatory Commission

Federal Aviation Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Airport Noise Compatibility Planning, 72055–72056
Aviation Insurance, 72055
Certification Procedures for Products and Parts, 72055
Criteria for Internet Communications of Aviation Weather, Notices to Airmen, and Aeronautical Data, 72056–72057
Fractional Aircraft Ownership Programs, 72056
Report of Inspections Required by Airworthiness Directives, 72054
Charter Renewals:
Commercial Space Transportation Advisory Committee, 72057
Passenger Facility Charge Approvals and Disapprovals, 72057–72060
User Fees:
Passenger Facility Charges, 72060–72061

Federal Communications Commission
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 71999–72001

Federal Election Commission
NOTICES
Meetings; Sunshine Act, 72001

Federal Energy Regulatory Commission
NOTICES
Applications:
Yuba County Water Agency, Yuba River Project, 71990–71991
Combined Filings, 71991–71993
Combined Filings:
AltaGas Power Holdings (U.S.) Inc., Veresen U.S. Power Inc., et al., 71993
Catalina Solar 2, LLC, et al., 71994–71995
Southwest Power Pool, Inc., et al., 71993–71994
Environmental Impact Statements; Availability, etc.:
Dominion Transmission, Inc., Lebanon West II Project, 71995–71998
Meetings:
Entergy Regional State Committee; Staff Attendances, 71998–71999

Federal Reserve System
NOTICES
Meetings; Sunshine Act, 72001–72002

Fish and Wildlife Service
NOTICES
Permit Applications:
Endangered Species; Marine Mammals, 72007–72009

Food and Drug Administration
RULES
Content and Format of Labeling for Human Prescription Drug and Biological Products:
Pregnancy and Lactation Labeling Requirements, 72064–72103
NOTICES
Guidance for Industry and Staff:
Pregnancy, Lactation, and Reproductive Potential—Labeling for Human Prescription Drug and Biological Products—Content and Format, 72104–72105

General Services Administration
PROPOSED RULES
Federal Acquisition Regulations:
Information on Corporate Contractor Performance and Integrity, 71975–71979

Government Ethics Office
RULES
Revision of Departmental Component Designations:
Post-Employment Conflict of Interest Restrictions, 71955–71957

Health and Human Services Department
See Children and Families Administration
See Food and Drug Administration
See National Institutes of Health
See Substance Abuse and Mental Health Services Administration

Indian Affairs Bureau
NOTICES
Designated Tribal Agents for Service of Notice under the Indian Child Welfare Act, 72009–72030

Interior Department
See Fish and Wildlife Service
See Indian Affairs Bureau
NOTICES
Permits:
Endangered Species; Marine Mammals, 72006–72007

International Trade Administration
NOTICES
Antidumping or Countervailing Duty Investigations, Orders, or Reviews:
Diamond Sawblades and Parts Thereof from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review; 2012–2013, 71980–71982

Labor Department
See Occupational Safety and Health Administration

National Aeronautics and Space Administration
PROPOSED RULES
Federal Acquisition Regulations:
Information on Corporate Contractor Performance and Integrity, 71975–71979

National Archives and Records Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 72033–72034

National Institutes of Health
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Health Information National Trends Survey, 72003–72004
Surveys and Interviews to Support an Evaluation of the Innovative Molecular Analysis Technologies Program, 72004–72005

National Oceanic and Atmospheric Administration
RULES
Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic:
Atlantic Migratory Group Cobia; 2014 Commercial Accountability Measure and Closure, 71959–71960
Fisheries of the Northeastern United States:
Atlantic Herring Fishery; Framework Adjustment 3, 71960–71972
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Economic Value of Puerto Rico's Coral Reef Ecosystems for Recreation/Tourism Uses, 71982
Meetings:
Atlantic Shark and Protected Species Safe Handling, Release, and Identification Workshops, 71982–71984

Occupational Safety and Health Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Methylene Chloride Standard, 72030–72031
Vinyl Chloride Standard, 72031–72033

Overseas Private Investment Corporation
NOTICES
Meetings; Sunshine Act, 72034

Railroad Retirement Board
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 72034–72035

Securities and Exchange Commission
NOTICES
Self-Regulatory Organizations; Proposed Rule Changes:
Chicago Board Options Exchange, Inc., 72044–72049
NASDAQ OMX BX, Inc., 72049–72054
New York Stock Exchange LLC, 72039–72043
NYSE Arca, Inc., 72036–72039

State Department
NOTICES
Determinations by the Secretary of State Relating to Iran Sanctions, 72054

Substance Abuse and Mental Health Services Administration
NOTICES
Certified Laboratories and Instrumented Initial Testing Facilities:
Urine Drug Testing for Federal Agencies, 72005–72006

Surface Transportation Board
NOTICES
Release of Waybill Data, 72061

Transportation Department
See Federal Aviation Administration
See Surface Transportation Board

Separate Parts In This Issue

Part II
Health and Human Services Department, Food and Drug Administration, 72064–72105

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

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

CFR PARTS AFFECTED IN THIS ISSUE

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

5 CFR
2641.....71955

7 CFR

Proposed Rules:
318.....71973
319.....71973

17 CFR

Proposed Rules:
1.....71973
15.....71973
17.....71973
19.....71973
32.....71973
37.....71973
38.....71973
140.....71973
150.....71973

21 CFR
201.....72064

34 CFR
600.....71957
668.....71957

48 CFR

Proposed Rules:
1.....71975
4.....71975
9.....71975
22.....71975
52.....71975

50 CFR
622.....71959
648.....71960

Rules and Regulations

Federal Register
Vol. 79, No. 233
Thursday, December 4, 2014

OFFICE OF GOVERNMENT ETHICS

5 CFR Part 2641

RIN 3209–AA14

Post-Employment Conflict of Interest Restrictions; Revision of Departmental Component Designations

AGENCY: Office of Government Ethics.

ACTION: Final rule.

SUMMARY: The Office of Government Ethics (OGE) is issuing this final rule to revoke the designation of one departmental component of one agency and designate a new bureau as a departmental component for purposes of the one-year post-employment conflict of interest restriction in the United States Code; to revoke the designation of two departmental components of another agency and designate their successor bureau as a departmental component; to change the name of an existing departmental component; and to revoke the designation of a departmental component that was abolished.

DATES: This rule is effective December 4, 2014, except for the amendments to Appendix B to part 2641 set forth in amendatory instruction 3, which are effective March 4, 2015.

FOR FURTHER INFORMATION CONTACT: Amy E. Braud, Associate Counsel, General Counsel and Legal Policy Division, Office of Government Ethics, Telephone: 202–482–9300; TTY: 800–877–8339; FAX: 202–482–9237.

SUPPLEMENTARY INFORMATION:

A. Substantive Discussion: Revocation and Addition of Departmental Components

The Director of OGE (Director) is authorized by 18 U.S.C. 207(h) to designate distinct and separate departmental or agency components in the executive branch for purposes of 18 U.S.C. 207(c). The representational bar of 18 U.S.C. 207(c) usually extends to the whole of any department or agency in which a former senior employee served in any capacity during the year prior to termination from a senior employee position. However, 18 U.S.C. 207(h) provides that whenever the Director of OGE determines that an agency or bureau within a department or agency in the executive branch exercises functions which are distinct and separate from the remaining functions of the department or agency and there exists no potential for use of undue influence or unfair advantage based on past Government service, the Director shall by rule designate such agency or bureau as a separate component of that department or agency. As a result, a former senior employee who served in a ''parent'' department or agency is not barred by 18 U.S.C. 207(c) from making communications to or appearances before any employees of any designated component of that parent, but is barred as to employees of that parent or of other components that have not been separately designated. Moreover, a former senior employee who served in a designated component of a parent department or agency is barred from communicating to or making an appearance before any employee of that component, but is not barred as to any employee of the parent or of any other component.

Under 18 U.S.C. 207(h)(2), component designations do not apply to persons employed at a rate of pay specified in or fixed according to subchapter II of 5 U.S.C. chapter 53 (the Executive Schedule). Component designations are listed in appendix B to 5 CFR part 2641.

The Director of OGE regularly reviews the component designations and determinations and, in consultation with the department or agency concerned, makes such additions and deletions as are necessary. Specifically, the Director ''shall, by rule, make or revoke a component designation after considering the recommendation of the designated agency ethics official.'' 5 CFR 2641.302(e)(3). Before designating an agency component as distinct and separate for purposes of 18 U.S.C. 207(c), the Director must find that there exists no potential for use of undue influence or unfair advantage based on past Government service, and that the component is an agency or bureau, within a parent agency, that exercises functions which are distinct and separate from the functions of the parent agency and from the functions of other components of that parent. 5 CFR 2641.302(c)(1).

Pursuant to the procedures prescribed in 5 CFR 2641.302(e), two departments forwarded written requests to OGE to amend their listings in appendix B. On June 10, 2014, OGE published for comment a proposed rule that modified the component designations for the two departments. *See* 79 FR 33138–33140 (June 10, 2014). OGE did not receive any responses to the proposed rule. After carefully reviewing the requested changes in light of the criteria in 18 U.S.C. 207(h) as implemented in 5 CFR 2641.302(c), the Director of OGE has determined to grant these requests and amend appendix B to 5 CFR part 2641 as explained below.

The Department of Health and Human Services has requested that OGE remove the Administration on Aging (AoA) from its list of component designations and designate in its place the Administration for Community Living as a distinct and separate component of the Department of Health and Human Services for purposes of 18 U.S.C. 207(c). On April 18, 2012, the AoA ceased to be an operating division within the Department of Health and Human Services and became a subcomponent of a new operating division within the Department, the Administration for Community Living.

The mission of the Administration for Community Living is to maximize the self-determination, well-being, and health of older adults, people with disabilities, and their families and caregivers. The Administration for Community Living is the primary entity within the Department to direct development, administration, and advancement of aging and disability programs.

In addition to the AoA, the Administration for Community Living is composed of the Administration on Intellectual and Developmental Disabilities and the Center for Disability and Aging Policy. The Administration on Intellectual and Developmental Disabilities advises the Secretary of the Department of Health and Human Services on issues that relate to individuals who have intellectual and

developmental disabilities. It provides support to the States and to local communities for programs that increase the independence and productivity of these individuals. The Center for Disability and Aging Policy plans and oversees the implementation of policies, programs, and special initiatives that address the needs of older Americans and persons with disabilities.

According to the Department of Health and Human Services, the Administration for Community Living exercises functions that are distinct and separate from the functions of the parent Department and from every other agency within the Department.

Accordingly, the Director is granting the request of the Department of Health and Human Services and is amending the Department of Health and Human Services listing in appendix B to part 2641 to remove the AoA from the component designation list and to designate the Administration for Community Living as a new component as discussed.

The Department of the Treasury has requested that OGE remove the Financial Management Service (FMS) and the Bureau of Public Debt (BPD) from its list of component designations and in their place designate the Bureau of the Fiscal Service as a distinct and separate component of the Department of the Treasury for purposes of 18 U.S.C. 207(c). The Department of the Treasury consolidated FMS and BPD into a new entity, the Bureau of the Fiscal Service. This consolidation was effective on October 7, 2012. *See* Treas. Order 136–01 (October 7, 2012). The new bureau will carry out the functions of the FMS and the BPD, which include borrowing the money needed to operate the Federal Government, administering the public debt, receiving and disbursing public monies, and maintaining Government accounts.

According to the Department of the Treasury, the functions of the Bureau of the Fiscal Service are distinct and separate from the functions of the parent Department and from every other agency within the Department. This distinction was previously recognized when OGE designated its predecessor bureaus, the FMS and the BPD, as components for purposes of 18 U.S.C. 207(c).

Accordingly, the Director is granting the request of the Department of the Treasury and is amending the Department of the Treasury listing in appendix B to part 2641 to remove the FMS and the BPD from the component designation list and to designate the Bureau of the Fiscal Service as a new component as discussed.

The Department of the Treasury has also requested that OGE revise the name of one component currently listed in appendix B to part 2641, the Bureau of the Mint. According to the Department, since the 1992 amendments to 31 U.S.C. 304, the statutory name, and the name used in all official publications, of this bureau is the ''United States Mint.'' The Director is therefore amending the Department of the Treasury listing in appendix B to reflect the current name of this component.

Additionally, the Department of the Treasury has requested that OGE remove the Office of Thrift Supervision (OTS) from its list of component designations. Under the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act), Pub. L. 111–203, 124 Stat. 1376, all OTS functions were distributed to the Office of the Comptroller of the Currency, the Federal Deposit Insurance Corporation, the Federal Reserve Board, and the Bureau of Consumer Financial Protection. Under Title III of the Dodd-Frank Act, all OTS functions relating to Federal savings and loan associations and the rulemaking authority of OTS relating to all savings associations, both Federal and State, were transferred to the Office of the Comptroller of the Currency as of July 21, 2011. Also as of July 21, 2011, the other functions of OTS were transferred to the Federal Deposit Insurance Corporation, the Federal Reserve Board, and the Bureau of Consumer Financial Protection. Pursuant to Section 313 of the Dodd-Frank Act, OTS was abolished 90 days after the date of the transfer of its functions to other agencies.

Because OTS has been abolished, the Director is granting the request of the Department of the Treasury and is amending the Department of the Treasury listing in appendix B to part 2641 to remove OTS from the component designation list. The Office of the Comptroller of the Currency has been designated as a component since January 1, 1991 and remains designated as a component.

As indicated in 5 CFR 2641.302(f), a designation ''shall be effective on the date the rule creating the designation is published in the **Federal Register** and shall be effective as to individuals who terminated senior service either before, on or after that date.'' Initial designations were effective as of January 1, 1991. The effective date of subsequent designations is indicated by means of parenthetical entries in appendix B. The new component designations made by this rulemaking document, as well as the name corrections being reflected herein (which do not affect the underlying component designation date), is effective December 4, 2014.

As also indicated in 5 CFR 2641.302(f), revocation is effective 90 days after the effective date of the rule that revokes the designation. Accordingly, the component designation revocations made in this rulemaking will take effect March 4, 2015. Revocations are not effective as to any individual terminating senior service prior to the expiration of the 90-day period.

B. Matters of Regulatory Procedure

Regulatory Flexibility Act

As Director of OGE, I certify under the Regulatory Flexibility Act (5 U.S.C. chapter 6) that this final rule will not have a significant economic impact on a substantial number of small entities because it affects only Federal departments and agencies and current and former Federal employees.

Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) does not apply to this final rule because it does not contain information collection requirements that require the approval of the Office of Management and Budget.

Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. chapter 25, subchapter II), this final rule will not significantly or uniquely affect small governments and will not result in increased expenditures by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million or more (as adjusted for inflation) in any one year.

Congressional Review Act

OGE has determined that this rulemaking involves a non-major rule under the Congressional Review Act (5 U.S.C. chapter 8) and will submit a report thereon to the U.S. Senate, House of Representatives and Government Accountability Office in accordance with that law at the same time this rulemaking document is sent to the Office of the Federal Register for publication in the **Federal Register.**

Executive Order 12866

In promulgating this final rule, OGE has adhered to the regulatory philosophy and the applicable principles of regulation set forth in section 1 of Executive Order 12866, Regulatory Planning and Review. This rule has not been reviewed by the Office of Management and Budget under Executive Order 12866 because it deals with agency organization, management,

and personnel matters and is not ''significant'' under the order.

Executive Order 12988

As Director of OGE, I have reviewed this final rule in light of section 3 of Executive Order 12988, Civil Justice Reform, and certify that it meets the applicable standards provided therein.

List of Subjects in 5 CFR Part 2641

Conflict of interests, Government employees.

Approved: November 4, 2014.

Walter M. Shaub, Jr.

Director, Office of Government Ethics.

Accordingly, for the reasons set forth in the preamble, OGE is amending 5 CFR part 2641 as follows:

PART 2641—POST-EMPLOYMENT CONFLICT OF INTEREST RESTRICTIONS

■ 1. The authority citation for part 2641 continues to read as follows:

Authority: 5 U.S.C. app. (Ethics in Government Act of 1978); 18 U.S.C. 207; E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306.

■ 2. Appendix B to part 2641 is amended by revising the listings for the Department of Health and Human Services and the Department of the Treasury to read as follows:

Appendix B to Part 2641—Agency Components for Purposes of 18 U.S.C. 207(c)

* * * * *

Parent: Department of Health and Human Services

Components:
Administration on Aging (effective May 16, 1997).
Administration for Children and Families (effective January 28, 1992).
Administration for Community Living (effective December 4, 2014).
Agency for Healthcare Research and Quality (formerly Agency for Health Care Policy and Research) (effective May 16, 1997).
Agency for Toxic Substances and Disease Registry (effective May 16, 1997).
Centers for Disease Control and Prevention (effective May 16, 1997).
Centers for Medicare and Medicaid Services (formerly Health Care Financing Administration).
Food and Drug Administration.
Health Resources and Services Administration (effective May 16, 1997).
Indian Health Service (effective May 16, 1997).
National Institutes of Health (effective May 16, 1997).
Substance Abuse and Mental Health Services Administration (effective May 16, 1997).

* * * * *

Parent: Department of the Treasury

Components:
Alcohol and Tobacco Tax and Trade Bureau (effective November 23, 2004).
Bureau of Engraving and Printing.
Bureau of the Public Debt.
Bureau of the Fiscal Service (effective December 4, 2014).
Comptroller of the Currency.
Financial Crimes Enforcement Center (FinCEN) (effective January 30, 2003).
Financial Management Service.
Internal Revenue Service.
Office of Thrift Supervision.
United States Mint (formerly listed as Bureau of the Mint).

■ 3. Appendix B to part 2641 is further amended by removing the Administration on Aging from the listing for the Department of Health and Human Services and by removing the Bureau of the Public Debt, the Financial Management Service, and the Office of Thrift Supervision from the listing for the Department of the Treasury.

[FR Doc. 2014–27284 Filed 12–3–14; 8:45 am]

BILLING CODE 6345–03–P

DEPARTMENT OF EDUCATION

34 CFR Parts 600 and 668

RIN 1840–AD15

[Docket ID ED–2014–OPE–0039]

Program Integrity: Gainful Employment; Correction

AGENCY: Department of Education.

ACTION: Final regulations; correction.

SUMMARY: On October 31, 2014, we published in the **Federal Register** final regulations for Program Integrity: Gainful Employment (Gainful Employment rule). This document corrects regulatory text, footnotes, and a chart in the Gainful Employment rule.

DATES: Effective July 1, 2015.

ADDRESSES: *Accessible Format:* Individuals with disabilities can obtain this document in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

FOR FURTHER INFORMATION CONTACT: John Kolotos, U.S. Department of Education, 1990 K Street NW., Room 8018, Washington, DC 20006–8502. Telephone: (202) 502–7762 or by email at: *gainfulemploymentregulations@ed.gov*.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service, toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: This document corrects*:* (1) Footnote text that was omitted from the Gainful Employment rule; (2) § 668.412 of the regulations to include the implementation date for the disclosure requirements; (3) the equations for calculating completion rates for full-time students in § 668.413(b)(1)(i) of the regulations; (4) § 668.413 to add mean earnings in addition to median earnings; and (5) the notification provisions in § 668.413(c)(2) of the regulations.

In the Gainful Employment rule:

- The text of certain footnotes was omitted;
- We discussed that institutions must begin complying with the requirements in § 668.412 of the regulations beginning January 1, 2017. However, that language was inadvertently omitted from the regulatory text;
- Dividing lines were omitted from the chart on page 64954 that would enhance the data presentation;
- We revised § 668.412(a)(11) of the proposed regulations to add mean earnings, in addition to median earnings, as a possible disclosure item to be included on the disclosure template, but we did not revise § 668.413 of the regulations to reflect this addition; and
- Section 668.413(c)(2) referred incorrectly to the cohort period with respect to the calculation of median loan debt.

Corrections

In FR Doc. No. 2014–25594, in the **Federal Register** of October 31, 2014 (79 FR 64890), make the following corrections:

■ 1. On page 64905, in the left-hand column, add footnote 22 to read as follows:

[22] IPEDS First-Look (July 2013), table 2. Average costs (in constant 2012–13 dollars) associated with attendance for full-time, first-time degree/certificate-seeking undergraduates at Title IV institutions operating on an academic year calendar system, and percentage change, by level of institution, type of cost, and other selected characteristics: United States, academic years 2010–11 and 2012–13.

■ 2. On page 64906, in the right-hand column, revise footnotes 46 and 47 to read as follows:

[46] NCES, ''Transferability of Postsecondary Credit Following Student Transfer or Coenrollment,'' NCES 2014–163. Available at: *http://nces.ed.gov/pubsearch/pubsinfo.asp?pubid=2014163.*

[47] NCES, ''Transferability of Postsecondary Credit Following Student Transfer or Coenrollment,'' NCES 2014–163, table 3.

■ 3. On page 64907, in the middle column, revise footnote 54 to read as follows:

[54] *Id.*

■ 4. On page 64954, the table is revised to read as follows:

	Date received from SSA	Number ED sent to SSA	Number SSA verified	Number SSA did not verify	Number with earnings	Number with zero earnings
2011 GE informational rates—includes non-Title IV.	3/5/12	811,718	797,070	14,708	699,024	98,046 [12.3% of verified].
2012 GE informational rates for reg neg Title IV only.	7/18/13	255,168	252,328	2,845	232,006	20,317 [7.96% of verified].
2012 GE post reg neg—Title IV only.	8/14/13	923,399	917,912	8,487	798,952	115,960 [12.6% of verified].
For College Scorecard—Title IV only derived from ED data on borrowers in FY 2007 iCDR cohort for selected institutions of higher education.	9/13/13	900,419 901,719 902,380 921,749	892,796 894,260 892,840 909,613	7,623 7,459 9,540 12,136	809,204 819,542 787,223 772,574	83,592. 74,718. 105,617. 137,039.
Totals	.....	3,626,267	3,589,509	36,758	3,188,543	400,966 [11.1% of verified].
For College Scorecard—Title IV only derived from ED data on borrowers in FY 2008 iCDR cohort for selected institutions of higher education.	12/13/13	969,145 985,742 490,305	954,728 970,742 480,421	14,417 15,000 9,884	857,539 865,060 411,917	97,189. 105,682. 68,504.
Totals	.....	2,445,192	2,405,891	39,301	2,134,516	271,375 [11.3% of verified].
Grand Totals	.....	8,061,744	7,959,705	102,099	7,053,041	906,664 [11.4% of verified].

§ 668.412 [Corrected]

■ 5. On page 65015, in the middle column, add paragraph (h) to § 668.412 to read as follows:

(h) *Implementation date.* Institutions must comply with the requirements of this section beginning January 1, 2017.

§ 668.413 [Corrected]

■ 6. In the table of contents for subpart Q, on page 65007, in the second line in the middle column, we revise the phrase ''median earnings'' to read ''mean and median earnings''.

■ 7. Beginning in the middle column on page 65015 and ending on page 65018, in each place in which the phrase ''median earnings'' appears, including in the heading of § 668.413, revise the phrase to read ''mean and median earnings''.

■ 8. On page 65015, revise the two, three-column equations in § 668.413(b)(1)(i) to read as follows:

$$\frac{\text{Number of full-time students in the enrollment cohort who completed the program within 100\% of the length of the program}}{\text{Number of full-time students in the enrollment cohort}}$$

and

Number of full-time students in the enrollment cohort who completed the program within 150% of the length of the program

Number of full-time students in the enrollment cohort

■ 9. On page 65018, in the left-hand column, revise § 668.413(c)(2) by removing the phrase ‘‘, in each case during the cohort period’’.

■ 10. On page 65033, in the right-hand column, add footnotes 259 and 260 to read as follows:

[259] NCES, ‘‘Transferability of Postsecondary Credit Following Student Transfer or Coenrollment,’’ NCES 2014–163. Available at: *http://nces.ed.gov/pubsearch/pubsinfo.asp?pubid=2014163.*

[260] NCES, ‘‘Transferability of Postsecondary Credit Following Student Transfer or Coenrollment,’’ NCES 2014–163, table 3.

Program Authority: 20 U.S.C. 1001, 1002, 1088.

Dated: November 25, 2014.

Arne Duncan,

Secretary of Education.

[FR Doc. 2014–28284 Filed 12–3–14; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 101206604–1758–02]

RIN 0648–XD601

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; 2014 Commercial Accountability Measure and Closure for Atlantic Migratory Group Cobia

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS implements accountability measures (AMs) for commercial Atlantic migratory group cobia in the exclusive economic zone (EEZ) of the South Atlantic. Commercial landings for Atlantic migratory group cobia, as estimated by the Science Research Director (SRD), are projected to reach the commercial annual catch limit (ACL) on December 11, 2014. Therefore, NMFS closes the commercial sector for Atlantic migratory group cobia on December 11, 2014, and it will remain closed throughout the remainder of the fishing year, through December 31, 2014. This closure is necessary to protect the resource of Atlantic migratory group cobia.

DATES: This rule is effective 12:01 a.m., local time, December 11, 2014, until 12:01 a.m., local time, January 1, 2015.

FOR FURTHER INFORMATION CONTACT: Britni LaVine, telephone: 727–824–5305, email: *britni.lavine@noaa.gov.*

SUPPLEMENTARY INFORMATION: The fishery for coastal migratory pelagic fish (king mackerel, Spanish mackerel, and cobia) is managed under the Fishery Management Plan for Coastal Migratory Pelagic Resources in the Gulf of Mexico and Atlantic Region (FMP). The FMP was prepared by the Gulf of Mexico and South Atlantic Fishery Management Councils (Councils) and is implemented under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

Separate migratory groups of cobia were established in Amendment 18 to the FMP. The southern boundary for Atlantic migratory group cobia occurs at the division between Gulf of Mexico and Atlantic migratory groups, which is set at the intercouncil jurisdictional boundary, off the Florida Keys. As specified in 50 CFR 600.105(c), the South Atlantic and Gulf of Mexico intercouncil boundary coincides with the line of demarcation between the Atlantic Ocean and the Gulf of Mexico, which begins at the intersection of the outer boundary of the EEZ, as specified in the Magnuson-Stevens Act, and 83°00′ W. longitude, proceeds northward along that meridian to 24°35′ N. latitude, (near the Dry Tortugas Islands), then eastward along that parallel, through Rebecca Shoal and the Quicksand Shoal, to the Marquesas Keys, and then through the Florida Keys to the mainland at the eastern end of Florida Bay, the line so running that the narrow waters within the Dry Tortugas Islands, the Marquesas Keys and the Florida Keys, and between the Florida Keys and the mainland, are within the Gulf of Mexico. The northern boundary for Atlantic migratory group cobia is at the jurisdictional boundary between the Mid-Atlantic and New England Councils. As specified in 50 CFR 600.105(a), the northern boundary begins at the intersection point of Connecticut, Rhode Island, and New York at 41°18′16.249″ N. latitude and 71°54′28.477″ W. longitude and proceeds south along 37°22′32.75″ E. longitude to the point of intersection with the outward boundary of the EEZ as specified in the Magnuson-Stevens Act.

The commercial ACL or commercial quota (quota) for Atlantic migratory group cobia is 125,712 lb (57,022 kg), round weight, for the current fishing year, January 1 through December 31, 2014, as specified in 50 CFR 622.384(d)(2).

The AMs specified at 50 CFR 622.388(f)(1)(i) require NMFS to close the commercial sector for Atlantic migratory group cobia when its quota is reached or is projected to be reached, by filing a notification with the Office of the Federal Register to close the commercial sector for the remainder of the fishing year. NMFS has determined that the quota for Atlantic migratory group cobia will have been reached by December 11, 2014. Accordingly, the commercial sector for Atlantic migratory group cobia is closed effective 12:01 a.m., local time, December 11, 2014, until 12:01 a.m., local time, January 1, 2015.

The possession limit for cobia located at 50 CFR 622.383(b), specifies that no person may possess more than two cobia per day in or from the EEZ in the Gulf of Mexico, Mid-Atlantic, or South Atlantic, regardless of the number of trips or duration of a trip. In addition, a person who fishes in the EEZ may not combine this harvest limitation with a harvest limitation applicable to state waters. Atlantic migratory group cobia taken in the EEZ may not be transferred at sea, regardless of where such transfer takes place, and may not be transferred in the EEZ.

During the closure, the possession limit for cobia remains in effect, however, in accordance with regulations at 50 CFR 622.384(e)(3), the sale or purchase of Atlantic migratory group cobia taken under the possession limit is prohibited. The prohibition on sale and purchase does not apply to the sale or purchase of Atlantic migratory group cobia that were harvested, landed ashore, and sold prior to 12:01 a.m., local time, December 11, 2014, and were held in cold storage by a dealer or processor.

Classification

The Regional Administrator, Southeast Region, NMFS, has determined this temporary rule is necessary for the conservation and management of Atlantic migratory group cobia and is consistent with the Magnuson-Stevens Act and other applicable laws.

This action is taken under 50 CFR 622.8(b) and is exempt from review under Executive Order 12866.

These measures are exempt from the procedures of the Regulatory Flexibility Act because the temporary rule is issued without opportunity for prior notice and comment.

This action responds to the best scientific information available. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirements to provide prior notice and opportunity for public comment, pursuant to the authority set forth at 5 U.S.C. 553(b)(B), as such prior notice and opportunity for public comment is unnecessary and contrary to the public interest. Such procedures are unnecessary and contrary to the public interest because the AMs for Atlantic migratory group cobia established by Amendment 18 to the FMP (76 FR 82058, December 29, 2011), and located at 50 CFR 622.388(f)(1)(i), have already been subject to notice and comment, and all that remains is to notify the public of the commercial closure for the remainder of the 2014 fishing year. Additionally, there is a need to immediately implement the closure to prevent further commercial harvest and prevent the ACL from being exceeded, which will protect the cobia resource. Prior notice and opportunity for public comment on this action would be contrary to the public interest, because those affected by the closure need as much advance notice as NMFS is able to provide.

For the aforementioned reasons, the AA also finds good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3).

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 28, 2014.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2014–28468 Filed 12–3–14; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 140221166–4963–02]

RIN 0648–BE01

Fisheries of the Northeastern United States; Atlantic Herring Fishery; Framework Adjustment 3

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS implements final regulations to establish a process for setting river herring (alewife and blueback) and shad (American and hickory) catch caps for the herring fishery. This action also sets these catch caps for the 2014 and 2015 fishing years. The river herring and shad caps in the herring fishery will limit how much of these species will be caught in the herring fishery. This action will allow the New England Fishery Management Council to set river herring and shad catch caps and associated measures in future years through specifications or frameworks, whichever is appropriate. The measures in this action are a positive step in conservation efforts for river herring and shad.

DATES: Effective December 4, 2014.

ADDRESSES: The New England Fishery Management Council developed an environmental assessment (EA) for this action that describes the action and other considered alternatives and provides a thorough analysis of the impacts of these final measures and alternatives. Copies of the framework, the EA, and the Regulatory Impact Review (RIR)/Initial Regulatory Flexibility Analysis (IRFA), are available upon request from Thomas A. Nies, Executive Director, New England Fishery Management Council, 50 Water Street, Newburyport, MA 01950. The EA/RIR/IRFA is accessible via the Internet at *http://www.greateratlantic.fisheries.noaa.gov/sustainable/species/atlherring/index.html.*

Copies of the small entity compliance guide are available from John K. Bullard, Regional Administrator, NMFS, Greater Atlantic Regional Fisheries Office, 55 Great Republic Drive, Gloucester, MA 01930–2298, or available on the Internet at *http://www.greateratlantic.fisheries.noaa.gov/sustainable/species/atlherring/index.html.*

FOR FURTHER INFORMATION CONTACT: Carrie Nordeen, Fishery Policy Analyst, 978–281–9272, fax 978–281–9135.

SUPPLEMENTARY INFORMATION:

Background

The New England Fishery Management Council adopted Framework Adjustment 3 to the Atlantic Herring Fishery Management Plan (FMP) at its September 24, 2013, meeting. The Council submitted Framework 3 to NMFS for review on January 3, 2014, and resubmitted it to NMFS on March 26, 2014. The Council reviewed the Framework 3 proposed rule regulations as drafted by NMFS, and deemed them to be necessary and appropriate as specified in section 303(c) of the Magnuson-Stevens Fishery Conservation and Management Act. The proposed rule for Framework 3 published in the **Federal Register** on June 13, 2014 (79 FR 33879), with a 30-day public comment period that ended July 14, 2014. NMFS received four comments on the proposed measures.

Framework 3 establishes a process for setting and modifying catch caps for river herring (alewife and blueback) and shad (American and hickory) catch caps in the Atlantic herring fishery (herring fishery), and sets specific river herring and shad catch caps for the 2014 and 2015 fishing years. Catch of river herring and shad for 2014 will count against the cap in 2014 after the effective date of this final rule.

River herring and shad are anadromous species that may co-occur seasonally with Atlantic herring and are harvested as a non-target species in the fishery. When river herring are encountered in the herring fishery, they are either discarded at sea (bycatch) or, because they closely resemble herring, they are retained and sold as part of the herring catch (incidental catch). According to the most recent river herring stock assessment (May 2012) conducted by the Atlantic States Marine Fisheries Commission (ASMFC), river herring populations have declined from historic levels and many factors will need to be addressed to allow their recovery, including: Fishing in both state and Federal waters; improvement of river passageways and water quality;

reduced predation; and understanding the effects of climate change. The Council has been working on addressing river herring and shad catch issues in the herring fishery, most recently in Amendment 5 to the FMP (79 FR 8786; February 13, 2014) (Amendment 5). Amendment 5 allowed for river herring and shad catch caps to be implemented through a framework adjustment. Framework 3 allows the Council to set river herring and shad catch caps and associated measures in future years through specifications or frameworks, whichever is appropriate.

Framework 3 outlines a process for setting and modifying the river herring and shad catch caps that includes: Identification of gears, areas, and trips that would be subject to the catch caps; changes to reporting requirements for vessels issued limited access and Herring Management Areas 2/3 open access herring permits; criteria that would trigger the closure of an area to directed herring fishing for a particular gear type; and a list of management measures related to setting catch caps that can be modified through the herring specifications process and/or framework adjustment process.

Area and Gear Provisions of the River Herring and Shad Catch Caps

Framework 3 establishes four distinct Catch Cap Areas that could have associated catch caps: Gulf of Maine (GOM); Cape Cod (CC); Southern New England/Mid-Atlantic (SNE/MA); and Georges Bank (GB) (Table 1). During a given fishing year, catch of river herring and shad from all herring trips landing more than 6,600 lb (3 mt) of herring will apply against the catch caps for specific fishing gears and areas. The Council considered alternatives for catch caps for all gear types used in the herring fishery, but ultimately decided to adopt catch caps for midwater trawl gear in the GOM, CC, and SNE/MA, as well as bottom trawl gear in SNE/MA. The selection of these gear types in these areas is based on recent fishery data that indicate where river herring and shad interactions are occurring, and to what extent they may be occurring by each gear type used in the herring fishery. Because current catch data indicate that river herring and shad are not caught by the herring fishery in GB, the Council did not specify catch caps for GB during 2014–2015. The Council may consider adjustments to the selected gears and areas that have associated catch caps in a future management action.

TABLE 1—RIVER HERRING AND SHAD CATCH CAP AREAS

Catch cap areas	Statistical areas
GOM	464, 465, 467, 511–515.
CC	521.
GB	522, 525–526, 541–543, 561–562, 640.
SNE/MA	533–534, 537–539, 611–616, 621–629, 631–639, 700–705, 707–711.

Reporting Requirements and Monitoring the River Herring and Shad Catch Caps

This action adjusts current Vessel Monitoring System (VMS) trip notification requirements in order for NMFS to monitor the catch caps. Vessel operators will have to report kept catch of all species by statistical area daily via VMS catch reports. The Council may consider adjustments to trip notification requirements in the future as necessary to ensure the effectiveness of the catch caps.

The Greater Atlantic Regional Fisheries Office will monitor the catch cap by estimating the total river herring and shad catch in the herring fishery using data from observed hauls on herring trips and extrapolating this data to unobserved herring trips. The rate of river herring and shad catch will be estimated as the ratio of observed river herring and shad catch (including discards) to the kept catch of all species on observed trips that land greater than 6,600 lb (3 mt) of herring. Total river herring and shad catch (in weight) will then be derived by multiplying the catch rate by total pounds of all kept species on all trips that land greater than 6,600 lb (3 mt) of herring. This methodology is identical to that used for catch cap accounting in the mackerel fishery. More information about our monitoring methodology for the river herring and shad catch can be found at *http://www.greateratlantic.fisheries.noaa.gov/aps/monitoring/riverherringshad.html.*

River Herring and Shad Catch Triggers and Closure Areas

This action specifies that when 95 percent of the river herring and shad catch for a gear-specific catch cap is projected to be reached in a Catch Cap Area, all vessels fishing with that gear type in the respective closure area will be subject to a reduced herring possession limit of 2,000 lb (0.9 mt) per trip, per calendar day, in or from that area for the remainder of the fishing year. Vessels using other gear types in the closure area will not be affected in that those vessels will not be subject to the 2,000-lb (0.9-mt) possession limit and could continue directed fishing for herring in those areas with other gear types. Vessels participating in the herring fishery outside of the catch cap closure area(s) will be able to use any gear type (consistent with other regulations) until the applicable herring annual catch limits/sub-annual catch limits are harvested. This 95-percent catch trigger is consistent with the trigger implemented for the river herring and shad catch cap in the mackerel fishery (79 FR 18834; April 4, 2014).

The Catch Cap Closure Areas are identical to the Catch Cap Areas for GB, GOM, and CC. For SNE/MA, the catch cap closure area is the inshore portion of the SNE/MA Catch Cap Area (Table 2).

TABLE 2—RIVER HERRING AND SHAD CATCH CAP CLOSURE AREAS

Catch cap closure areas	Statistical areas
GOM	464, 465, 467, 511–515.
CC	521.
GB	522, 525–526, 541–543, 561–562, 640.
SNE/MA	537–539, 611–616, 621–623, 625–627, 631–632, 635–636.

Modifying Future River Herring and Shad Catch Cap Management Measures

This action specifies the mechanisms to modify measures related to the catch caps. Measures related to the catch cap process that could be established in this framework may be modified in the future through the specifications or framework adjustment process, depending on whether the modification is suitable for either specifications or framework adjustment. New or additional measures (*e.g.,* new accountability measures to become effective when a catch cap is reached), or measures outside the scope already analyzed, could be implemented through another framework action or an amendment.

River Herring and Shad Catch Caps for Fishing Years 2014–2015

This action sets river herring and shad catch caps for the 2014–2015 fishing years (January 1–December 31) (Table 3). Catch of river herring and shad for 2014 will only be counted from the effective date of this action until December 31, 2014. All the catch caps in the GOM, CC, and SNE/MA Catch Cap Areas are based on the median value of estimated river herring and shad catch from 2008–2012. Current data are not sufficient to definitively

determine the magnitude of potential biological effects of such a cap on river herring and shad stocks. Using the median values is expected to provide an incentive for the industry to continue to avoid river herring and shad and help to minimize overall river herring and shad catch to the extent practicable, while still providing the opportunity to fully utilize the herring annual catch limit if the fleet can avoid river herring and shad.

TABLE 3—RIVER HERRING AND SHAD CATCH CAPS BY AREA AND GEAR TYPE FOR 2014 AND 2015

Catch cap area	Gear type	Catch cap (mt)
GOM	Midwater Trawl	86
CC	Midwater Trawl	13
SNE/MA	Midwater Trawl	124
	Bottom Trawl	89
GB	N/A	N/A

Due to very low observed river herring and shad catch in GB, the Council did not recommend a catch cap in the GB Catch Cap Area for the 2014–2015 fishing years. If the catch of river herring and shad increases in this area, the Council could consider setting a cap for this area in a future herring specifications.

Corrections

This rule also contains minor corrections to existing regulations. NMFS makes these adjustments under the authority of section 305(d) to the Magnuson-Stevens Act, which provides that the Secretary of Commerce may promulgate regulations necessary to ensure that amendments to a fishery management plan are carried out in accordance with the FMP and the Magnuson-Stevens Act. These adjustments, which are identified and described below, are necessary to clarify current regulations or the intent of the FMP and would not change the intent of any regulations.

NMFS clarifies the coordinates for the herring management areas, modified haddock stock areas, and river herring monitoring/avoidance areas at § 648.200(f) to more accurately define various areas. For example, some areas were intended to be based on statistical areas, but the previous coordinates were unintentionally misaligned with those statistical areas. This action updates those coordinates to correctly align them with the statistical areas upon which they were based. In addition, some area boundaries are being revised to correctly incorporate coastal bodies of water, as well as the legally defined U.S. Canada Maritime boundary. This action also moves the coordinates for the GOM and GB modified haddock stock areas in the regulations from § 648.10 to § 648.200(f) so that all the herring-related management areas are in a single location for easy reference. Finally, this action adds a possession limit regulation to § 648.204(a) to describe the possession limit requirements of the Herring Management Areas 2/3 Open Access Permit. This regulation was overlooked during rulemaking for Herring Amendment 5 and is consistent with the intent of that action.

Comments and Responses

NMFS received four comment letters in response to the proposed rule from The Herring Alliance; Wild Oceans; the Coalition for the Atlantic Herring Fishery's Orderly, Informed and Responsible Long Term Development (CHOIR); and an individual. The following summarizes the comments and provides our responses.

Comment 1: An individual commented that depleted runs of blueback herring and alewife in rivers and streams of Massachusetts suggest that conservation and management measures have not achieved sustainable levels of these fish. He urged NMFS to use precautionary management measures for the herring fishery to allow us to evaluate the benefits that restrictive and conservative measures would have on populations of river herring. The Herring Alliance noted that river herring and shad populations are near historic lows and that without sufficient federal management to complement state conservation measures, river herring and shad populations will not recover and fisheries for these species are unlikely to reopen.

Response: River herring are managed by the ASMFC and the individual Atlantic coastal states. According to the most recent ASMFC river herring stock assessment (May 2012), river herring populations have declined from historic levels and many factors will need to be addressed to allow their recovery, including fishing (in both state and Federal waters), river passageways, water quality, predation, and climate change. In an effort to aid in the recovery of depleted or declining stocks, the ASMFC, in cooperation with individual states, prohibited state waters commercial and recreational fisheries that did not have approved sustainable fisheries management plans, effective January 1, 2012. NMFS considers river herring to be a species of concern, but recently (78 FR 48944, August 12, 2013) determined that listing river herring, as either threatened or endangered, under the Endangered Species Act was not warranted. NMFS established a technical working group and will continue to work closely with the ASMFC and others to develop a long-term, dynamic conservation plan for river herring from Canada to Florida. The working group will evaluate the impact of ongoing restoration and conservation efforts, as well as new fisheries management measures, which should benefit the species. It will also review new information produced from ongoing research, including genetic analyses, ocean migration pattern research, and climate change impact studies, to assess whether recent reports, showing higher river herring counts in the last 2 years, represent sustained trends. NMFS intends to revisit its river herring status determination within the next 5 years. In addition to the these actions, Amendment 5 to the FMP established river herring monitoring and avoidance areas for the herring fishery. NMFS asserts that setting river herring and shad catch caps in the herring fishery is an additional positive step toward reducing the impacts of herring fishing on river herring and shad. The caps should further help minimize river herring and shad catch in the herring fishery to the extent practicable and increase the incentive for the herring fishery to avoid river herring and shad catch when possible.

Comment 2: Wild Oceans, CHOIR, and the Herring Alliance urged NMFS to approve and implement Framework 3, including the process for setting river herring and shad caps, applicable areas

and gears, and the caps and for 2014 and 2015.

Response: NMFS is implementing the measures as recommended by the Council.

Comment 3: Wild Oceans, CHOIR, and the Herring Alliance urged NMFS to quickly implement the measures in Framework 3. Wild Oceans commented that swift implementation is necessary in part because it believes that the measures to limit river herring and shad catch in the herring fishery are overdue. The Herring Alliance, Wild Oceans, and CHOIR urged NMFS to waive the 30-day delay in effectiveness required by the Administrative Procedure Act. CHOIR and the Herring Alliance requested that NMFS retroactively apply the river herring and shad catch caps to catch of herring, river herring, and shad, beginning January 1, 2014. The Herring Alliance believes that the herring fishing fleets had sufficient notice that this rule would take effect in 2014, and that the rule will not result in costs related to on-board changes to fishing vessels or changes to bycatch estimation methodologies.

Response: NMFS has determined that good cause exists to waive the 30-day delay in effectiveness for this action on the basis that it is important to implement the catch caps for the remainder of 2014 and it is in the public's interest to do so. The Council submitted its final version of Framework 3 for NMFS review in March 2014, meaning that final NMFS action would occur well after the herring fishery was underway. As a result, NMFS intended from the outset to implement these measures upon publication due to the need and the public interest. Even though it is near the end of 2014 and only one area remains open (Area 2) to the herring fishery, NMFS believes that it is still important to implement the measures upon publication. To further delay implementation would reduce the benefits of the caps as the herring fishery will likely have harvested the vast majority of its catch allocated for 2014. The Council intended that the caps apply to as much as the 2014 herring fishery as possible, but it did not recommend a retroactive application of the cap. The analysis to support this action does not describe retroactive catch caps nor does it analyze retroactive catch caps. Therefore, NMFS cannot retroactively apply the catch caps to the beginning of 2014. NMFS did retroactively apply catch against the river herring and shad cap for the mackerel fishery implemented in April 2014 because the Mid-Atlantic Council recomended and analyzed applying river herring and shad catch against the cap for all of 2014. The Council's timeline for submission provided for implementation late in the 2014 fishing year. Although the herring fishing fleets likely knew that the Council recommended this action, it also likely knew that implementation is dependent upon NMFS review and approval. Counting all river herring and shad catch since January 1, 2014, would unfairly penalize the herring fleet for measures that were not effective for the majority of their fishing year in 2014.

Comment 4: The Herring Alliance, Wild Oceans, and CHOIR all expressed concern that NMFS could have difficulty monitoring the catch caps with a 95-percent closure threshold. They commented that difficulty in monitoring the herring fishery could result in late closure, causing the herring fishery to exceed the applicable river herring and shad caps. The Herring Alliance commented that it is concerned that the measures in Framework 3 are not enough to account for scientific and management uncertainty surrounding river herring and shad. The Herring Alliance commented that the 95-percent closure threshold is not conservative enough in light of a recent catch overage in Herring Management Area 1B and frequent historical overages of the area-based quotas in the herring fishery. CHOIR urged NMFS to be highly vigilant in monitoring the caps, and the Herring Alliance commented that a lower cap is warranted until NMFS is able to provide observer coverage necessary to accurately monitor these catch caps.

Response: NMFS has a monitoring program in place for the herring fishery that enables it to project a closure date based on daily catch and weekly dealer data. NMFS is vigilant in monitoring this fishery and has effectively closed herring management areas before the area allocations the majority of the time. NMFS asserts that the 95-percent threshold is sufficient, but will advise the Council to reassess this threshold if it does not provide a sufficient buffer in the event the herring fishery has a very rapid harvest rate. NMFS cannot implement a lower closure threshold because one was not recommended by the Council. NMFS cannot implement different measures than what the Council recommended; it can only approve or disapprove the measures recommended by the Council.

Comment 5: CHOIR commented that NMFS should pay close attention to new data from herring fishing activity on Georges Bank and should support the development and implementation of a cap on Georges Bank. The Herring Alliance commented that NMFS should approve the cap designated for George Bank, ensure sufficient observer coverage in that area to accurately monitor catch, and establish a limit in the next appropriate action.

Response: NMFS and the Council will work together to examine catch on Georges Bank and all other herring management areas to determine whether to establish caps on Georges Bank or adjust the caps through the herring fishery specifications process.

Comment 6: The Herring Alliance, Wild Oceans, and CHOIR all stressed the importance of coordinating river herring and shad catch caps between the Mid-Atlantic and New England Councils. Commenters suggest that this would ensure that the Councils and NMFS sufficiently address river herring and shad catch in areas where the herring and mackerel fisheries overlap, and where vessels catch substantial amounts of both herring and mackerel on the same trip. Comments urged the creation of a single river herring and shad cap to address herring and mackerel fishery overlap. Comments recognized that the Councils and NMFS could develop joint caps for the 2016 fishing year, but not for 2014 and 2015.

Response: NMFS agrees that the New England and Mid-Atlantic Councils should work cooperatively to establish river herring and shad caps for the herring and mackerel fisheries that do not cause management inconsistency in the two fisheries, in particular where they overlap. The Council has indicated its intent in the Framework 3 document to work with the Mid-Atlantic Council in establishing a joint cap.

Comment 7: The Herring Alliance commented that the river herring and shad caps are a first step in management of river herring and shad, but ultimately insufficient, to prevent further population declines and rebuild these species. It commented that the Magnuson-Stevens Act requires all stocks in need of conservation and management to be added to an FMP, and therefore believes that river herring and shad must be added to the FMP as a federally managed species, as well as any other fishery FMP that manage fisheries that catch river herring and shad.

Response: Measures to help minimize the catch of any species may be added to a Federal FMP without also including that species in that FMP's stock in the fishery definition. Many measures have been implemented in the FMP to minimize bycatch to the extent practicable, most recently in Amendment 5 to the FMP. In addition to those measures, implementing river

herring and shad catch caps in the FMP is an additional way to minimize river herring and shad catch to the extent practicable in Federal waters while the effects of various threats (*e.g.,* water quality, fish passage, predation, habitat loss, fishing mortality, and climate change) on river herring and shad continue to be evaluated. NMFS and the Council continue to monitor and evaluate whether further management measures to address river herring and shad catch are necessary, including whether to include river herring and shad as stocks in the fishery.

There are many factors that must be considered when determining whether a species will be included as a stock in a fishery in a fishery management plan. Each Fishery Management Council is required by the Magnuson-Stevens Act to develop FMPs ''for each fishery under its authority that requires conservation and management'' (16 U.S.C. 1852(h)(1)). If a stock in a fishery is determined to be overfished or subject to overfishing, it must be included in an FMP. Section 303(a)(2) of the Magnuson-Stevens Act requires that each FMP contain, among other things, a description of the species of fish involved in the fishery, and a ''fishery'' is defined as ''one or more stocks of fish that can be treated as a unit for purposes of conservation and management and that are identified on the basis of geographic, scientific, technical, recreational, or economic characteristics'' (16 U.S.C. 1802(13)). The National Standard 1 Guidelines provide further guidance that Councils should determine ''which specific target stocks and/or non-target stocks to include in the fishery,'' as well as whether it would be appropriate to designate any ''ecosystem component species'' (50 CFR 600.310(d)(l)). When considering which stocks ''can be treated as a unit for purposes of conservation and management,'' and therefore constitute a ''fishery,'' National Standard 3 requires that, ''[t]o the extent practicable, an individual stock of fish shall be managed as a unit throughout its range, and interrelated stocks of fish shall be managed as a unit or in close coordination'' (16 U.S.C. 1851(a)(3)). The National Standard 3 Guidelines further instruct that the choice of a management unit ''depends on the focus of the FMP's objectives, and may be organized around biological, geographic, economic, technical, social, or ecological perspectives'' (50 CFR 600.320(d)(l)). Additionally, conservation and management measures shall, where practicable, minimize costs and avoid unnecessary duplication (16 U.S.C. 1851(a)(7)). Stocks in the fishery classifications must be monitored ''on a regular basis'' to determine whether reclassification through and Amendment to the FMP is necessary (50 CFR 600.310(d)(6)).

We considered whether the FMP's definition of stocks in the fishery complied with the Magnuson-Stevens Act in relation to Amendment 4 to the FMP in response to a court order in Flaherty v. Pritzker, 2014 WL 642658 (D.D.C. Feb. 19, 2014), and we found that it complied with the Magnuson-Stevens Act. The best available information at that time supported a conclusion that: It is impracticable to treat river herring and shad throughout their range in federal waters as a unit; there is insufficient information to support a finding that they are in need of conservation and management under the Magnuson-Stevens Act; and it would be impracticable and unnecessarily duplicative to undertake management and conservation of them in Federal waters at that time.

The states have historically managed shad and river herring in state waters under the ASMFC's Interstate Fishery Management Plan (ISFMP) for Shad and River Herring. In 1998, Amendment 1 to the ASMFC's ISFMP for Shad and River Herring prohibited a commercial ocean fishery for American shad, established fishing mortality targets for specific American shad river fisheries, and established a daily fish limit in recreational fisheries for American shad and hickory shad. In 2009, Amendment 2 to the ISFMP for Shad and River Herring required each state to close its rivers to river herring fishing unless that state could develop a plan that ensured that such fishing could be maintained at sustainable levels. Any such plans had to first be submitted to the ASMFC's Shad and River Herring Management Board for approval before a state could open the river to fishing. State river herring fisheries without such plans were required to close by January 1, 2012. In 2010, Amendment 3 to the ISFMP for Shad and River Herring established requirements for states to develop sustainable fishery plans in order to maintain a commercial American shad fishery. American shad fisheries without such plans were required to close by January 1, 2013.

The ASMFC's Shad and River Herring Management Board recommends river herring and shad management measures. At no time has the Shad and River Herring Management Board recommended that we create an FMP for river herring and shad in federal waters or designate river herring and/or shad as a stock in any Federal fishery. In the past, when the ASMFC believed that management in Federal waters was warranted, it requested the development of a Federal FMP, as in the case of lobster, striped bass, weakfish, and horseshoe crab.

Information currently available supports a conclusion that it is impracticable to treat shad and river herring as a ''unit'' on a regional or coast-wide scale as contemplated by National Standard 3. ASMFC stock assessments evaluated individual rivers. The best available information suggests that river herring and shad from different natal rivers co-occur in the ocean, but the full extent and rate of mixing are uncertain. Catch data do not always differentiate between river herring and shad species and have not been determined to sufficiently link fish caught in the ocean with individual source rivers or stocks.

The best available science is insufficient to support a finding that conservation and management of these stocks in Federal waters is necessary. The best available science for river herring was a 2012 benchmark assessment. This assessment found that of the 52 stocks of alewife and blueback herring for which data were available for use in the assessment, 23 were depleted from historic levels, 1 stock was increasing, and the status of 28 other stocks could not be determined because of insufficient data. The assessment was insufficient to conclude overfishing was occurring or that the stocks were overfished. Depletion was used instead of overfished because of the many factors (*e.g.,* water quality, fish passage, predation, habitat loss, and climate change) contributing to river herring's declining abundance. Also, the river herring assessment provided only river-by-river information, and did not include information about stocks regionally or coast-wide. Likewise, the 2007 shad stock assessment addressed stocks in 32 rivers. Of the 32 rivers, over half (19) were either stable or could not be determined. The assessments are available at: *http://www.asmfc.org.* The lack of adequate data prevented the ASMFC from developing estimates of abundance and fishing mortality in either assessment. The best scientific information currently available shows that encounters between the herring fishery in Federal waters and river herring are relatively rare (75 percent of sampled trips had no encounters), and that estimates about river herring catch in the herring fishery in Federal waters are highly variable and depend on gear, area, and season. Additionally, data suggest that vessels using small-mesh bottom trawl, and targeting species

other than Atlantic herring, are also encountering river herring. Because of the variability in encounters with river herring, there is a need for adequate sampling of the herring fishery by observers before any conclusions could be made based on the available information. In light of these significant data limitations, there is insufficient information to support a finding that river herring and shad are overfished or subject to overfishing. Further, given the scale and uncertainty associated with this information, including interactions between the herring fishery and river herring, there is insufficient information to support a finding that the river herring or shad stocks coast-wide otherwise require conservation and management.

Information currently available demonstrates that conservation and management of river herring and/or shad in Federal waters would be impracticable and unnecessarily duplicative. The limited available stock status information is primarily related to state waters. Data on the incidental catch of river herring and shad in Federal waters are uncertain. Given these limitations, relying on the ASMFC's management of river herring and shad is reasonable. As more information is gathered about the incidental catch of river herring and shad in Federal waters, and as stock status information is generated on a regional and/or coast-wide scale, the potential benefits of Federal management to these stocks, the regional economy, and competing stakeholder groups may outweigh the costs and duplication with ASMFC management.

While this comment reflects public interest in river herring and shad, it is not objective, science-based information that would satisfy NMFS's obligation to rely on the best available science. Typically, when new science is considered, it takes the form of a peer-reviewed journal article or a peer-reviewed stock assessment. Currently, the best available science on river herring and shad is the ASMFC's stock assessments. Amendment 5 to the FMP implemented bycatch measures to address the FMP's impact on river herring and shad and minimize bycatch of these species to the extent practicable. Those measures included increased at-sea sampling, bycatch accounting, promoting cooperative efforts with the industry to minimize bycatch, and set the foundation for implementing river herring and shad catch caps in this action. Data are not robust enough at this time to determine biologically-based river herring and shad catch caps and/or the potential impacts of such catch caps on the river herring and shad stocks. Setting a cap on the catch of these species in the herring fishery is a proactive action intended to manage and minimize catch to the extent practicable while allowing the herring fishery to continue to operate and fully utilize optimum yield in the upcoming fishing years, if river herring and shad can be avoided. The catch of river herring and shad in the herring fishery would likely be less under a catch cap. Additionally, there would be further incentive for the fleet to avoid river herring and shad to avoid triggering area closures resulting from the catch caps being fully harvested.

Establishing river herring and shad as stocks in FMP and implementing all of the MSA required provisions would require an amendment and is not appropriate for this framework adjustment. The river herring and shad catch caps implemented in this action provide further incentive for the herring industry to avoid river herring and shad catch and minimize the FMP's impact to the extent practicable. In light of the existing management of directed fisheries for river herring and shad in state waters through the ASMFC's ISFMP, and the information currently available, we conclude that the Council's decision to implement these catch caps while continuing the FMP's designation of Atlantic herring as the only stock in the fishery is reasonable and complies with the Magnuson-Stevens Act. Further, the Council has added the consideration of whether it should include river herring and shad as stocks in the fishery in the FMP as one of several management priorities that it expects to address in the upcoming year. We have urged the Council to consider this issue and plan to encourage them to make this a priority action. If the Council finds that river herring and shad should be included as stocks in the FMP, it will initiate an amendment to do so.

Comment 8: The Herring Alliance commented that NMFS must ensure that the methodology to set catch caps adheres to National Standard 2, National Standard 9, and the goals and objectives of Framework 3 (which the Herring Alliance stated is to reduce all catch—bycatch and incidental catch—of river herring and shad from recent levels).

Response: NMFS has determined that the measures in Framework 3 are consistent with the Magnuson-Stevens Act, the FMP, and applicable laws. Part of this decision includes NMFS's determination that the action is based on the best available science as required by National Standard 2, and helps the FMP minimize bycatch and bycatch mortality to the extent practicable, as required by National Standard 9.

The Council considered the most recent assessments for river herring and shad when developing these catch caps. These assessments are the best available science for river herring and shad. Data do not appear to be robust enough to determine a biologically based catch cap for these species or the potential effects on these populations of a coastwide catch cap. Nevertheless, the Council determined that capping the allowed level of river herring and shad in the herring fishery should provide a further incentive for the industry to avoid river herring and shad and will help minimize encounters with these species.

National Standard 9 Guidelines advise taking into account the net benefits to the nation of any proposed conservation and management measure, including: Negative impacts on affected stocks; incomes to fishery participants in directed fisheries; incomes accruing to those targeting the bycatch species; environmental consequences; non-market values of bycatch species (*e.g.,* recreational values); and impacts on other marine organisms. River herring and shad are caught incidentally in the herring fishery. River herring and shad are forage species that play an important role in the ecosystem, providing a benefit to recreational fishermen, and are of great interest to numerous stakeholders. While they do occur in Federal waters and are encountered in the herring fishery, river herring and shad are not target species in the fishery, and their rate of bycatch is very low overall. Even the rate of incidental catch of river herring and shad is relatively low. Available information and analysis have not shown a strong connection between the effects of bycatch—either in the herring fishery or in other fisheries subject to Federal management—and the stocks of these species.

Because discarding of river herring, shad, and other species does not generally occur after the fish is brought on board a vessel, the FMP and related measures in the Northeast Multispecies FMP use measures aimed at directly avoiding incidental catch of these species, thereby avoiding any possibility of bycatch or bycatch mortality. The Herring FMP also seeks to gather further information that may help design future avoidance measures while taking into account the net benefits to the nation of the herring fishery and its effect on other species, consistent with the National Standard Guidelines. A catch cap falls under the concept of reducing

bycatch by providing an incentive to avoid the incidental catch of river herring and shad by triggering a low herring possession limit once the cap is reached. Amendment 5 included the measure to allow implementing a river herring catch cap through a framework or the specifications process as well as improvements in monitoring and avoidance measures. Monitoring and avoidance are critical steps to a better understanding of the nature and extent of incidental catch and bycatch in the herring fishery in order to sufficiently analyze and, if necessary, address bycatch issues. Because the seasonal and inter-annual distribution of river herring and shad is highly variable in time and space, the most effective measures to address river herring and shad bycatch and bycatch mortality are those that increase catch monitoring and incidental catch and bycatch accounting, promote cooperative efforts with the industry, and reduce economic impacts to minimize incidental catch, bycatch, and bycatch mortality to the extent practicable. We have concluded that these catch caps, in addition to other measures in the FMP, reduce bycatch and bycatch mortality to the extent practicable.

Comment 9: The Herring Alliance commented that the best available science demonstrates that there are a number of approaches used to set catch limits in data poor species that are more appropriate than the methodology implemented in Framework 3, which is scaled up to achieve maximum herring catch. The Herring Alliance, Wild Oceans, and CHOIR commented that the cap should be biologically based, should be focused on the conservation of river herring and shad, and should reduce river herring and shad mortality. The Herring Alliance, Wild Oceans, and CHOIR recommended that the New England Council should request that the SSC review cap limits and the methodology used to set them.

Response: Data do not appear robust enough to determine a biologically-based cap at this time. Based on the best scientific information available, the Council determined, and NMFS agrees, that caps based on past performance of the herring fishery, scaled to the herring annual catch limit of 107,800 mt for 2013–2015, is an acceptable limit on the amount of catch in the herring fishery. As the Council considers additional information on the biology of river herring and shad, it can use that information to try to establish catch caps directly tied to river herring and shad biology.

Comment 10: The Herring Alliance, CHOIR, and Wild Oceans commented on various aspects of the FMP that are related to this action but are not within the scope of measures considered and approved as part of Framework 3. These include improvements to fishery observer provisions for the FMP, consideration of adding river herring and shad as stocks in the herring fishery, development of more robust catch monitoring provisions (not specific to river herring and shad), and development of consequences for vessels that dump catch at sea before it can be sampled by at-sea observers on herring vessels. Specifically, the commenters stated or implied that the measures that NMFS disapproved as part of Amendment 5 are integral to the effective monitoring and management of river herring and shad catch in the herring fishery.

Response: NMFS is working with the Council to develop measures related to these issues. Some of these issues are currently being considered in Framework 4 to the FMP. Other issues, such as considering whether to add river herring and shad as stocks in the fishery may be addressed in future actions. Although NMFS understands the connection between these measures and the river herring and shad catch caps, these additional issues and measures are not within the scope of this action.

Changes From Proposed Rule to Final Rule

In § 648.2, NMFS is clarifying the definitions for herring and blueback herring by including a definition for blueback herring and removing blueback herring from the definition of ''Herring.'' The proposed rule only included a definition for ''river herring and shad'' to include the four species of river herring and shad and their genus and species names.

In § 648.7(b)(3)(i), NMFS clarifies that the requirement for herring vessels to report total catch retained by statistical area only applies to herring vessels that are fishing with midwater trawl or bottom trawl gear. The proposed rule would have required all herring vessels issued a limited access herring permit or an Areas 2/3 open access herring permit to report total catch retained regardless of the gear type they use. NMFS will use the ''total catch retained'' portion of the report to monitor catch caps for river herring and shad, and haddock, which only apply to vessels using midwater trawl or bottom trawl gear. NMFS does not need the total catch retained information for other gear types and is therefore not requiring them to report it.

NMFS has also made some changes to the regulatory text in paragraphs as clarifications to the proposed rule. These changes do not modify the intent or the substance of the regulations. Clarifications are in sections and paragraphs: 648.7(b)(3)(i); 648.14(r)(1)(ii)(B); 648.200(f)(6) and (f)(7)(ii); 648.201(a)(2), (a)(4)(i) and (ii); and 648.204(a)(1) through (5).

Classification

The Assistant Administrator for Fisheries, NOAA, has determined that this rule is consistent with the national standards and other provisions of the MSA and other applicable laws.

The Assistant Administrator also finds that the need to immediately limit the amount of river herring and shad catch in the herring fishery constitutes good cause under authority contained in 5 U.S.C. 553(d)(3) to waive the 30-day delay in effective date. There is good cause to implement the river herring and shad catch caps upon publication of this final rule The Council intended for the caps to be in place for as much of the 2014 herring fishing year as possible. Delaying the effectiveness of the river herring and shad catch caps may cause the caps to be implemented after the herring fishery has already harvested the herring catch allocated to it for 2014, thereby undermining the benefits of implementing the catch caps that were specified by the Council to take effect in 2014. The herring fishery opened for the 2014 fishing year on January 1, 2014, and the herring fishery has already harvested more than 80 percent of the allocated catch for the year. The cap must be in place upon publication of this final rule in order to constrain river herring and shad catch on as much of the herring fishery in 2014 as possible. If the herring fishery continues to operate without a cap through the rest of 2014 in Area 2 primarily, the benefit of the caps in 2014 will be forgone altogether if the herring fishery catches its remaining allocation before the final rule makes the river herring and shad caps effective. The Council submitted its final version of Framework 3 for NMFS review in March 2014, meaning that final NMFS action would occur well after the herring fishery was underway. As a result, NMFS intended from the outset to implement these measures upon publication due to the need and the public interest. Even though it is near the end of 2014 and only one area remains open (Area 2) to the herring fishery, NMFS believes that it is still important to implement the measures upon publication. These species have a high level of importance in the ecosytems, the public is extremely interested in measures to protect them,

and this final rule implements measures that provide possible protection of these species from excessive catch in the herring fishery.

The Office of Management and Budget has determined that this rule is not significant according to Executive Order 12866.

This final rule does not contain policies with federalism or ''takings'' implications, as those terms are defined in E.O. 13132 and E.O. 12630, respectively.

NMFS, pursuant to section 604 of the Regulatory Flexibility Act (RFA), has completed a final regulatory flexibility analysis (FRFA) in support of Framework 3 in this final rule. The FRFA incorporates the IRFA, a summary of the significant issues raised by the public comments in response to the IRFA, NMFS responses to those comments, a summary of the analyses completed in the Framework 3 EA, and this portion of the preamble. A summary of the IRFA was published in the proposed rule for this action and is not repeated here. A description of why this action was considered, the objectives of, and the legal basis for this rule is contained in Framework 3 and in the preamble to the proposed and this final rule, and is not repeated here. All of the documents that constitute the FRFA are available from NMFS and a copy of the IRFA, the RIR, and the EA are available upon request (see **ADDRESSES**).

Summary of the Significant Issues Raised by the Public Comments in Response to the IRFA, a Summary of the Assessment of the Agency of Such Issues, and a Statement of Any Changes Made in the Proposed Rule as a Result of Such Comments

NMFS received no comments in response to the IRFA.

Description and Estimate of Number of Small Entities To Which the Final Rule Will Apply

On June 20, 2013, the Small Business Administration (SBA) issued a final rule revising the small business size standards for several industries effective July 22, 2013 (78 FR 37398). The rule increased the size standard for finfish fishing from $4.0 to $19.0 million, shellfish fishing from $4.0 to $5.0 million, and other marine fishing from $4.0 to $7.0 million. The IRFA that the Council and NMFS developed for this action used the SBA size standards that became effective in July 2013. On June 12, 2014, SBA issued an interim final rule revising the small business size standards for several industries effective July 14, 2014 (79 FR 33467). The rule increased the size standard from $19.0 to $20.5 million for finfish fishing, from $5 to $5.5 million for shellfish fishing, and from $7.0 million to $7.5 million for other marine fishing, for-hire businesses, and marinas.

This action will affect all limited access herring vessels (*i.e.,* category A, B, or C permit). In 2012, there were 94 fishing vessels that had a limited access herring permit. Vessels and/or permits may be owned by entities affiliated by stock ownership, common management, identity of interest, contractual relationships, or economic dependency. For the purposes of this analysis, affiliated ownership entities are determined by those entities with common ownership personnel as listed on permit application documentation. Only permits with identical ownership personnel are categorized as an ownership entity. For example, if five permits have the same seven personnel listed as co-owners on their application paperwork, those seven personnel form one ownership entity, covering those five permits. If one or several of the seven owners also own additional vessels, with different co-owners (*i.e.,* either sub-sets of the original seven personnel or new co-owners), those ownership arrangements are deemed to be separate ownership entities for the purpose of this analysis.

Pursuant to the Regulatory Flexibility Act, and prior to SBA's June 12, 2014, interim final rule, NMFS prepared an IRFA for this action using SBA's former size standards. Based on ownership criterion explained above and NMFS dealer-reported landings data for 3 years ending in 2012, and the July 2013 size standards for finfish and shellfish firms, the Council and NMFS determined that there are 72 directly regulated small entities and 6 large entities, as defined in section 601 of the RFA. Not all of these permitted firms were active: Only 25 directly regulated small entities and 4 large entities were actively fishing for herring during the last 3 years. NMFS has reviewed the analyses prepared for this action in light of the new size standards effective July 14, 2014. The new standards could result in no more than six additional entities being considered small.

Taking this change into consideration, NMFS has identified no additional significant alternatives that accomplish statutory objectives and minimize any significant economic impacts of this action on small entities. Further, the new size standards do not affect the decision to prepare a FRFA for this action. The IRFA described that the alternatives to the proposed action would have no economic benefits, and in some cases may be more costly for all entities regardless of whether they are classified as small or large under SBA standards. Therefore, the addition of no more than six small entities would not change the assessment of impacts described in the IRFA and supported in this FRFA.

Description of the Steps the Agency Has Taken To Minimize the Significant Economic Impact on Small Entities Consistent With the Stated Objectives of Applicable Statutes, Including a Statement of the Factual, Policy, and Legal Reasons for Selecting the Alternative Adopted in the Final Rule and Why Each One of the Other Significant Alternatives to the Rule Considered by the Agency Which Affect the Impact on Small Entities Was Rejected

During the development of Framework 3, NMFS and the Council considered ways to reduce the regulatory burden on, and provide flexibility for, the regulated entities in this action. Proposed actions and alternatives are described in detail in Framework 3, which includes an EA, RIR, and IRFA (available at **ADDRESSES**). The measures implemented by this final rule minimize the economic impacts on small entities to the extent practicable.

Overall, this rule minimizes economic impacts (*i.e.,* directed fishery closures) by dividing catch caps across various areas. If a catch cap in a given area for a specific gear is reached, the measures implemented by this action will close only that area to that gear type. Thus, the catch cap measures avoid closing the directed herring fishery in all areas due to a single catch cap overage. This seeks to minimize negative impacts on fishing businesses reliant on gear types subject to directed herring fishery closures in terms of forgone profits. The extent of these impacts depends on when an area is closed to directed fishing relative to nearby areas available for directed herring fishing. Further, the catch caps are not likely to preclude herring fishing in all areas and will provide midwater trawl vessels an opportunity to fish in Herring Management Area 3 (Georges Bank) without a catch cap, thereby potentially mitigating some of the negative impacts.

Small Entity Compliance Guide

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule or group of related rules for which an agency is required to prepare a FRFA, the agency will publish one or more guides to assist small entities in complying with the rule, and will designate such

publications as ''small entity compliance guides.'' The agency will explain the actions a small entity is required to take to comply with a rule or group of rules. As part of this rulemaking process, a letter to permit holders that also serves as a small entity compliance guide (the guide) was prepared. Copies of this final rule are available from the Greater Atlantic Regional Fisheries Office, and the guide (*i.e.,* permit holder letter) will be sent to all holders of permits for the herring fishery. The guide and this final rule will be available upon request.

Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

This action does not contain any new collection-of-information, reporting, recordkeeping, or other compliance requirements. This action does not duplicate, overlap, or conflict with any other Federal rules.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Recordkeeping and reporting requirements.

Dated: November 21, 2014.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 648 is amended as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. In § 648.2, the definition for ''herring'' is removed and the definitions for ''Blueback herring,'' ''River herring,'' and ''Shad,'' are added in alphabetical order to read as follows:

§ 648.2 Definitions.

* * * * *

Blueback herring means *Alosa aestivalis.*

* * * * *

River herring means alewife (*Alosa pseudoharengus*) and blueback herring (*Alosa aestivalis*).

* * * * *

Shad means American shad (*Alosa sapidissima*) and hickory shad (*Alosa mediocris*).

* * * * *

■ 3. In § 648.7, paragraph (b)(3)(i) introductory text is revised to read as follows:

§ 648.7 Recordkeeping and reporting requirements.

* * * * *

(b) * * *

(3) * * *

(i) *Atlantic herring owners or operators issued a limited access permit or Areas 2/3 open access permit.* The owner or operator of a vessel issued a limited access permit or Areas 2/3 open access permit to fish for herring must report catch (retained and discarded) of herring daily via VMS, unless exempted by the Regional Administrator. The report shall include at least the following information, and any other information required by the Regional Administrator: Fishing Vessel Trip Report serial number; month and day herring was caught; pounds retained for each herring management area; and pounds discarded for each herring management area. Additionally, the owner or operator of a vessel issued a limited access permit or Areas 2/3 open access permit to fish for herring using midwater trawl or bottom trawl gear must report daily via VMS the estimated total amount of all species retained (in pounds, landed weight) by statistical area for use in tracking catch against catch caps (haddock, river herring and shad) in the herring fishery. Daily Atlantic herring VMS catch reports must be submitted in 24-hr intervals for each day and must be submitted by 0900 hr (9:00 a.m.) of the following day. Reports are required even if herring caught that day has not yet been landed. This report does not exempt the owner or operator from other applicable reporting requirements of this section.

* * * * *

§ 648.10 [Amended]

■ 4. In § 648.10, paragraph (l) is removed and reserved.

■ 5. In § 648.14, paragraph (r)(1)(ii)(B) is revised to read as follows:

§ 648.14 Prohibitions.

* * * * *

(r) * * *

(1) * * *

(ii) * * *

(B) Fish for, possess, transfer, receive, or sell; or attempt to fish for, possess, transfer, receive, or sell; more than 2,000 lb (907.2 kg) of herring per trip; or land, or attempt to land more than 2,000 lb (907.2 kg) of herring per day in or from a management area closed pursuant to § 648.201(a), or from a river herring and shad catch cap closure area that has been closed to specified gear pursuant to § 648.201(a)(4)(ii), if the vessel has been issued and holds a valid herring permit.

* * * * *

■ 6. In § 648.200, paragraph (a) introductory text is revised, paragraph (b)(6) is added, and paragraphs (f) and (g) are revised to read as follows:

§ 648.200 Specifications.

(a) The Atlantic Herring Plan Development Team (PDT) shall meet at least every 3 years, but no later than July of the year before new specifications are implemented, with the Atlantic States Marine Fisheries Commission's (Commission) Atlantic Herring Plan Review Team (PRT) to develop and recommend the following specifications for a period of 3 years for consideration by the New England Fishery Management Council's Atlantic Herring Oversight Committee: Overfishing Limit (OFL), Acceptable Biological Catch (ABC), Annual Catch Limit (ACL), Optimum yield (OY), domestic annual harvest (DAH), domestic annual processing (DAP), U.S. at-sea processing (USAP), border transfer (BT), the sub-ACL for each management area, including seasonal periods as specified at § 648.201(d) and modifications to sub-ACLs as specified at § 648.201(f), the amount to be set aside for the RSA (from 0 to 3 percent of the sub-ACL from any management area), and river herring and shad catch caps, as specified in § 648.201(a)(4). Recommended specifications shall be presented to the New England Fishery Management Council.

* * * * *

(b) * * *

(6) River herring and shad catch caps may be allocated to the herring fishery by the following: Species, as defined in § 648.2, either separately or combined; area as specified in paragraph (f)(7) of this section; vessel permit; gear type; or any combination of these.

* * * * *

(f) *Management areas.* The specifications process establishes sub-ACLs and other management measures for the three management areas, which may have different management measures. Management Area 1 is subdivided into inshore and offshore sub-areas. The management areas are defined as follows:

(1) *Management Area 1 (Gulf of Maine):* All U.S. waters of the Gulf of Maine (GOM) north of a line extending from a point at 41°39′ N. lat, 70°00′ W. long. to 42°53′ 14.32125″ N. lat., 67° 44′ 33.01613″ W. long., thence northerly along the U.S.-Canada Maritime Boundary to the U.S.-Canadian border, to include state and Federal waters

adjacent to the states of Maine, New Hampshire, and Massachusetts. Management Area 1 is divided into Area 1A (inshore) and Area 1B (offshore). The line dividing these areas is described by the following coordinates:

Point	Latitude	Longitude	Note
1	41°58′ N	70° 00′ W	
2	42°38′ N	70° 00′ W	
3	42°53′ N	69° 40′ W	
4	43°12′ N	69° 00′ W	
5	43°40′ N	68° 00′ W	
6	43°58′16.0314″ N	67° 21′26.157″ W	[1]

[1] Point 6 falls on the U.S.-Canada Maritime Boundary.

(2) *Management Area 2 (South Coastal Area):* All state and Federal waters inclusive of sounds and bays, bounded on the east by 70°00′ W. long. and the outer limit of the U.S. Exclusive Economic Zone; bounded on the north and west by the southern coastline of Cape Cod, Massachusetts, and the coastlines of Rhode Island, Connecticut, New York, New Jersey, Delaware, Maryland, Virginia, and North Carolina; and bounded on the south by a line following the lateral seaward boundary between North Carolina and South Carolina from the coast to the Submerged Lands Act line, approximately 33°48′46.37″ N. lat, 78°29′46.46″ W. long., and then heading due east along 38°48′46.37″ N. lat. to the outer limit of the US Exclusive Economic Zone.

(3) *Management Area 3 (Georges Bank):* All U.S. waters east of 70°00′ W. long. and southeast of the line that runs from a point at 41°39′ N. lat. and 70°00′ W. long., northeasterly to U.S.-Canada Maritime Boundary at 42°53′14.32125″ N. lat., 67°44′33.01613″ W. long.

(4) *River Herring Monitoring/Avoidance Areas*—(i) *January–February River Herring Monitoring/Avoidance Areas.* The January–February River Herring Monitoring/Avoidance Areas include four sub-areas. Each sub-area includes the waters bounded by the coordinates below, connected in the order listed by straight lines unless otherwise noted.

(A) January–February River Herring Monitoring/Avoidance Sub-Area 1.

Point	Latitude	Longitude
JF1A	43°00′ N	71°00′ W
JF1B	43°00′ N	70°30′ W
JF1C	42°30′ N	70°30′ W
JF1D	42°30′ N	71°00′ W
JF1A	43°00′ N	71°00′ W

(B) January–February River Herring Monitoring/Avoidance Sub-Area 2.

Point	Latitude	Longitude
JF2A	42°00′ N	70°00′ W
JF2B	42°00′ N	69°30′ W
JF2C	41°30′ N	69°30′ W
JF2D	41°30′ N	70°00′ W
JF2A	42°00′ N	70°00′ W

(C) January–February River Herring Monitoring/Avoidance Sub-Area 3.

Point	Latitude	Longitude	Note
JF3A	41°30′ N	72°00′ W	
JF3B	41°30′ N	71°00′ W	
JF3C	40°30′ N	71°00′ W	
JF3D	40°30′ N	72°30′ W	
JF3E	[1]	72°30′ W	[3]
JF3F	[2]	72°00′ W	[3]
JF3A	41°30′ N	72°00′ W	

[1] The southernmost shoreline of Long Island, New York.
[2] The north-facing shoreline of Long Island, New York.
[3] Points JF3E and JF3F are connected following the coastline of the south fork of eastern Long Island, New York.

(D) January–February River Herring Monitoring/Avoidance Sub-Area 4.

Point	Latitude	Longitude	Note
JF4A	40°30′ N	74°00′ W	
JF4B	40°30′ N	72°30′ W	
JF4C	40°00′ N	72°30′ W	
JF4D	40°00′ N	72°00′ W	
JF4E	39°30′ N	72°00′ W	
JF4F	39°30′ N	73°30′ W	
JF4G	40°00′ N	73°30′ W	
JF4H	40°00′ N	74°00′ W	[1]
JF4A	40°30′ N	74°00′ W	[1]

[1] Points JF4H and JF4A are connected following 74 °W longitude and the easternmost shoreline of New Jersey, whichever is furthest east.

(ii) *March–April River Herring Monitoring/Avoidance Areas.* The March–April River Herring Monitoring/Avoidance Areas include five sub-areas. Each sub-area includes the waters bounded by the coordinates below, connected in the order listed by straight lines unless otherwise noted.

(A) March–April River Herring Monitoring/Avoidance Sub-Area 1.

Point	Latitude	Longitude
MA1A ...	43°00′ N	71°00′ W
MA1B ...	43°00′ N	70°30′ W
MA1C ...	42°30′ N	70°30′ W
MA1D ...	42°30′ N	71°00′ W
MA1A ...	43°00′ N	71°00′ W

(B) March–April River Herring Monitoring/Avoidance Sub-Area 2.

Point	Latitude	Longitude
MA2A ...	42°00′ N	70°00′ W
MA2B ...	42°00′ N	69°30′ W
MA2C ...	41°30′ N	69°30′ W
MA2D ...	41°30′ N	70°00′ W
MA2A ...	42°00′ N	70°00′ W

(C) March–April River Herring Monitoring/Avoidance Sub-Area 3.

Point	Latitude	Longitude	Note
MA3A ...	41°00′ N	[1]	
MA3B ...	41°00′ N	71°00′ W	
MA3C ..	40°30′ N	71°00′ W	
MA3D ..	40°30′ N	71°30′ W	
MA3E ...	40°00′ N	71°30′ W	
MA3F ...	40°00′ N	72°30′ W	
MA3G ..	[2]	72°30′ W	[3]
MA3A ...	41°00′ N	[1]	[3]

[1] The easternmost shoreline of Long Island, New York.
[2] The southernmost shoreline of Long Island, New York.
[3] Points MA3G and MA3A are connected following the southern shoreline of Long Island, New York.

(D) March–April River Herring Monitoring/Avoidance Sub-Area 4.

Point	Latitude	Longitude
MA4A ...	40°00′ N	73°30′ W
MA4B ...	40°00′ N	72°30′ W
MA4C ...	39°00′ N	72°30′ W
MA4D ...	39°00′ N	73°30′ W
MA4A ...	40°00′ N	73°30′ W

(E) March–April River Herring Monitoring/Avoidance Sub-Area 5.

Point	Latitude	Longitude	Note
MA5A ...	40°30′ N	74°00′ W	
MA5B ...	40°30′ N	73°30′ W	
MA5C ..	40°00′ N	73°30′ W	
MA5D ..	40°00′ N	74°00′ W	[1]
MA5A ...	40°30′ N	74°00′ W	[1]

[1] Points MA5D and MA5A are connected following 74 °W longitude and the easternmost shoreline of New Jersey, whichever is furthest east.

(iii) *May–June River Herring Monitoring/Avoidance Areas.* The May–June River Herring Monitoring/Avoidance Areas include two sub-areas. Each sub-area includes the waters bounded by the coordinates below, connected in the order listed by straight lines unless otherwise noted.

(A) May–June River Herring Monitoring/Avoidance Sub-Area 1.

Point	Latitude	Longitude
MJ1A ...	44°00′ N	69°30′ W
MJ1B ...	44°00′ N	69°00′ W
MJ1C ...	43°30′ N	69°00′ W
MJ1D ...	43°30′ N	69°30′ W
MJ1A ...	44°00′ N	69°30′ W

(B) May–June River Herring Monitoring/Avoidance Sub-Area 2.

Point	Latitude	Longitude
MJ2A ...	42°00′ N	70°00′ W
MJ2B ...	42°00′ N	69°30′ W
MJ2C ...	41°30′ N	69°30′ W
MJ2D ...	41°30′ N	70°00′ W
MJ2A ...	42°00′ N	70°00′ W

(iv) *July–August River Herring Monitoring/Avoidance Areas.* The July–August River Herring Monitoring/Avoidance Areas include two sub-areas. Each sub-area includes the waters bounded by the coordinates below, connected in the order listed by straight lines unless otherwise noted.

(A) July–August River Herring Monitoring/Avoidance Sub-Area 1.

Point	Latitude	Longitude	Note
JA1A	44°00′ N	70°00′ W	
JA1B	44°00′ N	69°30′ W	
JA1C	43°00′ N	69°30′ W	
JA1D	43°00′ N	70°00′ W	(1)
JA1A	44°00′ N	70°00′ W	(1)

1 The boundary from Points JA1D to JA1A excludes the portions Maquoit Bay and Middle Bay (Brunswick, ME) east of 70°00′ W.

(B) July–August River Herring Monitoring/Avoidance Sub-Area 2.

Point	Latitude	Longitude
JA2A	44°00′ N	69°00′ W
JA2B	44°00′ N	68°30′ W
JA2C	43°30′ N	68°30′ W
JA2D	43°30′ N	69°00′ W
JA2A	44°00′ N	69°00′ W

(v) *September–October River Herring Monitoring/Avoidance Areas.* The September–October River Herring Monitoring/Avoidance Areas include two sub-areas. Each sub-area includes the waters bounded by the coordinates below, connected in the order listed by straight lines unless otherwise noted.

(A) September–October River Herring Monitoring/Avoidance Sub-Area 1.

Point	Latitude	Longitude	Note
SO1A ...	44°30′ N	68°00′ W	
SO1B ...	44°30′ N	(1)	(2)
SO1C ...	44°00′ N	(3)	(2)
SO1D ...	44°00′ N	68°00′ W	
SO1A ...	44°30′ N	68°00′ W	

1 The intersection of 44°30′ N and the U.S.-Canada Maritime Boundary.
2 Point SO1B and Point SO1C are connected along the U.S.-Canada Maritime Boundary.
3 The intersection of 44°00′ N and the U.S.-Canada Maritime Boundary.

(B) September–October River Herring Monitoring/Avoidance Sub-Area 2.

Point	Latitude	Longitude
SO2A ...	43°00′ N	71°00′ W
SO2B ...	43°00′ N	70°30′ W
SO2C ...	42°30′ N	70°30′ W
SO2D ...	42°30′ N	71°00′ W
SO2A ...	43°00′ N	71°00′ W

(vi) *November–December River Herring Monitoring/Avoidance Areas.* The November–December River Herring Monitoring/Avoidance Areas include two sub-areas. Each sub-area includes the waters bounded by the coordinates below, connected in the order listed by straight lines unless otherwise noted.

(A) November–December River Herring Monitoring/Avoidance Sub-Area 1.

Point	Latitude	Longitude	Note
ND1A ...	43°00′ N	71°00′ W	
ND1B ...	43°00′ N	70°00′ W	
ND1C ...	42°00′ N	70°00′ W	
ND1D ...	42°00′ N	69°30′ W	
ND1E ...	41°30′ N	69°30′ W	
ND1F ...	41°30′ N	70°00′ W	
ND1G ..	(1)	70°00′ W	(3)
ND1H ...	42°00′ N	(2)	(3)
ND1I	42°00′ N	70°30′ W	
ND1J ...	42°30′ N	70°30′ W	
ND1K ...	42°30′ N	71°00′ W	
ND1A ...	43°00′ N	71°00′ W	

1 The south-facing shoreline of Cape Cod, Massachusetts.
2 The west-facing shoreline of Cape Cod, Massachusetts.
3 Point ND1G and ND1H are connected following the coastline of Cape Cod, Massachusetts.

(B) November–December River Herring Monitoring/Avoidance Sub-Area 2.

Point	Latitude	Longitude
ND2A ...	41°30′ N	72°00′ W
ND2B ...	41°30′ N	70°00′ W
ND2C ...	40°30′ N	70°00′ W
ND2D ...	40°30′ N	70°30′ W
ND2E ...	41°00′ N	70°30′ W
ND2F ...	41°00′ N	72°00′ W
ND2A ...	41°30′ N	72°00′ W

(5) *Gulf of Maine Modified Haddock Stock Area.* The Gulf of Maine Modified Haddock Stock Area is composed of the portions of Greater Atlantic Region Statistical Areas #464, #465, #511, #512, #513, #514, and #515 in U.S. waters, and is defined by the following points connected in the order listed by straight lines unless otherwise noted:

Point	Latitude	Longitude	Note
A	(1)	67°00′ W	
B	(2)	67°00′ W	(3)
C	42°20′ N	(4)	(3)
D	42°20′ N	70°00′ W	
E	(5)	70°00′ W	(6)
A	(1)	67°00′ W	(6)

1 The intersection of 67°00′ W longitude and the southern coast of Maine.
2 The intersection of 67°00′ W longitude and the U.S.-Canada Maritime Boundary.
3 From POINT B to POINT C along the U.S.-Canada Maritime Boundary.
4 The intersection of 42°20′ N latitude and the U.S.-Canada Maritime Boundary.
5 The intersection of 70°00′ W longitude and the northeast-facing shoreline of Cape Cod, Massachusetts.
6 From POINT E back to POINT A along the coastline of the United States.

(6) *Georges Bank Modified Haddock Stock Area.* The Georges Bank Modified Haddock Stock Area is composed of Greater Atlantic Region Statistical Areas #521, #522, #525, #526, #561, and #562, and is defined by the following points connected in the order listed by straight lines unless otherwise noted:

Point	Latitude	Longitude	Note
A	42°20′ N	70°00′ W	
B	42°20′ N	(1)	(2)
C	40°30′ N	(3)	(2)
D	40°30′ N	66°40′ W	
E	39°50′ N	66°40′ W	
F	39°50′ N	70°00′ W	(4)
A	42°20′ N	70°00′ W	(4)

1 The intersection of 42°20′ N latitude and the U.S.-Canada Maritime Boundary.
2 From POINT B to POINT C following the U.S.-Canada Maritime Boundary.
3 The intersection of 40°30′ N latitude and the U.S.-Canada Maritime Boundary.
4 From POINT F back to POINT A along 70°00′ W longitude and the coastlines of Nantucket Island and mainland Cape Cod, Massachusetts, whichever is further east.

(7) *River herring and shad catch cap areas*—(i) *Gulf of Maine Catch Cap Area.* The Gulf of Maine Catch Cap Area is composed of the portions of Greater Atlantic Region Statistical Areas #464, #465, #467, #511, #512, #513, #514, and #515 in U.S. waters. The Gulf of Maine Catch Cap Area is bounded on the west by the coastline of the United States, bounded on the east by the U.S.-Canada Maritime Boundary, and bounded on the south by the following coordinates connected by straight lines in the order listed:

Point	Latitude	Longitude
A	(1)	70°00′ W
B	42°20′ N	70°00′ W
C	42°20′ N	(2)

1 The intersection of 70°00′ W longitude and the northwest facing shoreline of Cape Cod, Massachusetts
2 The intersection of 42°00′ N latitude and the U.S.-Canada Maritime Boundary.

(ii) *Cape Cod Catch Cap Area.* The Cape Cod Catch Cap Area is composed of Greater Atlantic Region Statistical Area #521, and is defined by the

following points connected in the order listed by straight lines unless otherwise noted:

Point	Latitude	Longitude	Note
A	(1)	70°00′ W	
B	42°20′ N	70°00′ W	
C	42°20′ N	68°50′ W	
D	41°00′ N	68°50′ W	
E	41°00′ N	69°30′ W	
F	41°10′ N	69°30′ W	
G	41°10′ N	69°50′ W	
H	41°20′ N	69°50′ W	
I	41°20′ N	(2)	(3)
J	(4)	70°00′ W	(3)
K	(5)	70°00′ W	(6)
A	(1)	70°00′ W	(6)

[1] The intersection of 70°00′ W longitude and the northeast-facing shoreline of Cape Cod, Massachusetts

[2] The intersection of 41°20′ N latitude and the northeast-facing shoreline of Nantucket Island.

[3] From Point I to Point J along the northeast-facing shoreline of Nantucket Island.

[4] The intersection of 70°00′ W longitude and the northeast-facing shoreline of Nantucket Island.

[5] The intersection of 70°00′ W longitude and the south-facing shoreline of mainland Cape Cod, Massachusetts.

[6] From Point K back to Point A along the east-facing shoreline of Cape Cod, Massachusetts.

(iii) *Georges Bank Catch Cap Area.* The Georges Bank Catch Cap Area is composed of the portions of Greater Atlantic Region Statistical Areas #522, #525, #526, #541, #542, #543, #561, #562, and #640 in U.S. waters, and is defined by the following points, connected in the order listed by straight lines unless otherwise noted:

Point	Latitude	Longitude	Note
A	(1)	70°00′ W	
B	(2)	70°00′ W	(3)
C	41°20′ N	(4)	(3)
D	41°20′ N	69°50′ W	
E	41°10′ N	69°50′ W	
F	41°10′ N	69°30′ W	
G	41°00′ N	69°30′ W	
H	41°00′ N	68°50′ W	
I	42°20′ N	68°50′ W	
J	42°20′ N	(5)	(6)
A	(1)	70°00′ W	(6)

[1] The intersection of 70°00′ W longitude and the outer limit of the U.S. Exclusive Economic Zone.

[2] The intersection of 70°00′ W longitude and the south-facing shoreline of Nantucket Island.

[3] From Point B to Point C along the south- and east-facing shorelines of Nantucket Island.

[4] The intersection of 41°20′ N latitude and the northeast-facing shoreline of Nantucket Island.

[5] The intersection of 42°20′ N latitude and the U.S.-Canada Maritime Boundary.

[6] From Point J back to Point A along the U.S.-Canada Maritime Boundary and the outer limit of the U.S. Exclusive Economic Zone.

(iv) *Southern New England/Mid-Atlantic Catch Cap Area.* The coordinates of this area are the same as Management Area 2 (South Coastal Area), as specified in paragraph (f)(2) of this section.

(8) *River herring and shad catch cap closure areas—(i) Gulf of Maine Catch Cap Closure Area.* The coordinates of this area are the same as the Gulf of Maine Catch Cap Area, as specified in paragraph (f)(7)(i) of this section.

(ii) *Cape Cod Catch Cap Closure Area.* The coordinates of this area are the same as the Cape Cod Catch Cap Area, as specified in paragraph (f)(7)(ii) of this section.

(iii) *Georges Bank Catch Cap Closure Area.* The coordinates of this area are the same as the Georges Bank Catch Cap Area, as specified in paragraph (f)(7)(iii) of this section.

(iv) *Southern New England/Mid-Atlantic Catch Cap Closure Area.* The Southern New England/Mid-Atlantic Catch Cap Closure Area is composed of the portions of Greater Atlantic Region Statistical Areas #537, #538, #539, #611, #612, #613, #614, #615, #616, #621, #622, #623, #625, #626, #627, #631, #632, #635, and #636 in US waters, and is defined by the following coordinates, connected by straight lines in the order listed unless otherwise noted:

Point	Latitude	Longitude	Note
A	35°00′ N	(1)	
B	35°00′ N	74°00′ W	
C	37°00′ N	74°00′ W	
D	37°00′ N	73°00′ W	
E	38°00′ N	73°00′ W	
F	38°00′ N	72°00′ W	
G	39°00′ N	72°00′ W	
H	39°00′ N	71°40′ W	
I	39°50′ N	71°40′ W	
J	39°50′ N	70°00′ W	
K	(2)	70°00′ W	(3)
A	35°00′ N	(1)	(3)

[1] The intersection of 35°00′ N latitude and the mainland shoreline of North Carolina.

[2] The intersection of 70°00′ W longitude and the south-facing shoreline of mainland Cape Cod, Massachusetts.

[3] From Point K back to Point A along the mainland shoreline of the United States.

(g) All aspects of the following measures can be modified through the specifications process:

(1) AMs;

(2) Possession limits;

(3) River Herring Monitoring/Avoidance Areas; and

(4) River herring and shad catch caps.

■ 7. In § 648.201, paragraphs (a)(2) is revised, paragraph (a)(4) is added, and paragraph (e) is revised to read as follows:

§ 648.201 AMs and harvest controls.

(a) * * *

(2) When the Regional Administrator has determined that the GOM and/or GB incidental catch cap for haddock in § 648.85(d) has been caught, no vessel issued a Federal Atlantic herring permit and fishing with midwater trawl gear in the applicable Accountability Measure (AM) Area, *i.e.,* the Herring GOM Haddock AM Area or Herring GB Haddock AM Area, as defined in § 648.86(a)(3)(ii)(A)(*2*) and (*3*) of this part, may fish for, possess, or land herring in excess of 2,000 lb (907.2 kg) per trip in or from the applicable AM Area, and from landing herring more than once per calendar day, unless all herring possessed and landed by a vessel were caught outside the applicable AM Area and the vessel's gear is not available for immediate use as defined in § 648.2 while transiting the applicable AM Area. Upon this determination, the haddock possession limit is reduced to 0 lb (0 kg) in the applicable AM area for a vessel issued a Federal Atlantic herring permit and fishing with midwater trawl gear or for a vessel issued an All Areas Limited Access Herring Permit and/or an Areas 2 and 3 Limited Access Herring Permit fishing on a declared herring trip, regardless of area fished or gear used, in the applicable AM area, unless the vessel also possesses a Northeast multispecies permit and is operating on a declared (consistent with § 648.10(g)) Northeast multispecies trip.

* * * * *

(4) *River herring and shad catch cap.* (i) The catch from all trips that land more than 6,600 lb (3 mt) of herring shall apply to the river herring and shad catch cap in the herring fishery. Caps by gear and by area shall be established through the specifications process described in § 648.201.

(ii) Beginning on the date that NMFS projects that river herring and shad catch will reach 95 percent of a catch cap for specified gear applicable to an area specified in § 648.200(f)(7) for the remainder of the fishing year, NMFS shall prohibit vessels from fishing for, possessing, catching, transferring, or landing more than 2,000 lb (907.2 kg) of Atlantic herring per trip using the applicable gear in the applicable catch cap closure area, specified in § 648.200(f)(8), and from landing herring more than once per calendar day, except as provided in paragraphs (b) and (c) of this section. NMFS shall implement these restrictions in accordance with the APA.

* * * * *

(e) Up to 500 mt of the Area 1A sub-ACL shall be allocated for the fixed gear fisheries in Area 1A (weirs and stop seines) that occur west of 67°16.8′ W. long (Cutler, Maine). This set-aside shall

be available for harvest by fixed gear within the specified area until November 1 of each fishing year. Any portion of this allocation that has not been utilized by November 1 shall be restored to the sub-ACL allocation for Area 1A.

* * * * *

■ 8. In § 648.204, paragraph (a) is revised to read as follows:

§ 648.204 Possession restrictions.

(a) A vessel must be issued and possess a valid limited access herring permit to fish for, possess, or land more than 6,600 lb (3 mt) of Atlantic herring from any herring management area in the EEZ, provided none of the harvest restrictions specified in § 648.201 has been implemented.

(1) A vessel issued an All Areas Limited Access Herring Permit may fish for, possess, or land Atlantic herring with no possession restriction from any of the herring management areas defined in § 648.200(f), provided none of the accountability measures or harvest restrictions specified in § 648.201 have been implemented.

(2) A vessel issued only an Areas 2 and 3 Limited Access Herring Permit may fish for, possess, or land Atlantic herring with no possession restriction only from Area 2 or Area 3, as defined in § 648.200(f), provided none of the accountability measures or harvest restrictions specified in § 648.201 have been implemented. Such a vessel may fish in Area 1 only if issued an open access herring permit or a Limited Access Incidental Catch Herring Permit, and only as authorized by the respective permit.

(3) A vessel issued a Limited Access Incidental Catch Herring Permit may fish for, possess, or land up to, but no more than, 55,000 lb (25 mt) of Atlantic herring in any calendar day, and is limited to one landing of herring per calendar day, from any management area defined in § 648.200(f), provided none of the accountability measures or harvest restrictions specified in § 648.201 have been implemented.

(4) A vessel issued an All Areas Open Access Permit may fish for, possess, or land up to, but no more than, 6,600 lb (3 mt) of Atlantic herring from any herring management area per trip, and is limited to one landing of herring per calendar day, provided none of the accountability measures or harvest restrictions specified in § 648.201 have been implemented.

(5) A vessel issued an Areas 2/3 Open Access Permit may fish for, possess, or land up to, but no more than, 20,000 lb (9 mt) of Atlantic herring from only Area 2 or Area 3, as defined in § 648.200(f), per trip, and is limited to one landing of herring per calendar day, provided none of the accountability measures or harvest restrictions specified in § 648.201 have been implemented.

(6) A vessel issued a herring permit may possess herring roe provided that the carcasses of the herring from which it came are not discarded at sea.

* * * * *

■ 9. In § 648.206, paragraphs (b)(36) and (37) are revised and (b)(38) is added to read as follows:

§ 648.206 Framework provisions.

* * * * *

(b) * * *

(36) River herring and shad catch caps, including species-specific caps, and vessels, permits, trips, gears, and areas to which caps apply;

(37) River herring and shad Catch Cap Areas and Catch Cap Closure Areas; and

(38) Any other measure currently included in the FMP.

* * * * *

[FR Doc. 2014–28131 Filed 12–2–14; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 79, No. 233
Thursday, December 4, 2014

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

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Parts 318 and 319

[Docket No. APHIS–2010–0082]

RIN 0579–AD71

Establishing a Performance Standard for Authorizing the Importation and Interstate Movement of Fruits and Vegetables

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: We are reopening the comment period for our proposed rule that would amend our regulations governing the importation and interstate movement of fruits and vegetables by broadening our existing performance standard to provide for approval of all new fruits and vegetables for importation or interstate movement into or within the United States using a notice-based process. This action will allow interested persons additional time to prepare and submit comments.

DATES: The comment period for the proposed rule published on September 9, 2014 (79 FR 53346–53352) is reopened. We will consider all comments that we receive on or before January 9, 2015.

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

- Federal eRulemaking Portal: Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2010-0082.*
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS–2010–0082, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2010-0082* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Ms. Nicole L. Russo, Assistant Director, Regulatory Coordination and Compliance, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1231; (301) 851–2159.

SUPPLEMENTARY INFORMATION: On September 9, 2014, we published in the **Federal Register** (79 FR 53346–53352) a proposal to amend our regulations governing the importations of fruits and vegetables by broadening our existing performance standard to provide for approval of all new fruits and vegetables for importation into the United States using a notice-based process. We also proposed to remove the region- or commodity-specific phytosanitary requirements currently found in these regulations. Likewise, we proposed an equivalent revision of the performance standard in our regulations governing the interstate movement of fruits and vegetables from Hawaii and the U.S. territories (Guam, Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands) and the removal of commodity-specific phytosanitary requirements from those regulations. This proposal would allow for the approval of requests to authorize the importation or interstate movement of new fruits and vegetables in a manner that enables a more flexible and responsive regulatory approach to evolving pest situations in both the United States and exporting countries. It would not however, alter the science-based process in which the risk associated with importation or interstate movement of a given fruit or vegetable is evaluated or the manner in which risks associated with the importation or interstate movement of a fruit or vegetable are mitigated.

Comments on the proposed rule were required to be received on or before November 10, 2014. We are reopening the comment period on Docket No. APHIS–2010–0082 for an additional 60 days. We will also accept all comments received between November 11, 2014 (the day after the close of the original comment period) and the date of this notice. This action will allow interested persons additional time to prepare and submit comments.

Authority: 7 U.S.C. 450, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 1st day of December 2014.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2014–28488 Filed 12–3–14; 8:45 am]

BILLING CODE 3410–34–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Parts 1, 15, 17, 19, 32, 37, 38, 140, and 150

RIN 3038–AD99; 3038–AD82

Position Limits for Derivatives and Aggregation of Positions

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of proposed rulemaking; reopening of comment periods.

SUMMARY: On December 12, 2013, the Commodity Futures Trading Commission (''Commission'') published in the **Federal Register** a notice of proposed rulemaking (the ''Position Limits Proposal'') to establish speculative position limits for 28 exempt and agricultural commodity futures and options contracts and the physical commodity swaps that are economically equivalent to such contracts. On November 15, 2013, the Commission published in the **Federal Register** a notice of proposed rulemaking (the ''Aggregation Proposal'') to amend existing regulations setting out the Commission's policy for aggregation under its position limits regime. The Commission's Agricultural Advisory Committee has scheduled a public meeting to be held on December 9, 2014, which will consider, among other matters, deliverable supply and exemptions for bona fide hedging positions. To provide commenters with a sufficient period of time to respond to questions raised and points made at the Agricultural Advisory Committee meeting, the Commission is reopening the comment periods for an additional 45 days. Comments should be limited to the

following issues as they pertain to agricultural commodities: Hedges of a physical commodity by a commercial enterprise; and the process for estimating deliverable supplies used in the setting of spot month limits.

DATES: The comment periods for the Aggregation Proposal published November 15, 2013, at 78 FR 68946, and for the Position Limits Proposal published December 12, 2013, at 78 FR 75680, will reopen on December 9, 2014, and close on January 22, 2015.

ADDRESSES: You may submit comments, identified by RIN 3038–AD99 for the Position Limits Proposal or RIN 3038–AD82 for the Aggregation Proposal, by any of the following methods:

- *Agency Web site: http://comments.cftc.gov;*
- *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581;
- *Hand Delivery/Courier:* Same as Mail, above; or
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow instructions for submitting comments.

Please submit your comments using only one method. All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov.* You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that may be exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted under § 145.9 of the Commission's regulations (17 CFR 145.9).

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from *http://www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the rulemaking will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

FOR FURTHER INFORMATION CONTACT: Stephen Sherrod, Senior Economist, Division of Market Oversight, (202) 418–5452, *ssherrod@cftc.gov;* or Riva Spear Adriance, Senior Special Counsel, Division of Market Oversight, (202) 418–5494, *radriance@cftc.gov;* Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Background

The Commission has long established and enforced speculative position limits for futures and options contracts on various agricultural commodities as authorized by the Commodity Exchange Act (''CEA'').[1] The part 150 position limits regime [2] generally includes three components: (1) The level of the limits, which set a threshold that restricts the number of speculative positions that a person may hold in the spot-month, individual month, and all months combined,[3] (2) exemptions for positions that constitute bona fide hedging transactions and certain other types of transactions,[4] and (3) rules to determine which accounts and positions a person must aggregate for the purpose of determining compliance with the position limit levels.[5] The Position Limits Proposal generally sets out proposed changes to the first and second components of the position limits regime and would establish speculative position limits for 28 exempt and agricultural commodity futures and option contracts, and physical commodity swaps that are ''economically equivalent'' to such contracts (as such term is used in CEA section 4a(a)(5)).[6] The Aggregation Proposal generally sets out proposed changes to the third component of the position limits regime.[7]

The Commission published the Position Limits Proposal and the Aggregation Proposal separately because it believes that the proposed amendments regarding aggregation of positions could be appropriate regardless of whether the Position Limits Proposal is finalized.[8] If the Aggregation Proposal is finalized first, the modifications would apply to the current position limits regime for futures and option contracts on nine enumerated agricultural commodities. If the Position Limits Proposal is subsequently finalized, the modifications in the Aggregation Proposal would apply to the position limits regime for 28 exempt and agricultural commodity futures and options contracts and the physical commodity swaps that are economically equivalent to such contracts.

In order to provide interested parties with an opportunity to comment on the Aggregation Proposal during the comment period on the Position Limits Proposal, the Commission extended the comment period for the Aggregation Proposal to February 10, 2014, the same end date as the comment period for the Position Limits Proposal.[9]

Subsequent to publication of the Position Limits Proposal and the Aggregation Proposal, the Commission directed staff to schedule a June 19, 2014, public roundtable to consider certain issues regarding position limits for physical commodity derivatives. The roundtable focused on hedges of a physical commodity by a commercial enterprise, including gross hedging, cross-commodity hedging, anticipatory hedging, and the process for obtaining a non-enumerated exemption. Discussion included the setting of spot month limits in physical-delivery and cash-settled contracts and a conditional spot-month limit exemption. Further, the roundtable included discussion of: The aggregation exemption for certain ownership interests of greater than 50 percent in an owned entity; and aggregation based on substantially identical trading strategies. As well, the Commission invited comment on whether to provide parity for wheat contracts in non-spot month limits. In conjunction with the roundtable, staff questions regarding these topics were posted on the Commission's Web site.

To provide commenters with a sufficient period of time to respond to questions raised and points made at the roundtable, the Commission published a notice in the **Federal Register** on May 29, 2014, reopening the comment periods for the Position Limit Proposal and the Aggregation Proposal for three weeks, from June 12, 2014 to July 3, 2014. The Commission published notice in the **Federal Register** on July 3, 2014, further extending the comment periods to August 4, 2014.

Comment letters received on the Position Limits Proposal are available at *http://comments.cftc.gov/PublicComments/CommentList.aspx?id=1436.* Comment letters received on the Aggregation Proposal are available at *http://comments.cftc.gov/PublicComments/CommentList.aspx?id=1427.*

[1] 7 U.S.C. 1 *et seq.*

[2] *See* 17 CFR part 150. Part 150 of the Commission's regulations establishes federal position limits on futures and option contracts in nine enumerated agricultural commodities.

[3] *See* 17 CFR 150.2.

[4] *See* 17 CFR 150.3.

[5] *See* 17 CFR 150.4.

[6] *See* Position Limits for Derivatives, 78 FR 75680 (Dec. 12, 2013).

[7] *See* Aggregation of Positions, 78 FR 68946 (Nov. 15, 2013).

[8] *See* Aggregation Proposal, 78 FR at 68947.

[9] *See* 79 FR 2394 (Jan. 14, 2014).

II. Reopening of Comment Period

The Commission's Agricultural Advisory Committee has scheduled a meeting to be held on December 9, 2014, and adopted an agenda that includes consideration, among other matters, of two issues associated with the Position Limits rulemaking: Deliverable supply and exemptions for bona fide hedging positions. To provide interested persons with a sufficient period of time to respond to questions raised and points made at the Agricultural Advisory Committee meeting, the Commission is reopening both the Position Limit Proposal and the Aggregation Proposal for an additional 45-day comment period. Comments should be limited to the following issues as they pertain to agricultural commodities: Hedges of a physical commodity by a commercial enterprise; and the process for estimating deliverable supplies used in the setting of spot month limits, as each pertains to agricultural commodities.

Both comment periods will reopen on December 9, 2014, and close on January 22, 2015.

Issued in Washington, DC, on December 1, 2014, by the Commission.

Christopher J. Kirkpatrick,

Secretary of the Commission.

Note: The following appendices will not appear in the Code of Federal Regulations.

Appendices to Position Limits for Derivatives and Aggregation of Positions Reopening of Comment Periods—Commission Voting Summary and Commissioner's Statement

Appendix 1—Commission Voting Summary

On this matter, Chairman Massad and Commissioners Wetjen, Bowen, and Giancarlo voted in the affirmative. No Commissioner voted in the negative.

Appendix 2—Statement of Commissioner Sharon Y. Bowen

I support this reopening of the comment period for our position limits rule. As I've previously said, this is a key rule and we are well-served by giving stakeholders another chance to comment.

However, we cannot allow this rule to linger indefinitely on our docket. It has been over a year since we re-proposed this rule and nearly four years since it was first proposed. We need to finish this rule next year, and I believe we can release a final rule by spring 2015.

As we continue to finalize and fine-tune our Dodd-Frank rulemakings, we have to avoid the temptation to simply ratchet back or weaken prior versions of those rules. In fact, I think the best way of viewing changes to our rules is not that we are tweaking them, but rather that we are enhancing them. Sometimes that may mean making the rules more cost-effective and leaner, but at other times that will mean making them stronger than before. Enhancing a rule can mean reducing burdens to business while strengthening protections for the public. I believe our position limits proposal is exactly the sort of rule that needs to be enhanced, and I look forward to working with my fellow Commissioners to finish and release this rule in a timely fashion.

[FR Doc. 2014–28482 Filed 12–3–14; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1, 4, 9, 22, and 52

[FAR Case: 2013–020; Docket No. 2013–0020; Sequence No. 1]

RIN 9000–AM74

Federal Acquisition Regulation: Information on Corporate Contractor Performance and Integrity

AGENCIES: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule.

SUMMARY: DoD, GSA, and NASA are proposing to amend the Federal Acquisition Regulation (FAR) to implement a section of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2013 to include in the Federal Awardee Performance and Integrity Information System (FAPIIS), to the extent practicable, identification of any immediate owner or subsidiary, and all predecessors of an offeror that held a Federal contract or grant within the last three years. The objective is to provide a more comprehensive understanding of the performance and integrity of the corporation before awarding a Federal contract.

DATES: Interested parties should submit written comments to the Regulatory Secretariat at one of the addresses shown below on or before February 2, 2015 to be considered in the formation of the final rule.

ADDRESSES: Submit comments in response to FAR Case 2013–020 by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching for ''FAR Case 2013–020''. Select the link ''Comment Now'' that corresponds with ''FAR Case 2013–020.'' Follow the instructions provided at the ''Comment Now'' screen. Please include your name, company name (if any), and ''FAR Case 2013–020'' on your attached document.
- *Fax:* 202–501–4067.
- *Mail:* General Services Administration, Regulatory Secretariat (MVCB), ATTN: Ms. Hada Flowers, 1800 F Street NW., 2nd floor, Washington, DC 20405.

Instructions: Please submit comments only and cite ''FAR Case 2013–020'' in all correspondence related to this case. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Ms. Cecelia L. Davis, Procurement Analyst, at 202–219–0202 for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755. Please cite FAR Case 2013–020.

SUPPLEMENTARY INFORMATION:

I. Background

DoD, GSA, and NASA are proposing to revise the FAR to implement section 852 of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112–239) with regard to Federal contracts. Section 852 requires that the FAPIIS include, to the extent practicable, information on any parent, subsidiary, or successor entities to a corporation in a manner designed to give the acquisition officials using the database a comprehensive understanding of the performance and integrity of the corporation in carrying out Federal contracts and grants. This proposed rule addresses the collection of information with regard to offerors that are responding to a solicitation for a Federal contract. The data on immediate owner and direct subsidiaries of an entity will be available through FAPIIS, based on the data obtained from offerors in response to the FAR provision 52.204–17, Ownership or Control of Offeror, which was published in the **Federal Register** at 79 FR 31187, on May 30, 2014, as a final rule under FAR Case 2012–024.

II. Discussion and Analysis

A. Information Required

1. Owner/Subsidiary (Proposed FAR 9.104–6(a)(2)(i))

After reviewing section 852, the Defense Acquisition Regulation Council and the Civilian Agency Acquisition

Council (the Councils) determined that the further the distance between the entities, the less relevant the information is likely to be for establishing responsibility of the offeror. Furthermore, the cost and complexity maintaining a system that monitors the interrelationships of companies and their changes in ownership, and direct and indirect subsidiaries that could occur may be resource intensive for both the Government and the contractor and outweigh the benefits. Therefore, the Councils have determined that it is not practicable to establish interrelationships beyond the immediate owner and the direct subsidiary. The data on the immediate owner of an entity will be available through FAPIIS, based on the data obtained from offerors in response to the FAR provision 52.204–17, Ownership or Control of Offeror, which was published in the **Federal Register** at 79 FR 31187, on May 30, 2014, as a final rule under FAR Case 2012–024, effective November 1, 2014. This proposed rule 2013–020 will not be finalized until after the final rule under FAR Case 2012–024 becomes effective. For discussion of subsidiaries, see the information below in paragraph B.

2. Predecessor/Successor (Proposed FAR 9.1046(a)(2)(ii))

Although the law requested information on successor entities, the Councils concluded that any entity making an offer would have to be the successor, because by definition the predecessor no longer exists, having been replaced by the successor. Therefore, the proposed provision requests offerors to provide information about all predecessors of the offeror that received a Federal contract or grant within the last three years. The information on predecessors of the offeror provided from the proposed provision at FAR 52.204–WW will be shown with the entity's record in the System for Award Management (SAM) and in FAPIIS.

With regard to identification of predecessors, the Councils have limited the identification of predecessor entities to within the last three years. This timeframe is consistent with the period required by FAR 42.1503(g) for consideration of most past performance information, and the timeframe generally used when reviewing prospective contractor's integrity and past performance information within the last three years to make a responsibility determination.

B. Source of Information on Ownership and Predecessor of Offeror

By obtaining the information on ownership directly from each offeror, the Government can define exactly what information it is seeking. Furthermore, there is already a final FAR rule (FAR case 2012–024, Commercial and Government Entity Code (CAGE), published in the **Federal Register** at 79 FR 3118, on May 30, 2014; effective November 1, 2014) that provides information on owners of each offeror. It is not necessary to request information on subsidiaries from the offeror, because if the subsidiary is in the SAM database, the subsidiary will provide the information on its immediate owner, which would then be shared with FAPIIS. If the subsidiary has not received any Government awards, the subsidiary will have no information available in FAPIIS, making it unnecessary for the owner to identify such a relationship. The following example demonstrates how FAPIIS will link owners with subsidiaries:

If companies B, C, and D have reported that—
B is owned by A;
C is owned by A; and
D is owned by C,
Then FAPIIS will identify—
Subsidiaries B and C for offeror A;
Owner A for offeror B;
Owner A and subsidiary D for offeror C; and
Immediate owner C (not higher-level owner A) for offeror D.

The Councils propose a new provision 52.204–WW, entitled ''Predecessor of Offeror'' to gather information on all predecessors of the offeror that held a Federal contract or grant within the last three years.

C. Definitions (Proposed FAR 52.204–WW and FAR 52.204–17(a))

1. ''Owner.'' The proposed definition of the term ''owner'' is consistent with the definition in the provision 52.204–17, Ownership or Control of Offeror (see final rule for FAR Case 2012–024, Commercial and Government Entity Code, published in the **Federal Register** at 79 FR 31187, on May 30, 2014 and effective November 1, 2014).

2. ''Subsidiary.'' The term ''subsidiary'' is used throughout the FAR without definition, except as used with regard to inverted domestic corporations (FAR 9.108–1). The Councils have not defined ''subsidiary'' in this case, because it is necessary for the term ''subsidiary'' to be the exact reverse of the term ''immediate owner.'' Any offeror that identifies an entity as its immediate owner is the subsidiary of that other entity. These relationships will be identified in FAPIIS, based on the identified immediate owners. Therefore, it is unnecessary to define ''subsidiary.''

3. ''Predecessor'' and ''successor.'' The Councils have proposed definitions of ''predecessor'' and ''successor'' to be included in paragraph (a) of the proposed provision 52.204–WW, Predecessor of Offeror. The term ''successor'' does not include new offices/divisions of the same company. An entity that has only changed its name will not be considered to be a successor. Identification of changes in name is not necessary for purposes of this case, because as long as the CAGE Code is still the same, FAPIIS will provide the prior information relating to the entity. A ''predecessor'' means an entity that is replaced by a successor and includes any predecessors of the predecessor. A ''successor'' means an entity that has replaced a predecessor by acquiring the assets and carrying out the affairs of the predecessor under a new name (often through acquisition or merger). The term ''successor'' does not include new offices/divisions of the same company or a company that only changes its name. The extent of the responsibility of the successor for the liabilities of the predecessor may vary, depending on State law and specific circumstances.

D. Use of Information on Other Entities

FAR 9.104–3(c) already sets forth the FAR policy on consideration of the integrity and past performance of affiliates, which as defined in the FAR includes owners and subsidiaries, when they may adversely affect the prospective contractor's responsibility. The Councils have not proposed any change to this policy because it is adequate to protect the interests of the Government.

E. Availability to the Public

The statute specifically requires the additional information on corporate structure to be available ''in a manner designed to give the acquisition officials using the database a comprehensive understanding of the performance and integrity of the corporation in carrying out Federal contracts and grants.'' However, section 3010 of the Supplemental Appropriations Act, 2010 (Pub. L. 111–212) added the requirement that all the information in FAPIIS, except for past performance information, shall be posted on a publicly available Internet Web site. Therefore, any information in FAPIIS with regard to immediate owner, subsidiaries, and predecessors, will be available to the public.

F. Applicability

This rule applies to commercial items, including commercially available off-the-shelf items, as well as acquisitions below the simplified acquisition threshold.

The information on predecessors is needed for all offerors for which a CAGE code is required. The information will be stored in the SAM database.

Determinations and findings were signed in February 2010 under FAR Case 2008–027, that section 872 of the NDAA for FY 2009, which established the FAPIIS database, applies to the acquisition of commercial items, including commercially available off-the-shelf (COTS) items. That determination stated that an exemption for commercial item acquisitions (including COTS items) would exclude a significant portion of Federal contractors, thereby undermining an overarching public policy to achieve greater integrity and performance quality in contracting. We should apply extensions of information to be used in FAPIIS to acquisitions of commercial items, including COTS items, for the same reasons we stated with regard to the original statute that established FAPIIS.

The representation will also apply to solicitations that do not exceed the simplified acquisition threshold.

Determinations and findings will be approved by the appropriate authorities prior to publication of the final rule.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under Section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

DoD, GSA, and NASA do not expect this rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because the burden is minimal to provide the CAGE Code and the name of all predecessors that held a Federal contract or grant within the last three years. However, an Initial Regulatory Flexibility Analysis (IRFA) has been performed and is summarized as follows:

The objective of this rule is to provide acquisition officials using FAPIIS a comprehensive understanding of the performance and integrity of the corporation in carrying out Federal contracts. The legal basis for the rule is section 852 of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112–239).

The proposed provision in this rule would require each offeror to represent whether the offeror is or is not, within the last three years, a successor to a predecessor that held a Federal contract or grant within the last three years. If the offeror has indicated that it is such a successor, then the offeror must provide the CAGE code and legal name of all predecessors that held a Federal contract or grant within the last three years. The data on immediate owner and direct subsidiaries of an entity will be available through FAPIIS, based on the data obtained from offerors in response to the FAR provision 52.204–17, Ownership or Control of Offeror, that requires this information for the CAGE code. The Federal Government received offers from approximately 413,800 unique vendors in FY 2011. Approximately 275,900 of these offers were by unique small businesses, which will be required to respond to the proposed provision.

The proposed rule requires approximately one submission per year, with an estimated average of .1 preparation hours per response. The response time will be less for most respondents, only required to check a box. Only those respondents that check ''is'' will have to provide a minimal amount of information (CAGE Code and legal name of all predecessors that held a Federal contract or grant within the last three years). A mid-level professional skill would be required in some instances to know whether the entity is a successor, as defined in the proposed rule.

The rule does not duplicate, overlap, or conflict with any other Federal rules.

There are no exemptions from the rule for small entities, because the law does not provide for any such exemption. However, the proposed rule limits the review of predecessor entities to three years.

The Regulatory Secretariat has submitted a copy of the IRFA to the Chief Counsel for Advocacy of the Small Business Administration. A copy of the IRFA may be obtained from the Regulatory Secretariat. DoD, GSA and NASA invite comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD, GSA, and NASA will also consider comments from small entities concerning the existing regulations in subparts affected by the rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (FAR Case 2013–020), in correspondence.

V. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) applies. The proposed rule contains information collection requirements. Accordingly, the Regulatory Secretariat has submitted a request for approval of a new information collection requirement concerning Identification of Predecessor Entities to the Office of Management and Budget.

A. Public reporting burden for this collection of information is estimated to average .1 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The annual reporting burden estimated as follows:

Respondents: 413,800.

Responses per respondent: 1.

Total annual responses: 413,800.

Preparation hours per response: .1.

Total response Burden Hours: 41,380.

B. Request for Comments Regarding Paperwork Burden.

Submit comments, including suggestions for reducing this burden, not later than February 2, 2015 to: FAR Desk Officer, OMB, Room 10102, NEOB, Washington, DC 20503, and a copy to the General Services Administration, Regulatory Secretariat Division (MVCB), ATTN: Ms. Hada Flowers, 1800 F Street NW., 2nd floor, Washington, DC 20405.

Public comments are particularly invited on: whether this collection of information is necessary for the proper performance of functions of the FAR, and will have practical utility; Whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Requesters may obtain a copy of the supporting statement from the General Services Administration, Regulatory Secretariat Division (MVCB), ATTN: Ms. Hada Flowers, 1800 F Street NW., 2nd floor, Washington, DC 20405. Please cite ''OMB Control Number 9000–00XX; Identification of Predecessors,'' in all correspondence.

List of Subjects in 48 CFR Parts 1, 4, 9, 22, and 52

Government procurement.

Dated: November 25, 2014.

William Clark,

Acting Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

Therefore, the DoD, GSA, and NASA propose amending 48 CFR parts 1, 4, 9, 22, and 52 as set forth below:

■ 1. The authority citation for 48 CFR parts 1, 4, 9, 22, and 52 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 51 U.S.C. 20113.

PART 1—FEDERAL ACQUISITION REGULATIONS SYSTEM

1.106 [Amended]

■ 2. Amend section 1.106, in the table following the introductory text, by adding in numerical sequence, FAR segment ''52.204–WW'' and its corresponding OMB Control No. ''9000–00XX''.

PART 4—ADMINISTRATIVE MATTERS

■ 3. Amend section 4.1202 by redesignating paragraphs (a)(6) through (29) as paragraphs (a)(7) through (30), respectively; and adding a new paragraph (6) to read as follows;

4.1202 Solicitation provision and contract clause.

(a) * * *

(6) 52.204–WW, Predecessor of Offeror.

* * * * *

■ 4. Amend section 4.1804 by adding paragraph (d) to read as follows:

4.1804 Solicitation provisions and contract clause.

* * * * *

(d) Insert the provision at 52.204–WW, Predecessor of Offeror, in all solicitations that include the provision at 52.204–16, Commercial and Government Entity Code Reporting.

PART 9—CONTRACTOR QUALIFICATIONS

■ 5. Amend section 9.104–6 by revising paragraphs (a) and (b) to read as follows:

9.104–6 Federal Awardee Performance and Integrity Information System.

(a)(1) Before awarding a contract in excess of the simplified acquisition threshold, the contracting officer shall review the integrity and performance information available in the Federal Awardee Performance and Integrity Information System (FAPIIS), available at *www.ppirs.gov,* then select FAPIIS, including FAPIIS information from the System for Award Management Exclusions and the Past Performance Information Retrieval System (PPIRS).

(2) In accordance with 41 U.S.C. 2313(d)(3), FAPIIS also identifies—

(i) An affiliate that is an immediate owner or subsidiary of the offeror, if any (see 52.204–17, Ownership or Control of Offeror); and

(ii) All predecessors of the offeror that held a Federal contract or grant within the last three years (see 52.204–WW, Predecessor of Offeror).

(b) When making a responsibility determination, the contracting officer shall consider all the information available through FAPIIS with regard to the offeror and any immediate owner, predecessor, or subsidiary identified for that offeror in FAPIIS, as well as other past performance information on the offeror (see subpart 42.15).

(1) For evaluation of information available through FAPIIS relating to an affiliate of the offeror, see 9.104–3(c).

(2) For source selection evaluations of past performance, see 15.305(a)(2). Contracting officers shall use sound judgment in determining the weight and relevance of the information contained in FAPIIS and how it relates to the present acquisition. Since FAPIIS may contain information on any of the offeror's previous contracts and information covering a five-year period, some of that information may not be relevant to a determination of present responsibility, *e.g.,* a prior administrative action such as debarment or suspension that has expired or otherwise been resolved, or information relating to contracts for completely different products or services.

* * * * *

■ 6. Amend section 9.105–1 by revising introductory paragraph (c) to read as follows:

9.105–1 Obtaining information.

* * * * *

(c) In making the determination of responsibility, the contracting officer shall consider information available through FAPIIS (see 9.104–6) with regard to the offeror and any immediate owner, predecessor, or subsidiary identified for that offeror in FAPIIS, including information that is linked to FAPIIS such as from the System for Award Management Exclusions, and the Past Performance Information Retrieval System (PPIRS), as well as any other relevant past performance information on the offeror (see 9.104–1(c) and subpart 42.15). In addition, the contracting officer should use the following sources of information to support such determinations:

* * * * *

PART 22—APPLICATION OF LABOR LAWS TO GOVERNMENT ACQUISITIONS

22.1006 [Amended]

■ 7. Amend section 22.1006 by removing from paragraph (a)(2)(i)(C) the words ''52.204–8(c)(2)(iii) or (iv)'' and adding ''52.204–8(c)(2)'' in its place; and removing from paragraph (e)(4)(i) the words ''52.204–8(c)(2)(iv)'' and adding ''52.204–8(c)(2)'' in its place.

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 8. Amend section 52.204–8 by—

■ a. Revising the date of the clause;

■ b. Redesignating paragraphs (c)(2)(ii) thru (vii) as paragraphs (c)(2)(iii) thru (viii), respectively; and

■ c. Adding new paragraph (c)(2)(ii).

The revised and added text reads as follows:

52.204–8 Annual Representations and Certifications.

* * * * *

Annual Representations and Certifications (Date)

* * * * *

(c) * * *

(2) * * *

____ (ii) 52.204–WW, Predecessor of Offeror.

* * * * *

■ 9. Add section 52.204–WW, to read as follows:

52.204–WW Predecessor of Offeror.

As prescribed in 4.1804(d), insert the following provision:

Predecessor of Offeror (Date)

(a) *Definitions.* As used in this provision—

Commercial and Government Entity (CAGE) code means—

(1) An identifier assigned to entities located in the United States and its outlying areas by the Defense Logistics Agency (DLA) Logistics Information Service to identify a commercial or government entity, or

(2) An identifier assigned by a member of the North Atlantic Treaty Organization (NATO) or by NATO's Maintenance and Supply Agency (NAMSA) to entities located outside the United States and its outlying areas that DLA Logistics Information Service records and maintains in the CAGE master file. This type of code is known as an NCAGE code.

Predecessor means an entity that is replaced by a successor and includes any predecessors of the predecessor.

Successor means an entity that has replaced a predecessor by acquiring the assets and carrying out the affairs of the

predecessor under a new name (often through acquisition or merger). The term ''successor'' does not include new offices/divisions of the same company or a company that only changes its name. The extent of the responsibility of the successor for the liabilities of the predecessor may vary, depending on State law and specific circumstances.

(b) The offeror represents that it ❑ is or ❑ is not a successor to a predecessor that held a Federal contract or grant within the last three years.

(c) If the offeror has indicated ''is'' in paragraph (b) of this provision, enter the following information for all predecessors of the offeror that held a Federal contract or grant within the last three years (If more than one predecessor list in reverse chronological order):

Predecessor CAGE code: _____ (or mark ''Unknown'').

Predecessor legal name: _____.

(Do not use a ''doing business as'' name.)

(End of provision)

* * * * *

■ 10. Amend section 52.212–3 by—

■ a. Revising the date of the clause;

■ b. Removing from the introductory paragraph the words ''paragraphs (c) through (p)'' and adding ''paragraphs (c) through (q)'' in its place;

■ c. Adding to paragraph (a), in alphabetical order, the definitions ''predecessor'' and ''successor'';

■ d. Removing from paragraph (b)(2) the words ''paragraphs at (c) through (p)'' and adding ''paragraphs at (c) through (q)'' in its place; and

■ e. Adding paragraph (q).

The revised text reads as follows:

52.212–3 Offeror Representations and Certifications—Commercial Items.

* * * * *

Offeror Representations and Certifications—Commercial Items (Date)

* * * * *

(a) * * *

Predecessor means an entity that is replaced by a successor and includes any predecessors of the predecessor.

* * * * *

Successor means an entity that has replaced a predecessor by acquiring the assets and carrying out the affairs of the predecessor under a new name (often through acquisition or merger). The term ''successor'' does not include new offices/divisions of the same company or a company that only changes its name. The extent of the responsibility of the successor for the liabilities of the predecessor may vary, depending on State law and specific circumstances.

* * * * *

(q) Predecessor of Offeror. (Applies in all solicitations that include the provision at 52.204–16, Commercial and Government Entity Code Reporting.)

(1) The offeror represents that it ❑ is or ❑ is not a successor to a predecessor that held a Federal contract or grant within the last three years.

(2) If the offeror has indicated ''is'' in paragraph (q)(1) of this provision, enter the following information for all predecessors that held a Federal contract or grant within the last three years (If more than one predecessor, list in reverse chronological order):

Predecessor CAGE code: _____ (or mark ''Unknown'').

Predecessor legal name: _____.

(Do not use a ''doing business as'' name)

* * * * *

[FR Doc. 2014–28484 Filed 12–3–14; 8:45 am]

BILLING CODE 6820–EP–P

Notices

Federal Register
Vol. 79, No. 233
Thursday, December 4, 2014

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

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–900]

Diamond Sawblades and Parts Thereof From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review; 2012–2013

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on diamond sawblades and parts thereof (diamond sawblades) from the People's Republic of China (the PRC). The period of review (POR) is November 1, 2012, through October 31, 2013. The Department has preliminarily determined that certain companies covered by this review made sales of subject merchandise at less than normal value. Interested parties are invited to comment on these preliminary results.

DATES: *Effective Date:* December 4, 2014.

FOR FURTHER INFORMATION CONTACT: Yang Jin Chun or Michael Romani, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–5760 and (202) 482–0198, respectively.

Scope of the Order

The merchandise subject to the order is diamond sawblades and parts thereof. The diamond sawblades subject to the order are currently classifiable under subheadings 8202 to 8206 of the Harmonized Tariff Schedule of the United States (HTSUS), and may also enter under 6804.21.00. While the HTSUS subheadings are provided for convenience and customs purposes, the written description is dispositive. A full description of the scope of the order is contained in the Preliminary Decision Memorandum.[1]

Rescission of Review in Part

We are rescinding the review in part with respect to Husqvarna (Hebei) Co., Ltd., and Hebei Husqvarna-Jikai Diamond Tools Co., Ltd.[2]

Preliminary Determination of No Shipments

Qingdao Shinhan Diamond Industrial Co., Ltd., which received a separate rate in previous segments of the proceeding and is subject to this review, reported that it did not have any exports of subject merchandise during the POR.[3] U.S. Customs and Border Protection (CBP) data for the POR corroborated this company's no-shipment claim.[4] Additionally, we requested that CBP report any contrary information.[5] To date, CBP has not responded to our inquiry with any contrary information and we have not received any evidence that this company had any shipments of the subject merchandise sold to the United States during the POR.[6] Consistent with the Department's refinement to its assessment practice in non-market economy (NME) cases regarding no shipment claims, we are completing the review with respect to this company and will issue appropriate instructions to CBP based on the final results of the review.[7]

Methodology

The Department has conducted this review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (the Act). Export price and constructed export price have been calculated in accordance with section 772 of the Act. Because the PRC is a NME within the meaning of section 771(18) of the Act, normal value has been calculated in accordance with section 773(c) of the Act.

For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. The Preliminary Decision Memorandum is a public document and is on file electronically *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and to all parties in the Central Records Unit, room 7046 of the main Department of Commerce building.[8] In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly on the Internet at *http://enforcement.trade.gov/frn/index.html.*

Preliminary Results of Review

The Department preliminarily determines that the following weighted-average dumping margins exist:

Exporter	Margin (percent)
Bosun Tools Co., Ltd	11.21
Chengdu Huifeng Diamond Tools Co., Ltd	7.87
Danyang City Ou Di Ma Tools Co., Ltd	7.87
Danyang NYCL Tools Manufacturing Co., Ltd	7.87
Danyang Tsunda Diamond Tools Co., Ltd	7.87
Danyang Weiwang Tools Manufacturing Co., Ltd	7.87
Guilin Tebon Superhard Material Co., Ltd	7.87
Hangzhou Deer King Industrial and Trading Co., Ltd	7.87
Hangzhou Kingburg Import & Export Co., Ltd	7.87

[1] *See* the Memorandum from Deputy Assistant Secretary Christian Marsh to Acting Assistant Secretary Ronald K. Lorentzen entitled ''Decision Memorandum for Preliminary Results of 2012–2013 Antidumping Duty Administrative Review: Diamond Sawblades and Parts Thereof from the People's Republic of China'' dated concurrently with and hereby adopted by this notice (Preliminary Decision Memorandum).

[2] *See* Preliminary Decision Memorandum at 4–5 for more details on this rescission in part.

[3] *See* Qingdao Shinhan Diamond Industrial Co., Ltd.'s no shipment letter dated Febuary 28, 2014.

[4] *See* the CBP data attached to the letter to all interested parties dated January 24, 2014.

[5] *See* CBP message number 4261305 dated September 18, 2014.

[6] CBP only responds to the Department's inquiry when there are records of shipments from the company in question. *See, e.g., Certain Hot-Rolled Flat-Rolled Carbon Quality Steel Flat Products From Brazil: Notice of Rescission of Antidumping Duty Administrative Review,* 75 FR 65453, 65454 (October 25, 2010).

[7] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011), and the ''Assessment Rates'' section below.

[8] ACCESS is the new acronym for Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (IA ACCESS). We changed the Web site location from *http://iaaccess.trade.gov* to *http://access.trade.gov. See* 19 CFR 351.303, as amended in *Enforcement and Compliance; Change of Electronic Filing System Name,* 79 FR 69046 (November 20, 2014).

Exporter	Margin (percent)
Huzhou Gu's Import & Export Co., Ltd[9]	7.87
Jiangsu Fengtai Diamond Tool Manufacture Co., Ltd	7.87
Jiangsu Inter-China Group Corporation	7.87
Jiangsu Youhe Tool Manufacturer Co., Ltd	7.87
Pujiang Talent Diamond Tools Co., Ltd	7.87
Qingdao Hyosung Diamond Tools Co., Ltd	7.87
Qingyuan Shangtai Diamond Tools Co., Ltd	7.87
Quanzhou Zhongzhi Diamond Tool Co. Ltd	7.87
Rizhao Hein Saw Co., Ltd	7.87
Saint-Gobain Abrasives (Shanghai) Co., Ltd	7.87
Shanghai Jingquan Ind. Trade Co., Ltd	7.87
Weihai Xiangguang Mechanical Industrial Co., Ltd	3.79
Xiamen ZL Diamond Technology Co., Ltd[10]	7.87
Zhejiang Wanli Tools Group Co., Ltd	7.87
PRC-Wide Entity[11]	164.09

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). Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs no later than 30 days after the date of publication of these preliminary results of review.[12] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[13] Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than five days after the cases briefs are filed.

Interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety by the Department's ACCESS by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice.[14] Hearing requests should contain (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. The Department intends to issue the final results of this review, including the results of its analysis of issues raised by parties in their comments, within 120 days after the publication of these preliminary results, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(2).

Assessment Rates

Upon issuing the final results of review, the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review.[15] If a respondent's weighted-average dumping margin is above *de minimis* (*i.e.,* 0.5 percent) in the final results of this review, we will calculate an importer-specific assessment rate on the basis of the ratio of the total amount of dumping calculated for the importer's examined sales and the total entered value of those sales in accordance with 19 CFR 351.212(b)(1). Specifically, the Department will apply the assessment rate calculation method adopted in *Final Modification for Reviews.*[16] Where an importer- (or customer-) specific *ad valorem* rate is zero or *de minimis,* we will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[17]

For Husqvarna (Hebei) Co., Ltd., for which the review is rescinded, the antidumping duty shall be assessed at the rate equal to the cash deposit of the estimated antidumping duty required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(2). We will instruct CBP accordingly.

Pursuant to a refinement to the Department's assessment practice in NME cases,[18] for entries that were not reported in the U.S. sales databases submitted by companies individually examined during this review, the Department will instruct CBP to liquidate such entries at the PRC-wide rate. In addition, if the Department determines that an exporter under review had no shipments of the subject merchandise, any suspended entries that entered under that exporter's case number (*i.e.,* at that exporter's rate) will be liquidated at the PRC-wide rate.[19] The Department intends to issue appropriate assessment instructions directly to CBP 15 days after publication of the final results of review.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for shipments of the subject merchandise from the PRC 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) For subject merchandise exported by the companies listed above that have separate rates, the

[9] Huzhou Gu's Import & Export Co., Ltd., uses the name Huzhou Gu's Imp. & Exp. Co., Ltd., interchangeably. *See Diamond Sawblades and Parts Thereof From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review; 2011–2012,* 78 FR 77098, 77100 n.14 (December 20, 2013) (*3rd Review Prelim*), unchanged in *Diamond Sawblades and Parts Thereof From the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2011–2012,* 79 FR 35723 (June 24, 2014) (*3rd Review Final*).

[10] Xiamen ZL Diamond Technology Co., Ltd., stated in its separate rate application that its name before the POR was Xiamen ZL Diamond Tools Co., Ltd., for which we initiated this review in *Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part,* 78 FR 79392, 79395 (December 30, 2013). *See* Xiamen ZL Diamond Technology Co., Ltd.'s February 26, 2014, separate rate application at 2.

[11] The PRC-wide entity includes the following companies: ATM Single Entity, Central Iron and Steel Research Institute Group, China Iron and Steel Research Institute Group, Danyang Aurui Hardware Products Co., Ltd., Danyang Dida Diamond Tools Manufacturing Co., Ltd., Danyang Huachang Diamond Tools Manufacturing Co., Ltd., Electrolux Construction Products (Xiamen) Co. Ltd., Fujian Quanzhou Wanlong Stone Co., Ltd., Hebei Jikai Industrial Group Co., Ltd., Huachang Diamond Tools Manufacturing Co., Ltd., Hua Da Superabrasive Tools Technology Co., Ltd., Jiangsu Fengyu Tools Co., Ltd., Jiangyin Likn Industry Co., Ltd., Protech Diamond Tools, Quanzhou Shuangyang Diamond Tools Co., Ltd., Quanzhou Zongzhi Diamond Tool Co. Ltd., Shanghai Deda Industry & Trading Co., Ltd., Shanghai Robtol Tool Manufacturing Co., Ltd., Shanghai Starcraft Tools Company Limited, Shijiazhuang Global New Century Tools Co., Ltd., Sichuan Huili Tools Co., Task Tools & Abrasives, Wanli Tools Group, Wuhan Wanbang Laser Diamond Tools Co., Wuxi Lianhua Superhard Material Tools Co., Ltd., Zhejiang Tea Import & Export Co., Ltd., Zhejiang Wanda Import and Export Co., Zhejiang Wanda Tools Group Corp., and Zhejiang Wanli Super-hard Materials Co., Ltd. ATM Single Entity includes Advanced Technology & Materials Co., Ltd., Beijing Gang Yan Diamond Products Co., Yichang HXF Circular Saw Industrial Co., Ltd. (currently HXF Saw Co., Ltd.) (HXF), Cliff (Tianjin) International Ltd (Cliff), and AT&M International Trading Co., Ltd. Cliff also used the company name Cliff International Ltd. *See 3rd Review Prelim,* 78 FR at 77099, n.4, and the accompanying Preliminary Decision Memorandum at 5, n.24, unchanged in *3rd Review Final* for HXF's name change and Cliff's use of another company name.

[12] *See* 19 CFR 351.309(c).

[13] *See* 19 CFR 351.309(c)(2).

[14] *See* 19 CFR 351.310(c).

[15] *See* 19 CFR 351.212(b)(1).

[16] *See Antidumping Proceeding: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification,* 77 FR 8103 (February 14, 2012) (*Final Modification for Reviews*).

[17] *See* 19 CFR 351.106(c)(2).

[18] For a full discussion of this practice, *see Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

[19] *Id.*

cash deposit rate will be that established in the final results of review (except, if the rate is zero or *de minimis,* then zero cash deposit will be required); (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate; (3) for all PRC exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be that for the PRC-wide entity; and (4) for all non-PRC exporters of subject merchandise which 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 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 Department's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213.

Dated: November 26, 2014.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

A. Summary
B. Background
C. Scope of the Order
D. Request To Modify the Physical Characteristics
E. Rescission of Review in Part
F. Preliminary Determination of No Shipments
G. Discussion of the Methodology
  1. Non-Market Economy Country Status
  2. Separate Rates
  3. Surrogate Country
H. Fair Value Comparisons
  1. Determination of Comparison Method
  2. Results of the Differential Pricing Analysis
  3. U.S. Price
  4. Normal Value
  5. Factor Valuations
I. Currency Conversion
J. Recommendation

[FR Doc. 2014–28531 Filed 12–3–14; 8:45 am]

BILLING CODE 3510–DS–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: Economic Value of Puerto Rico's Coral Reef Ecosystems for Recreation/Tourism Uses.

OMB Control Number: 0648–xxxx.

Form Number(s): None.

Type of Request: Regular (request for a new information collection).

Number of Respondents: 4,600.

Average Hours per Response: Resident interviews, 1 hour; visitor screening surveys, 5 minutes; visitor interviews, 35 minutes, expenditure mail-back surveys for residents and visitors, 20 minutes.

Burden Hours: 2,550.

Needs and Uses: This request is for a new information collection.

NOAA and the U.S. Environmental Protection Agency (EPA) have entered a partnership to estimate the market and non-market economic values of Puerto Rico's coral reef ecosystems. Estimates will be made for all ecosystem services for the Guanica Bay Watershed and for recreation-tourism for all of Puerto Rico's coral reef ecosystems.

We will conduct surveys of visitors to Puerto Rico and residents of Puerto Rico who use the coral reef ecosystems to estimate the amount and type of use, their spending while undertaking coral reef use activities, the economic value of reef attributes (*e.g.* water clarity/visibility, coral abundance and diversity, fish and invertebrate abundance and diversity, and opportunity to see large wildlife) and how economic value changes with changes in reef attributes.

Affected Public: Individuals or households.

Frequency: One time.

Respondent's Obligation: Voluntary.

This information collection request may be viewed at reginfo.gov. Follow the instructions to view Department of Commerce collections currently under review by OMB.

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* or fax to (202) 395–5806.

Dated: November 28, 2014.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2014–28469 Filed 12–3–14; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD605

Schedules for Atlantic Shark Identification Workshops and Protected Species Safe Handling, Release, and Identification Workshops

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public workshops.

SUMMARY: Free Atlantic Shark Identification Workshops and Protected Species Safe Handling, Release, and Identification Workshops will be held in January, February, and March of 2015. Certain fishermen and shark dealers are required to attend a workshop to meet regulatory requirements and to maintain valid permits. Specifically, the Atlantic Shark Identification Workshop is mandatory for all federally permitted Atlantic shark dealers. The Protected Species Safe Handling, Release, and Identification Workshop is mandatory for vessel owners and operators who use bottom longline, pelagic longline, or gillnet gear, and who have also been issued shark or swordfish limited access permits. Additional free workshops will be conducted during 2015 and will be announced in a future notice.

DATES: The Atlantic Shark Identification Workshops will be held on January 22, February 26, and March 19, 2015.

The Protected Species Safe Handling, Release, and Identification Workshops will be held on January 14, January 21, February 12, February 19, March 10, and March 12, 2015.

See **SUPPLEMENTARY INFORMATION** for further details.

ADDRESSES: The Atlantic Shark Identification Workshops will be held in Kenner, LA; Norfolk, VA; and Fort Pierce, FL.

The Protected Species Safe Handling, Release, and Identification Workshops will be held in Panama City, FL; Portsmouth, NH; Manahawkin, NJ;

Wilmington, NC; Largo, FL; and Houston, TX.

See **SUPPLEMENTARY INFORMATION** for further details on workshop locations.

FOR FURTHER INFORMATION CONTACT: Rick Pearson by phone: (727) 824–5399, or by fax: (727) 824–5398.

SUPPLEMENTARY INFORMATION: The workshop schedules, registration information, and a list of frequently asked questions regarding these workshops are posted on the Internet at: *http://www.nmfs.noaa.gov/sfa/hms/workshops/*.

Atlantic Shark Identification Workshops

Since January 1, 2008, Atlantic shark dealers have been prohibited from receiving, purchasing, trading, or bartering for Atlantic sharks unless a valid Atlantic Shark Identification Workshop certificate is on the premises of each business listed under the shark dealer permit that first receives Atlantic sharks (71 FR 58057; October 2, 2006). Dealers who attend and successfully complete a workshop are issued a certificate for each place of business that is permitted to receive sharks. These certificate(s) are valid for 3 years. Approximately 104 free Atlantic Shark Identification Workshops have been conducted since January 2007.

Currently, permitted dealers may send a proxy to an Atlantic Shark Identification Workshop. However, if a dealer opts to send a proxy, the dealer must designate a proxy for each place of business covered by the dealer's permit which first receives Atlantic sharks. Only one certificate will be issued to each proxy. A proxy must be a person who is currently employed by a place of business covered by the dealer's permit; is a primary participant in the identification, weighing, and/or first receipt of fish as they are offloaded from a vessel; and who fills out dealer reports. Atlantic shark dealers are prohibited from renewing a Federal shark dealer permit unless a valid Atlantic Shark Identification Workshop certificate for each business location that first receives Atlantic sharks has been submitted with the permit renewal application. Additionally, trucks or other conveyances that are extensions of a dealer's place of business must possess a copy of a valid dealer or proxy Atlantic Shark Identification Workshop certificate.

Workshop Dates, Times, and Locations

1. January 22, 2015, 12 p.m.–4 p.m., LaQuinta Inn & Suites, 2610 Williams Boulevard, Kenner, LA 70062.

2. February 26, 2015, 12 p.m.–4 p.m., LaQuinta Inn & Suites, 1387 North Military Highway, Norfolk, VA 23502.

3. March 19, 2015, 12 p.m.–4 p.m., LaQuinta Inn & Suites, 2655 Crossroads Parkway, Fort Pierce, FL 34945.

Registration

To register for a scheduled Atlantic Shark Identification Workshop, please contact Eric Sander at *esander@peoplepc.com* or at (386) 852–8588.

Registration Materials

To ensure that workshop certificates are linked to the correct permits, participants will need to bring the following specific items to the workshop:

- Atlantic shark dealer permit holders must bring proof that the attendee is an owner or agent of the business (such as articles of incorporation), a copy of the applicable permit, and proof of identification.
- Atlantic shark dealer proxies must bring documentation from the permitted dealer acknowledging that the proxy is attending the workshop on behalf of the permitted Atlantic shark dealer for a specific business location, a copy of the appropriate valid permit, and proof of identification.

Workshop Objectives

The Atlantic Shark Identification Workshops are designed to reduce the number of unknown and improperly identified sharks reported in the dealer reporting form and increase the accuracy of species-specific dealer-reported information. Reducing the number of unknown and improperly identified sharks will improve quota monitoring and the data used in stock assessments. These workshops will train shark dealer permit holders or their proxies to properly identify Atlantic shark carcasses.

Protected Species Safe Handling, Release, and Identification Workshops

Since January 1, 2007, shark limited-access and swordfish limited-access permit holders who fish with longline or gillnet gear have been required to submit a copy of their Protected Species Safe Handling, Release, and Identification Workshop certificate in order to renew either permit (71 FR 58057; October 2, 2006). These certificate(s) are valid for 3 years. As such, vessel owners who have not already attended a workshop and received a NMFS certificate, or vessel owners whose certificate(s) will expire prior to the next permit renewal, must attend a workshop to fish with, or renew, their swordfish and shark limited-access permits. Additionally, new shark and swordfish limited-access permit applicants who intend to fish with longline or gillnet gear must attend a Protected Species Safe Handling, Release, and Identification Workshop and submit a copy of their workshop certificate before either of the permits will be issued. Approximately 190 free Protected Species Safe Handling, Release, and Identification Workshops have been conducted since 2006.

In addition to certifying vessel owners, at least one operator on board vessels issued a limited-access swordfish or shark permit that uses longline or gillnet gear is required to attend a Protected Species Safe Handling, Release, and Identification Workshop and receive a certificate. Vessels that have been issued a limited-access swordfish or shark permit and that use longline or gillnet gear may not fish unless both the vessel owner and operator have valid workshop certificates onboard at all times. Vessel operators who have not already attended a workshop and received a NMFS certificate, or vessel operators whose certificate(s) will expire prior to their next fishing trip, must attend a workshop to operate a vessel with swordfish and shark limited-access permits that uses longline or gillnet gear.

Workshop Dates, Times, and Locations

1. January 14, 2015, 9 a.m.–5 p.m., Hilton Garden Inn, 1101 US Highway 231, Panama City, FL 32405.

2. January 21, 2015, 9 a.m.–5 p.m., Holiday Inn, 300 Woodbury Avenue, Portsmouth, NH 03878.

3. February 12, 2015, 9 a.m.–5 p.m., Holiday Inn, 151 Route 72 East, Manahawkin, NJ 08050.

4. February 19, 2015, 9 a.m.–5 p.m., Hilton Garden Inn, 6745 Rock Spring Road, Wilmington, NC 28405.

5. March 10, 2015, 9 a.m.–5 p.m., Holiday Inn Express, 210 Seminole Boulevard, Largo, FL 33770.

6. March 12, 2015, 9 a.m.–5 p.m., Holiday Inn Express, 8080 Main Street, Houston, TX 77025.

Registration

To register for a scheduled Protected Species Safe Handling, Release, and Identification Workshop, please contact Angler Conservation Education at (386) 682–0158.

Registration Materials

To ensure that workshop certificates are linked to the correct permits, participants will need to bring the following specific items with them to the workshop:

• Individual vessel owners must bring a copy of the appropriate swordfish and/or shark permit(s), a copy of the vessel registration or documentation, and proof of identification.

• Representatives of a business-owned or co-owned vessel must bring proof that the individual is an agent of the business (such as articles of incorporation), a copy of the applicable swordfish and/or shark permit(s), and proof of identification.

• Vessel operators must bring proof of identification.

Workshop Objectives

The Protected Species Safe Handling, Release, and Identification Workshops are designed to teach longline and gillnet fishermen the required techniques for the safe handling and release of entangled and/or hooked protected species, such as sea turtles, marine mammals, and smalltooth sawfish. In an effort to improve reporting, the proper identification of protected species will also be taught at these workshops. Additionally, individuals attending these workshops will gain a better understanding of the requirements for participating in these fisheries. The overall goal of these workshops is to provide participants with the skills needed to reduce the mortality of protected species, which may prevent additional regulations on these fisheries in the future.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 1, 2014.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2014–28502 Filed 12–3–14; 8:45 am]

BILLING CODE 3510–22–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB–2014–0032]

Agency Information Collection Activities: Comment Request

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Consumer Financial Protection Bureau (Bureau) is proposing a new information collection titled, ''CFPB'S Consumer Complaint Intake System Company Portal Boarding Form Information Collection System.''

DATES: Written comments are encouraged and must be received on or before February 2, 2015 to be assured of consideration.

ADDRESSES: You may submit comments, identified by the title of the information collection, OMB Control Number (see below), and docket number (see above), by any of the following methods:

• Electronic: *http://www.regulations.gov.* Follow the instructions for submitting comments.

• Mail: Consumer Financial Protection Bureau (Attention: PRA Office), 1700 G Street NW., Washington, DC 20552.

• Hand Delivery/Courier: Consumer Financial Protection Bureau (Attention: PRA Office), 1275 First Street NE., Washington, DC 20002.

Please note that comments submitted after the comment period will not be accepted. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or social security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT: Documentation prepared in support of this information collection request is available at *www.regulations.gov.* Requests for additional information should be directed to the Consumer Financial Protection Bureau, (Attention: PRA Office), 1700 G Street NW., Washington, DC 20552, (202) 435–9575, or email: *PRA@cfpb.gov. Please do not submit comments to this mailbox.*

SUPPLEMENTARY INFORMATION:

Title of Collection: CFPB'S Consumer Complaint Intake System Company Portal Boarding Form Information Collection System.

OMB Control Number: 3170–XXXX.

Type of Review: New collection (Request for a new OMB control number.

Affected Public: Private sector.

Estimated Number of Respondents: 50,000.

Estimated Total Annual Burden Hours: 12,500.

Abstract: The Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, Title X, provides for the Bureau's consumer complaint handling function. Among other things, the Bureau is to facilitate the centralized collection of, monitoring of, and response to complaints concerning consumer financial products and services. The support the appropriate routing of complaints to the companies that are the subjects of the complaints, the Bureau is developing a form which will allow companies to proactively participate in the Bureau's Company Portal (Company Portal), a secure, Web-based interface between the Bureau's Office of Consumer Response (Consumer Response) and companies. The Company Portal allows companies to view and respond to complaints submitted through the Bureau's complaint handling system. Many companies have sought to register with the Company Portal before consumer complaints have been submitted to the Bureau about their companies to ensure early notice of potential complaints and allow companies' users to acclimate to the software and security protocols needed to access the Company Portal. The Bureau's proposed form, the Company Portal Boarding Form (Boarding Form), will serve to streamline information collection from these companies, result in a greatly enhanced and efficient experience from both the consumers and companies' perspectives.

Request for Comments: Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Bureau, including whether the information will have practical utility; (b) The accuracy of the Bureau's estimate of the burden of the collection of information, including the validity of the methods and the assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record.

Dated: November 19, 2014.

Nellisha Ramdass,

Acting Chief Information Officer, Bureau of Consumer Financial Protection.

[FR Doc. 2014–28511 Filed 12–3–14; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF ENERGY

Bonneville Power Administration

[BPA File No.: BP–16]

Fiscal Year (FY) 2016–2017 Proposed Power and Transmission Rate Adjustments Public Hearing and Opportunities for Public Review and Comment

AGENCY: Bonneville Power Administration (BPA or Bonneville), Department of Energy (DOE).

ACTIONS: Notice of FY 2016–2017 Proposed Power and Transmission Rate Adjustments.

SUMMARY: BPA is holding a consolidated rate proceeding, Docket No. BP–16, to establish power and transmission rates for FY 2016–2017.

The Pacific Northwest Electric Power Planning and Conservation Act (Northwest Power Act) provides that BPA must establish and periodically review and revise its rates so that they recover, in accordance with sound business principles, the costs associated with the acquisition, conservation, and transmission of electric power, including amortization of the Federal investment in the Federal Columbia River Power System (FCRPS) over a reasonable number of years, and BPA's other costs and expenses. The Northwest Power Act also requires that BPA's rates be established based on the record of a formal hearing, and for transmission rates only, that the costs of the Federal transmission system be equitably allocated between Federal and non-Federal power utilizing the system. By this notice, BPA announces the commencement of a power and transmission rate adjustment proceeding for power, transmission, control area services, and ancillary services rates to be effective on October 1, 2015.

DATES: Anyone wishing to become a party to the BP–16 proceeding must provide written notice, via U.S. Mail or electronic mail, which must be received by BPA no later than 3:00 p.m. on December 12, 2014.

The BP–16 rate adjustment proceeding begins with a prehearing conference at 9:00 a.m. on December 10, 2014, in the BPA Rates Hearing Room, 1201 NE Lloyd Boulevard, Suite 200, Portland, Oregon 97232.

Written comments by non-party participants must be received by February 26, 2015, to be considered in the Administrator's Record of Decision (ROD).

ADDRESSES:

1. Petitions to intervene should be directed to: Hearing Clerk—L–7, Bonneville Power Administration, 905 NE 11th Avenue, Portland, Oregon 97232, or may be emailed to *rateclerk@bpa.gov.* In addition, copies of the petition must be served concurrently on BPA's General Counsel and directed to both Mr. Kurt Casad, LP–7, and Mr. Barry Bennett, LT–7, Office of General Counsel, 905 NE 11th Avenue, Portland, Oregon 97232, or via email to *krcasad@bpa.gov* and *bbennett@bpa.gov* (see section III.A. for more information regarding interventions).

2. Written comments by participants should be submitted to the Public Engagement Office, DKE–7, Bonneville Power Administration, P.O. Box 14428, Portland, Oregon 97293. Participants may also submit comments by email at: *www.bpa.gov/comment.* BPA requests that all comments and documents intended to be part of the Official Record in this rate proceeding contain the designation BP–16 in the subject line.

FOR FURTHER INFORMATION CONTACT: Ms. Michelle Whalen, DKC–7, Public Affairs Specialist, Bonneville Power Administration, P.O. Box 3621, Portland, Oregon 97208; by phone toll free at 1–800–622–4520; or via email to *mewhalen@bpa.gov.* Responsible Officials: Mr. Raymond D. Bliven, Power Rates Manager, is the official responsible for the development of BPA's power rates, and Ms. Rebecca E. Fredrickson, Transmission Rates Manager, is the official responsible for the development of BPA's transmission, ancillary, and control area services rates.

SUPPLEMENTARY INFORMATION:

Table of Contents

Part I. Introduction and Procedural Background
Part II. Scope of BP–16 Rate Proceeding
Part III. Public Participation in BP–16
Part IV. Summary of Rate Proposals
Part V. Proposed BP–16 Rate Schedules

Part I—Introduction and Procedural Background

Section 7(i) of the Northwest Power Act, 16 U.S.C. 839e(i), requires that BPA's rates be established according to certain procedures, including publication in the **Federal Register** of this notice of the proposed rates; one or more hearings conducted as expeditiously as practicable by a Hearing Officer; opportunity for both oral presentation and written submission of views, data, questions, and arguments related to the proposed rates; and a decision by the Administrator based on the record. BPA's rate proceedings are further governed by BPA's Procedures Governing Bonneville Power Administration Rate Hearings, 51 **Federal Register** 7611 (1986), which implement and expand the statutory requirements.

This proceeding is being conducted under the rule for general rate proceedings, section 1010.4 of BPA's Procedures. A proposed schedule for the proceeding is provided below. A final schedule will be established by the Hearing Officer at the prehearing conference.

Prehearing Conference/BPA Initial Proposal—December 10, 2014
Parties File Petitions to Intervene—December 12, 2014
Clarification—December 17–19, 2014
Motions to Strike—January 13, 2015
Data Request Deadline—January 13, 2015
Answers to Motions to Strike—January 21, 2015
Data Response Deadline—January 21, 2015
Parties file Direct Case—February 4, 2015
Clarification—February 11–13, 2015
Motions to Strike—February 17, 2015
Data Request Deadline—February 17, 2015
Answers to Motions to Strike—February 24, 2015
Data Response Deadline—February 24, 2015
Close of Participant Comments—February 26, 2015
Litigants file Rebuttal—March 16, 2015
Clarification—March 19–20, 2015
Motions to Strike—March 24, 2015
Data Request Deadline—March 24, 2015
Answers to Motions to Strike—March 31, 2015
Data Response Deadline—March 31, 2015
Cross-Examination—April 1–3 and 6–7, 2015
Initial Briefs Filed—May 1, 2015
Oral Argument—May 8, 2015
Draft ROD issued—June 12, 2015
Briefs on Exceptions—July 1, 2015
Final ROD—Final Studies—July 24, 2015

Section 1010.7 of BPA's Procedures prohibits *ex parte* communications. The *ex parte* rule applies to all BPA and DOE employees and contractors. Except as provided below, any outside communications with BPA and/or DOE personnel regarding the merits of any issue in BPA's rate proceeding by other Executive Branch agencies, Congress, existing or potential BPA customers (including tribes), or nonprofit or public interest groups are considered outside communications and are subject to the *ex parte* rule. The rule does not apply to communications relating to: (1) Matters of procedure only (the status of the rate proceeding, for example); (2) exchanges of data in the course of business or under the Freedom of Information Act; (3) requests for factual information; (4) matters for which BPA is responsible under statutes other than the ratemaking provisions; or (5) matters which all parties agree may be made on an *ex parte* basis. The *ex parte* rule remains in effect until the Administrator's Final ROD is issued, which is scheduled to occur on or about July 24, 2015.

Part II—Scope of BP–16 Rate Proceeding

A. Joint Rate Proceeding

BPA is holding one power and transmission rate proceeding with one procedural schedule, one record, and one ROD.

B. 2014 Integrated Program Review

BPA began its 2014 Integrated Program Review (IPR) process in May 2014. The IPR process is designed to allow an opportunity to review and comment on BPA's expense and capital spending level estimates before the estimates are used to set rates. On October 2, 2014, BPA issued the Final Close-Out Report for the IPR. In the Final Close-Out Report, BPA established the program level cost estimates that are used in the Initial Proposal to establish both the power and transmission rates.

C. Scope of the Rate Proceeding

This section provides guidance to the Hearing Officer as to those matters that are within the scope of the rate proceeding and those that are outside the scope. In addition to the items listed below, any other issue that is not a rates issue is outside the scope of this proceeding.

1. Program Cost Estimates

Some of the decisions that determine program costs and spending levels have been made in the IPR public review process outside the rate proceeding. See section II.B. BPA's spending levels for investments and expenses are not determined or subject to review in rate proceedings.

Pursuant to section 1010.3(f) of BPA's Procedures, the Administrator directs the Hearing Officer to exclude from the record all argument, testimony, or other evidence that challenges the appropriateness or reasonableness of the Administrator's decisions on cost and spending levels. If any re-examination of spending levels is necessary, such re-examination will occur outside of the rate proceeding. The above exclusion does not extend to those portions of the revenue requirements related to interest rate forecasts, interest expense and credit, Treasury repayment schedules, forecasts of depreciation and amortization expense, forecasts of system replacements used in repayment studies, Residential Exchange Program benefits, purchased power expenses, transmission acquisition expense incurred by Power Services, generation acquisition expense incurred by Transmission Services, minimum required net revenue, use of financial reserves, and the costs of risk mitigation actions resulting from the expense and revenue uncertainties included in the risk analysis. The Administrator also directs the Hearing Officer to exclude argument and evidence regarding BPA's debt management practices and policies. See section II.C.5.

2. Tiered Rate Methodology (TRM)

The TRM restricts BPA and customers with Contract High Water Mark (CHWM) contracts from proposing changes to the TRM's ratesetting guidelines unless certain procedures have been successfully concluded. No proposed changes have been subjected to the required procedures.

Pursuant to § 1010.3(f) of BPA's Procedures, the Administrator hereby directs the Hearing Officer to exclude from the record all argument, testimony, or other evidence that seeks in any way to propose revisions to the TRM made by BPA, customers with a CHWM contract, or their representatives, unless it can be established that the TRM procedures for proposing a change to the TRM have been concluded. This restriction does not extend to a party or customer that does not have a CHWM contract.

3. Service to the Direct Service Industries (DSIs)

BPA's decisions to serve Alcoa and Port Townsend along with the method and level of service to be provided DSIs in the FY 2016–2017 rate period will not be determined in this proceeding. The decision to serve the DSIs was made in the record of decision on the Alcoa and Port Townsend contracts. The decision was not challenged in the Ninth Circuit Court of Appeals.

Pursuant to § 1010.3(f) of BPA's Procedures, the Administrator directs the Hearing Officer to exclude from the record all argument, testimony, or other evidence that seeks in any way to revisit the appropriateness or reasonableness of BPA's decisions regarding service to the DSIs, including BPA's decision to offer contracts to the DSIs and the method or level of service.

4. Generation Inputs

BPA provides a portion of the available generation from the FCRPS to enable Transmission Services to meet its various requirements. Transmission Services uses these generation inputs to provide ancillary and control area services.

Pursuant to § 1010.3(f) of BPA's Procedures, the Administrator directs the Hearing Officer to exclude from the record all argument, testimony, or other evidence that seeks in any way to revisit issues regarding reliability of the transmission system, dispatcher standing orders, e-Tag requirements and definitions, open access transmission tariff (OATT) provisions, and business practices. These non-rates issues are generally addressed by BPA in accordance with industry, reliability, and other compliance standards and criteria and are not matters appropriate for the rate proceeding.

5. Federal and Non-Federal Debt Service and Debt Management

During the 2014 IPR and in other forums, BPA provided the public with background information on BPA's internal Federal and non-Federal debt management policies and practices. While these policies and practices are not decided in the IPR forum, these discussions were intended to inform interested parties about these matters so that they would better understand BPA's debt structure. BPA's debt management policies and practices remain outside the scope of the rate proceeding.

Pursuant to § 1010.3(f) of BPA's Procedures, the Administrator hereby directs the Hearing Officer to exclude from the record all argument, testimony, or other evidence that seeks in any way to address the appropriateness or reasonableness of BPA's debt management policies and practices. This exclusion does not encompass how debt management actions are reflected in ratemaking.

6. Potential Environmental Impacts

Environmental impacts are addressed in a concurrent National Environmental Policy Act (NEPA) process. See section II.D.

Pursuant to § 1010.3(f) of BPA's Procedures, the Administrator directs the Hearing Officer to exclude from the record all argument, testimony, or other evidence that seeks in any way to address the potential environmental impacts of the rates being developed in this rate proceeding.

7. 2008 Average System Cost Methodology (2008 ASCM) and Average System Cost Determinations

Section 5(c) of the Northwest Power Act established the Residential Exchange Program, which provides benefits to residential and farm consumers of Pacific Northwest utilities based, in part, on a utility's ''average system cost'' (ASC) of resources. On September 4, 2009, the Federal Energy Regulatory Commission (Commission) granted final approval of BPA's 2008 ASCM. The 2008 ASCM is not subject to challenge or review in a section 7(i) proceeding. Determinations of the ASCs

of participating utilities are made in separate processes conducted pursuant to the ASCM. Those processes began with ASC filings on June 2, 2014, and are continuing through July 2015. The determinations of ASCs are not subject to challenge or review in a section 7(i) proceeding.

Pursuant to § 1010.3(f) of BPA's Procedures, the Administrator hereby directs the Hearing Officer to exclude from the record all argument, testimony, or other evidence that seeks in any way to visit or revisit the appropriateness or reasonableness of the 2008 ASCM or that seeks in any way to visit or revisit the appropriateness or reasonableness of any of the ongoing ASC determinations.

8. Rate Period High Water Mark (RHWM) Process

Under the Tiered Rate Methodology (TRM), BPA has established FY 2016–2017 RHWMs for Public customers that signed contracts for firm requirements power service providing for tiered rates, referred to as CHWM contracts. In this RHWM Process, which preceded the BP–16 rate proceeding, BPA established the maximum planned amount of power a customer is eligible to purchase at Tier 1 rates during the rate period, the Above-RHWM Loads for each customer, the System Shaped Load for each customer, the Tier 1 System Firm Critical Output, RHWM Augmentation, the Rate Period Tier 1 System Capability (RT1SC), and the monthly/diurnal shape of RT1SC. The RHWM Process provided customers an opportunity to review, comment, and, if necessary, challenge BPA's RHWM determinations.

Pursuant to § 1010.3(f) of BPA's Procedures, the Administrator hereby directs the Hearing Officer to exclude from the record all argument, testimony, or other evidence that seeks in any way to visit or revisit BPA's determination of a customer's FY 2016–2017 RHWM or other RHWM Process determinations.

9. 2012 Residential Exchange Program Settlement Agreement (2012 REP Settlement)

On July 26, 2011, the Administrator executed the 2012 REP Settlement resolving longstanding litigation over BPA's implementation of the Residential Exchange Program (REP) under section 5(c) of the Northwest Power Act, 16 U.S.C. 839c(c). The Administrator's findings regarding the legal, factual, and policy challenges to the 2012 REP Settlement are thoroughly explained in the REP–12 Record of Decision (REP–12 ROD). The 2012 REP Settlement and REP–12 ROD were approved by U.S. Court of Appeals for the Ninth Circuit in *Association of Public Agency Customers* v. *Bonneville Power Administration,* 733 F.3d 939 (9th Cir. 2013).

Because the 2012 REP Settlement was part of the REP–12 ROD, and approved by the Court, challenges to BPA's decision to adopt the 2012 REP Settlement and implement its terms in BPA's rate proceedings are not within the scope of this proceeding. Pursuant to § 1010.3(f) of BPA's Procedures, the Administrator hereby directs the Hearing Officer to exclude from the record all argument, testimony, or other evidence that seeks in any way to visit or revisit BPA's determination to adopt the 2012 REP Settlement or its terms in this rate proceeding.

10. Transfer Service for Southeast Idaho Load Service

Because of the termination of grandfathered contracts, BPA is developing a new transmission service plan for its preference customers located in Southeast Idaho. The cost allocation issue related to this plan is an appropriate issue in this rate proceeding. However, all decisions regarding the development of the new plan of service itself are outside the scope of the rate proceeding.

Pursuant to § 1010.3(f) of BPA's Procedures, the Administrator directs the Hearing Officer to exclude from the record all argument, testimony, or other evidence that seeks in any way to visit or revisit BPA's strategy or acquisition decisions for Southeast Idaho Load Service.

D. The National Environmental Policy Act (NEPA)

BPA is in the process of assessing the potential environmental effects of its proposed power and transmission rates, consistent with NEPA. The NEPA process is conducted separately from the rate proceeding. As discussed in section II.C.6., all evidence and argument addressing potential environmental impacts of rates being developed in the BP–16 rate proceeding are excluded from the rate proceeding hearing record. Instead, comments on environmental effects should be directed to the NEPA process.

Because this proposal involves BPA's ongoing business practices related to rates, BPA is reviewing the proposal for consistency with BPA's Business Plan Environmental Impact Statement (Business Plan EIS), completed in June 1995 (BOE/EIS–0183). This policy-level EIS evaluates the environmental impacts of a range of business plan alternatives for BPA that could be varied by applying various policy modules, including one for rates. Any combination of alternative policy modules should allow BPA to balance its costs and revenues. The Business Plan EIS also includes response strategies, such as adjustments to rates, that BPA could implement if BPA's costs exceed its revenues.

In August 1995, the BPA Administrator issued a ROD (Business Plan ROD) that adopted the Market-Driven Alternative from the Business Plan EIS. This alternative was selected because, among other reasons, it allows BPA to: (1) Recover costs through rates; (2) competitively market BPA's products and services; (3) develop rates that meet customer needs for clarity and simplicity; (4) continue to meet BPA's legal mandates; and (5) avoid adverse environmental impacts. BPA also committed to apply as many response strategies as necessary when BPA's costs and revenues do not balance.

In April 2007, BPA completed and issued a Supplement Analysis to the Business Plan EIS. This Supplement Analysis found that the Business Plan EIS's relationship-based and policy-level analysis of potential environmental impacts from BPA's business practices remains valid, and that BPA's current business practices remain consistent with BPA's Market-Driven Alternative approach. The Business Plan EIS and ROD thus continue to provide a sound basis for making determinations under NEPA concerning BPA's policy-level decisions, including rates.

Because the proposed rates likely would assist BPA in accomplishing the goals identified in the Business Plan ROD, the proposal appears consistent with these aspects of the Market-Driven Alternative. In addition, this rate proposal is similar to the type of rate designs evaluated in the Business Plan EIS; thus, implementation of this rate proposal would not be expected to result in environmental impacts significantly different from those examined in the Business Plan EIS. Therefore, BPA expects that this rate proposal will likely fall within the scope of the Market-Driven Alternative that was evaluated in the Business Plan EIS and adopted in the Business Plan ROD.

As part of the Administrator's ROD that will be prepared for the BP–16 rate proceeding, BPA may tier its decision under NEPA to the Business Plan ROD. However, depending upon the ongoing environmental review, BPA may instead issue another appropriate NEPA document. Comments regarding the potential environmental effects of the proposal may be submitted to Katherine Pierce, NEPA Compliance Officer, KEC–

4, Bonneville Power Administration, 905 NE 11th Avenue, Portland, OR 97232. Any such comments received by the comment deadline for Participant Comments identified in section III.A. below will be considered by BPA's NEPA compliance staff in the NEPA process that will be conducted for this proposal.

Part III—Public Participation in BP–16

A. Distinguishing Between ''Participants'' and ''Parties''

BPA distinguishes between ''participants in'' and ''parties to'' the hearings. Separate from the formal hearing process, BPA will receive written comments, views, opinions, and information from participants, who may submit comments without being subject to the duties of, or having the privileges of, parties. Participants' written comments will be made part of the official record and considered by the Administrator. Participants are not entitled to participate in the prehearing conference; may not cross-examine parties' witnesses, seek discovery, or serve or be served with documents; and are not subject to the same procedural requirements as parties. BPA customers whose rates are subject to this proceeding, or their affiliated customer groups, may not submit participant comments. Members or employees of organizations that have intervened in the rate proceeding may submit participant comments as private individuals (that is, not speaking for their organizations) but may not use the comment procedures to address specific issues raised by their intervenor organizations.

Written comments by participants will be included in the record if they are received by February 26, 2015. Written views, supporting information, questions, and arguments should be submitted to the address listed in the **ADDRESSES** section of this notice.

Entities or persons become parties to the proceeding by filing petitions to intervene, which must state the name and address of the entity or person requesting party status and the entity's or person's interest in the hearing. BPA customers and affiliated customer groups will be granted intervention based on petitions filed in conformance with BPA's Procedures. Other petitioners must explain their interests in sufficient detail to permit the Hearing Officer to determine whether the petitioners have a relevant interest in the hearing. Pursuant to Rule 1010.1(d) of BPA's Procedures, BPA waives the requirement in Rule 1010.4(d) that an opposition to an intervention petition be filed and served 24 hours before the prehearing conference. The time limit for opposing a timely intervention will be established at the prehearing conference. Any party, including BPA, may oppose a petition for intervention. All petitions will be ruled on by the Hearing Officer. Late interventions are strongly disfavored. Opposition to an untimely petition to intervene must be filed and received by BPA within two days after service of the petition.

B. Developing the Record

The hearing record will include, among other things, the transcripts of the hearing, written evidence and argument entered into the record by BPA and the parties, written comments from participants, and other material accepted into the record by the Hearing Officer. The Hearing Officer will review the record and certify the record to the Administrator for final decision.

The Administrator will develop final rates based on the record and such other materials and information as may have been submitted to or developed by the Administrator. The Administrator will serve copies of the Final ROD on all parties. BPA will file its rates with the Commission for confirmation and approval after issuance of the Final ROD.

Part IV—Summary of Rate Proposals

A. Summary of the Power Rate Proposal

1. Power Rates

BPA is proposing four different rates for Federal power sales and services. The General Transfer Agreement Service (GTA) rate schedule, currently included as a power rate schedule, is being moved to the General Rate Schedule Provisions. The proposed GTA charges are expanded to recover Western Electricity Coordinating Council (WECC) and Peak Reliability (Peak) costs BPA incurs based on transfer customer loads outside of the BPA balancing authority area.

Priority Firm Power Rate (PF–16)—The PF rate schedule applies to net requirements power sales to public body, cooperative, and Federal agency customers made pursuant to section 5(b) of the Northwest Power Act and includes the PF Public rates for the sale of firm requirements power under CHWM Contracts and the PF Exchange rates for sales under Residential Purchase and Sale Agreements. The PF Public rate applies to customers taking load following or Slice/block service. Consistent with the TRM, Tier 1 rates include three charges: (1) Customer charges; (2) a demand charge; and (3) a load shaping charge. In addition, four Tier 2 rates, corresponding to contract options, are applied to customers that have elected to purchase power from BPA for service to their Above-RHWM Load.

The PF rate is a collection of rates charged on the basis of percentage of cost responsibility, marginal changes in demand and energy usage, customer purchase elections for BPA service to loads in excess of power purchased at Tier 1 rates, product and service choices, transfer load delivery and operating reserves, and applicability of rate discounts. Very few of BPA's customers have exactly the same mix of PF rate components in common. Therefore, BPA has developed a quantification of the PF rate that measures the impact on an average customer purchasing at Tier 1 rates. This quantification, the Tier 1 Average Net Cost, is increasing 6.7 percent in this proposal, from $31.50/MWh for the PF–14 rate to $33.60/MWh for the PF–16 rate.

The Base PF Exchange rate and its associated surcharges apply to the sale of power to regional utilities that participate in the REP established under section 5(c) of the Northwest Power Act. 16 U.S.C. 839c(c). The Base PF Exchange rate establishes the threshold for participation in the REP; only utilities with ASCs above the appropriate Base PF Exchange rate may receive REP benefits. If a utility meets the threshold, a utility-specific PF Exchange rate will be established in this proceeding for each eligible utility. The utility-specific PF Exchange rate is used in calculating the REP benefits each participant will receive during FY 2016–2017.

In addition, the proposed PF–16 rate schedule includes rates for customers with non-Federal resources that have elected to take Diurnal Flattening Service or Secondary Crediting Service, and a melded PF rate for any Public customer that elects a power sales contract other than a CHWM Contract for firm requirements service.

New Resource Firm Power Rate (NR–16)—The NR–16 rate applies to net requirements power sales to investor-owned utilities (IOUs) made pursuant to section 5(b) of the Northwest Power Act for resale to ultimate consumers, direct consumption, construction, testing and start-up, and station service. The NR–16 rate is also applied to sales of firm power to Public customers when this power is used to serve new large single loads. In addition, BPA is proposing NR rates for services to support Public customers serving new large single loads with non-Federal resources. In the Initial Proposal BPA is forecasting no

sales at the NR rate. The average NR–16 rate in the Initial Proposal is $76.60/MWh, a decrease of 1.4 percent from the NR–14 rate.

Industrial Firm Power Rate (IP–16)—The IP rate is applicable to firm power sales to DSI customers authorized by section 5(d)(1)(A) of the Northwest Power Act. 16 U.S.C. § 839c(d)(1)(A). In the Initial Proposal BPA is forecasting annual sales of 316 average megawatts (aMW) to DSIs. See section IV.A.2c. The average IP–16 rate in the Initial Proposal is $41.53/MWh, an increase of 6.6 percent over the IP–14 rate.

Firm Power and Surplus Products and Services Rate (FPS–16)—The FPS rate schedule is applicable to sales of various surplus power products and surplus transmission capacity, for use inside and outside the Pacific Northwest. The rates for these products are negotiated between BPA and the purchasers. In addition, the FPS–16 rate schedule includes rates for customers with non-Federal resources, the Unanticipated Load Service rate, rates for other capacity, energy, and scheduling products and services, and rates for reserve services for use outside the BPA balancing authority area.

2. Ancillary Service and Control Area Service Rates

Beginning in May 2014, BPA held rate case workshops and solicited stakeholder comments concerning generation inputs issues that form the foundation of most ancillary service and control area service rates. Over the following months, BPA and stakeholders developed a settlement agreement that covers most ancillary and control area service rates. The settlement agreement rates are at the same level as current rates except for a five percent increase for the Operating Reserves rates. The settlement agreement also provides for other changes to the rate schedules, and specifies the amount of balancing reserve capacity to be provided during the rate period as well as an acquisition budget for balancing reserve capacity.

BPA asked all entities that intended to be parties to the BP–16 rate proceeding to either sign the agreement or declare their intention to contest the agreement by September 25, 2014. By that deadline, 29 parties signed or agreed not to contest the settlement agreement. No party declared an intent to contest the agreement.

BPA will file the BP–16 generation inputs settlement agreement as part of the BP–16 Initial Proposal. Parties will be given an opportunity to contest the agreement pursuant to a timeline established by the Hearing Officer.

3. Risk Mitigation Tools

The main financial risk mitigation tool BPA relies upon is financial liquidity, which consists of cash, other investments in the Bonneville Fund at the U.S. Treasury, and a short-term liquidity facility with the U.S. Treasury. BPA proposes to include provisions for two rate adjustments in the power rate schedules and in certain ancillary and control area services rate schedules: The Cost Recovery Adjustment Clause (CRAC), which can generate additional cash within the rate period, and the Dividend Distribution Clause (DDC), which can return cash to customers when BPA's financial reserves attributed to power are larger than needed to meet its Treasury Payment Probability (TPP) standard. When available liquidity and the CRAC are insufficient to meet the TPP standard, BPA includes Planned Net Revenues for Risk (PNRR) in its rates.

In the Initial Proposal, BPA proposes to include no PNRR and to cap the maximum revenue recoverable through the CRAC at $300 million per year. BPA is proposing some minor changes to the risk mitigation tools in the BP–16 Initial Proposal, including a revision to the metric used to determine whether a CRAC or DDC triggers. The thresholds for triggering the CRAC and DDC remain unchanged from the BP–14 rate case (equivalent reserve levels of $0 and $750 million, respectively, in financial reserves attributed to Power). BPA also proposes to continue the National Marine Fisheries Service FCRPS Biological Opinion Adjustment (NFB Adjustment) and the Emergency NFB Surcharge, given that litigation regarding the Biological Opinion continues.

B. Summary of the Transmission Rate Proposal

BPA is proposing an overall 5.6 percent increase in transmission rates. BPA is also proposing to develop a WECC and Peak rate.

BPA is proposing four different rates for the use of its Network segment, four different rates for use of intertie segments, and several other rates for various purposes.

The four rates for use of the Network segment are:

Formula Power Transmission Rate (FPT–16)—The FPT rate is based on the cost of using specific types of facilities, including a distance component for the use of transmission lines, and is charged on a contract demand basis.

Integration of Resources Rate (IR–16)—The IR rate is a postage stamp, contract demand rate for the use of the Network, similar to Point-to-Point (PTP) service (see below), and includes Scheduling, System Control, and Dispatch Service.

Network Integration Transmission Rate (NT–16)—The NT rate applies to customers taking network integration service under the Open Access Transmission Tariff (OATT) and allows customers to flexibly serve their retail load.

Point-to-Point Rate (PTP–16)—The PTP rate is a contract demand rate that applies to customers taking Point-to-Point service on BPA's network facilities under the OATT. It provides customers with flexible service from identified Points of Receipt to identified Points of Delivery. There are separate PTP rates for long-term firm service; daily firm and non-firm service; and hourly firm and non-firm service.

BPA is proposing four rates for intertie use:

The Southern Intertie Rate (IS–16) is a contract demand rate that applies to customers taking Point-to-Point service under the OATT on the Southern Intertie.

The Montana Intertie Rate (IM–16) applies to customers taking Point-to-Point service on the Eastern Intertie.

The Townsend-Garrison Transmission Rate (TGT–16) is a rate for firm service over BPA's section of the Montana Intertie and is available to parties to the Montana Intertie Agreement.

The Eastern Intertie Rate (IE–16) is a rate for non-firm service on the portion of the Eastern Intertie capacity that exceeds BPA's firm transmission rights and is available to parties to the Montana Intertie Agreement.

Other proposed transmission rates are:

The Use-of-Facilities Rate (UFT–16) establishes a formula rate for the use of a specific facility based on the annual cost of that facility.

The Advance Funding Rate (AF–16) allows BPA to collect the capital and related costs of specific facilities through an advance-funding mechanism.

The Scheduling, System Control, and Dispatch Service Rate and the Reactive Supply and Voltage Control from Generation Sources Service Rate are for required ancillary services for transmission service on the Network, the Southern Intertie, and the Montana Intertie.

The WECC and Peak rates recover WECC and Peak costs assessed to BPA to cover WECC and Peak reliability functions.

The Oversupply Rate (OS–16) recovers the costs BPA incurs to displace generation under the

oversupply management protocol, Attachment P to BPA's OATT.

Other charges that may apply include a Delivery Charge for the use of low-voltage delivery substations; a Reservation Fee for customers that postpone their service commencement dates; incremental rates for transmission requests that require new facilities; a penalty charge for failure to comply with dispatch, curtailment, redispatch, or load shedding orders; and an Unauthorized Increase Charge for customers that exceed their contracted amounts. BPA is proposing to eliminate the Power Factor Penalty Charge.

Part V—Proposed BP–16 Rate Schedules

BPA's proposed BP–16 Power Rate Schedules and Transmission Rate Schedules are a part of this notice and are available for viewing and downloading on BPA's Web site at *http://www.bpa.gov/goto/BP16.* Copies of the proposed rate schedules also are available for viewing in BPA's Public Reference Room at the BPA Headquarters, 1st Floor, 905 NE 11th Avenue, Portland, OR 97232.

Issued this 19th day of November, 2014.

Elliot E. Mainzer,

Administrator and Chief Executive Officer.

[FR Doc. 2014–28463 Filed 12–3–14; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2246–069]

Yuba County Water Agency; Notice of Application Accepted for Filing, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Application for Temporary Variance of Minimum Flow Requirement.

b. *Project No.:* 2246–069.

c. *Date Filed:* November 25, 2014.

d. *Applicant:* Yuba County Water Agency (licensee).

e. *Name of Project:* Yuba River Project.

f. *Location:* North Yuba River, Middle Yuba River, and Oregon Creek in Yuba, Nevada, and Sierra counties, CA.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Curt Aikens, General Manager, Yuba County Water Agency, 1200 F Street, Marysville, CA 95901–4740, (530) 741–5015.

i. *FERC Contact:* Mr. John Aedo, (415) 369–3335, or *john.aedo@ferc.gov*.

j. Deadline for filing comments, motions to intervene, protests, and recommendations is 30 days from the issuance date of this notice by the Commission (December 26, 2014). The Commission strongly encourages electronic filing. Please file motions to intervene, protests, comments, or recommendations using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp*. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp*. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov*, (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. Please include the project number (P–2246–069) on any comments, motions to intervene, protests, or recommendations filed.

k. *Description of Request:* The licensee requests a temporary variance of the minimum flow requirements in the lower Yuba River below Englebright Dam, which requires a minimum flow of 1,000 cubic feet per second (cfs) from January 1 to 15. In order to conserve water resources during the current drought and make best biological use of a limited water supply, the licensee proposes to instead release 550 cfs from January 1 to January 16, 2015. In addition, the licensee requests that minimum flow compliance during this period be based on a 5-day running average of average daily streamflows, with instantaneous flows never less than 90 percent of the specified 550 cfs minimum flow and never less than 550 cfs for more than 48 hours. The proposed variance would be in addition to the one already requested variance for December 1–31, 2014 and January 16 to March 31, 2015 period. Take note that the December 1–31 variance was granted by Commission order dated November 25, 2014.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp*. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov*, for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All comments, motions to intervene, or protests should relate to project works which are the subject of the variance. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: November 26, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–28492 Filed 12–3–14; 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 corporate filings:

Docket Numbers: EC15–36–000.

Applicants: Verso Androscoggin Power LLC.

Description: Application for Approval under Section 203 of the Federal Power Act of Verso Androscoggin Power LLC.

Filed Date: 11/25/14.

Accession Number: 20141125–5397.

Comments Due: 5 p.m. ET 12/16/14.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG15–18–000.

Applicants: Spinning Spur Wind Three, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Spinning Spur Wind Three, LLC.

Filed Date: 11/26/14.

Accession Number: 20141126–5093.

Comments Due: 5 p.m. ET 12/17/14.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER14–2574–003.

Applicants: California Independent System Operator Corporation.

Description: Compliance filing per 35: 2014–11–25_Errata_FRAC–MOO to be effective 11/1/2014.

Filed Date: 11/25/14.

Accession Number: 20141125–5338.

Comments Due: 5 p.m. ET 12/16/14.

Docket Numbers: ER15–15–001.

Applicants: California Independent System Operator Corporation.

Description: Tariff Amendment per 35.17(b): 2014–11–25_DeficiencyResponse_CommitmentCosts to be effective 12/1/2014.

Filed Date: 11/25/14.

Accession Number: 20141125–5313.

Comments Due: 5 p.m. ET 12/5/14.

Docket Numbers: ER15–142–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Report Filing: 2014–11–26_Marshall—MRES Attachment O Supplement to be effective N/A.

Filed Date: 11/26/14.

Accession Number: 20141126–5143.

Comments Due: 5 p.m. ET 12/17/14.

Docket Numbers: ER15–359–001.

Applicants: Samchully Power & Utilities 1 LLC.

Description: Tariff Amendment per 35.17(b): Supplement to MBR Application to be effective 12/15/2014.

Filed Date: 11/25/14.

Accession Number: 20141125–5335.

Comments Due: 5 p.m. ET 12/16/14.

Docket Numbers: ER15–482–000.

Applicants: South Carolina Electric & Gas Company.

Description: Compliance filing per 35: Order 676 H Compliance filing to be effective 2/2/2015.

Filed Date: 11/25/14.

Accession Number: 20141125–5285.

Comments Due: 5 p.m. ET 12/16/14.

Docket Numbers: ER15–483–000.

Applicants: New York Independent System Operator, Inc.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): 205 filing MST revision to clarify eligibility for DAMAP and BPCG payments to be effective 1/25/2015.

Filed Date: 11/25/14.

Accession Number: 20141125–5306.

Comments Due: 5 p.m. ET 12/16/14.

Docket Numbers: ER15–484–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): 1891R3 Westar Energy, Inc. NITSA and NOA to be effective 8/1/2014.

Filed Date: 11/25/14.

Accession Number: 20141125–5312.

Comments Due: 5 p.m. ET 12/16/14.

Docket Numbers: ER15–485–000.

Applicants: New York Independent System Operator, Inc.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): 205 filing re: graduated transmission demand curve—transmission shortage costs to be effective 12/31/9998.

Filed Date: 11/25/14.

Accession Number: 20141125–5334.

Comments Due: 5 p.m. ET 12/16/14.

Docket Numbers: ER15–486–000.

Applicants: Peninsula Power, LLC.

Description: Initial rate filing per 35.12 Peninsula Power,LLC (FERC Electric Tariff) to be effective 1/1/2015.

Filed Date: 11/26/14.

Accession Number: 20141126–5001.

Comments Due: 5 p.m. ET 12/17/14.

Docket Numbers: ER15–487–000*; ER15–488–000; ER15–489–000.*

Applicants: Peetz Logan Interconnect, LLC, Sagebrush, a California partnership, Sky River LLC.

Description: Request for Waiver of Order No. 676–H Compliance Requirements of Peetz Logan Interconnect, LLC, Sagebrush, a California partnership, and Sky River LLC.

Filed Date: 11/25/14.

Accession Number: 20141125–5383.

Comments Due: 5 p.m. ET 12/16/14.

Docket Numbers: ER15–490–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): 1892R3 Westar Energy, Inc. NITSA and NOA to be effective 8/1/2014.

Filed Date: 11/26/14.

Accession Number: 20141126–5040.

Comments Due: 5 p.m. ET 12/17/14.

Docket Numbers: ER15–491–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): 1893R3 Westar Energy, Inc. (Savonburg) NITSA and NOA to be effective 8/1/2014.

Filed Date: 11/26/14.

Accession Number: 20141126–5043.

Comments Due: 5 p.m. ET 12/17/14.

Docket Numbers: ER15–493–000.

Applicants: Duke Energy Conesville, LLC.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): Amendment to Reactive Rate Schedule to be effective 12/1/2014.

Filed Date: 11/26/14.

Accession Number: 20141126–5063.

Comments Due: 5 p.m. ET 12/17/14.

Docket Numbers: ER15–494–000.

Applicants: Duke Energy Dicks Creek, LLC.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): Amendment to Reactive Rate Schedule to be effective 12/1/2014.

Filed Date: 11/26/14.

Accession Number: 20141126–5064.

Comments Due: 5 p.m. ET 12/17/14.

Docket Numbers: ER15–495–000.

Applicants: Duke Energy Killen, LLC.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): Amendment to Reactive Rate Schedule to be effective 12/1/2014.

Filed Date: 11/26/14.

Accession Number: 20141126–5068.

Comments Due: 5 p.m. ET 12/17/14.

Docket Numbers: ER15–496–000.

Applicants: Duke Energy Zimmer, LLC.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): Amendment to Reactive Rate Schedule to be effective 12/1/2014.

Filed Date: 11/26/14.

Accession Number: 20141126–5082.
Comments Due: 5 p.m. ET 12/17/14.

Docket Numbers: ER15–497–000.
Applicants: Duke Energy Ohio, Inc.
Description: Tariff Withdrawal per 35.15: Cancellation of Rate Schedule 66 to be effective 11/30/2014.
Filed Date: 11/26/14.
Accession Number: 20141126–5084.
Comments Due: 5 p.m. ET 12/17/14.

Docket Numbers: ER15–498–000.
Applicants: Duke Energy Miami Fort, LLC.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): Amendment to Reactive Rate Schedule to be effective 12/1/2014.
Filed Date: 11/26/14.
Accession Number: 20141126–5091.
Comments Due: 5 p.m. ET 12/17/14.

Docket Numbers: ER15–499–000.
Applicants: Southern California Edison Company.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): LGIA with Alta Windpower Development, LLC to be effective 1/26/2015.
Filed Date: 11/26/14.
Accession Number: 20141126–5096.
Comments Due: 5 p.m. ET 12/17/14.

Docket Numbers: ER15–500–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): 1889R3 Westar Energy, Inc. NITSA and NOA to be effective 8/1/2014.
Filed Date: 11/26/14.
Accession Number: 20141126–5139.
Comments Due: 5 p.m. ET 12/17/14.

Docket Numbers: ER15–501–000.
Applicants: Trans Bay Cable LLC.
Description: Compliance filing per 35: Revised Appendix I to the TO tariff to be effective 10/29/2014.
Filed Date: 11/26/14.
Accession Number: 20141126–5145.
Comments Due: 5 p.m. ET 12/17/14.

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 5:00 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 26, 2014.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2014–28465 Filed 12–3–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER14–2658–001.
Applicants: NV Energy, Inc.
Description: Compliance filing per 35: OATT Order No. 792 Compliance Filing-Revisions to Attachment O to be effective 8/4/2014.
Filed Date: 11/26/14.
Accession Number: 20141126–5244.
Comments Due: 5 p.m. ET 12/17/14.

Docket Numbers: ER15–52–002.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Tariff Amendment per 35.17(b): 2014–11–26 GVTC Clean up Amendment Filing to be effective 12/6/2014.
Filed Date: 11/26/14.
Accession Number: 20141126–5200.
Comments Due: 5 p.m. ET 12/17/14.

Docket Numbers: ER15–118–001.
Applicants: Morris Cogeneration, LLC.
Description: Compliance filing per 35: Amendment Refile to be effective 10/17/2014.
Filed Date: 11/26/14.
Accession Number: 20141126–5153.
Comments Due: 5 p.m. ET 12/17/14.

Docket Numbers: ER15–502–000.
Applicants: Bayou Cove Peaking Power, LLC.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): Reactive Service Rate Filing to be effective 2/1/2015.
Filed Date: 11/26/14.
Accession Number: 20141126–5213.
Comments Due: 5 p.m. ET 12/17/14.

Docket Numbers: ER15–503–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): 2014–11–26_Rattlesnake SA 847-Wind Belt SA 852 Termination to be effective 11/27/2014.
Filed Date: 11/26/14.
Accession Number: 20141126–5214.
Comments Due: 5 p.m. ET 12/17/14.

Docket Numbers: ER15–504–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): Original Service Agreement No. 4035; Queue No. U2–028A_AT1 to be effective 10/27/2014.
Filed Date: 11/26/14.
Accession Number: 20141126–5215.
Comments Due: 5 p.m. ET 12/17/14.

Docket Numbers: ER15–505–000.
Applicants: Portland General Electric Company.
Description: Compliance filing per 35: NAESB Standards Compliance Filing to be effective 2/1/2015.
Filed Date: 11/26/14.
Accession Number: 20141126–5216.
Comments Due: 5 p.m. ET 12/17/14.

Docket Numbers: ER15–506–000.
Applicants: DeSoto County Generating Company, LLC.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): Revised Reactive Rate Schedule to be effective 12/1/2014.
Filed Date: 11/26/14.
Accession Number: 20141126–5218.
Comments Due: 5 p.m. ET 12/17/14.

Docket Numbers: ER15–507–000.
Applicants: NorthWestern Corporation.
Description: Compliance filing per 35: OATT Order No. 676–H Compliance Filing and Request for Partial Waiver (Montana) to be effective 2/2/2015.
Filed Date: 11/26/14.
Accession Number: 20141126–5243.
Comments Due: 5 p.m. ET 12/17/14.

Docket Numbers: ER15–508–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): 1887R3 Westar Energy, Inc. NITSA and NOA to be effective 8/1/2014.
Filed Date: 11/26/14.
Accession Number: 20141126–5246.
Comments Due: 5 p.m. ET 12/17/14.

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 5:00 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.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2014–28466 Filed 12–3–14; 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 corporate filings:

Docket Numbers: EC15–35–000.

Applicants: AltaGas Power Holdings (U.S.) Inc., Veresen U.S. Power Inc.

Description: Joint Application for Authorization Under Section 203 of the Federal Power Act, Request for Expedited Consideration and Confidential Treatment of AltaGas Power Holdings (U.S.) Inc., et al.

Filed Date: 11/21/14.

Accession Number: 20141121–5261

Comments Due: 5 p.m. ET 12/12/14.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER12–162–009; ER11–3876–012; ER11–2044–012; ER10–2611–010.

Applicants: Bishop Hill Energy II LLC, Cordova Energy Company LLC, MidAmerican Energy Company, Saranac Power Partners, L.P.

Description: Notification of Change in Status of the Berkshire Hathaway Parties.

Filed Date: 11/21/14.

Accession Number: 20141121–5248.

Comments Due: 5 p.m. ET 12/12/14.

Docket Numbers: ER15–162–001.

Applicants: Southwest Power Pool, Inc.

Description: Tariff Amendment per 35.17(b): 2881R1 Substitute City of Chanute, KS NITSA NOA to be effective 8/1/2014.

Filed Date: 11/24/14.

Accession Number: 20141124–5101.

Comments Due: 5 p.m. ET 12/15/14.

Docket Numbers: ER15–428–001.

Applicants: Nevada Power Company.

Description: Compliance filing per 35: Errata to Order No. 1000 Third Regional Compliance Filing to be effective 1/1/2015.

Filed Date: 11/21/14.

Accession Number: 20141121–5218.

Comments Due: 5 p.m. ET 12/12/14.

Docket Numbers: ER15–463–000.

Applicants: San Gorgonio Westwinds II, LLC.

Description: Initial rate filing per 35.12, MBR Application to be effective 1/9/2015.

Filed Date: 11/21/14.

Accession Number: 20141121–5202.

Comments Due: 5 p.m. ET 12/12/14.

Docket Numbers: ER15–464–000.

Applicants: Idaho Power Company.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): Order No. 676–H Waiver Request and Compliance Filing to be effective 2/1/2015.

Filed Date: 11/24/14.

Accession Number: 20141124–5008.

Comments Due: 5 p.m. ET 12/15/14.

Docket Numbers: ER15–465–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Request for Waiver of Midcontinent Independent System Operator, Inc.

Filed Date: 11/21/14.

Accession Number: 20141121–5245.

Comments Due: 5 p.m. ET 12/12/14.

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 5:00 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 24, 2014.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2014–28470 Filed 12–3–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER15–212–001.

Applicants: Southwest Power Pool, Inc.

Description: Tariff Amendment per 35.17(b): 2900R1 Substitute Kansas Municipal Energy Agency NITSA NOA to be effective 8/1/2014.

Filed Date: 11/24/14.

Accession Number: 20141124–5118.

Comments Due: 5 p.m. ET 12/15/14.

Docket Numbers: ER15–232–001.

Applicants: Southwest Power Pool, Inc.

Description: Tariff Amendment per 35.17(b): 2415R3 Substitute Kansas Municipal Energy Agency NITSA & NOA to be effective 8/1/2014.

Filed Date: 11/24/14.

Accession Number: 20141124–5158.

Comments Due: 5 p.m. ET 12/15/14.

Docket Numbers: ER15–466–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): 2014–11–24 City of Alexandria to Schedules 7,8,9 to be effective 12/1/2014.

Filed Date: 11/24/14.

Accession Number: 20141124–5120.

Comments Due: 5 p.m. ET 12/15/14.

Docket Numbers: ER15–467–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): 2014–11–24 SA 2414 ATC-Dairyland T–T 1st Rev. to be effective 10/25/2014.

Filed Date: 11/24/14.

Accession Number: 20141124–5135.

Comments Due: 5 p.m. ET 12/15/14.

Docket Numbers: ER15–468–000.

Applicants: Bayonne Plant Holding, L.L.C.

Description: Request for Limited Waiver of Bayonne Plant Holding, L.L.C.

Filed Date: 11/24/14.

Accession Number: 20141124–5155.

Comments Due: 5 p.m. ET 12/15/14.

Docket Numbers: ER15–469–000.

Applicants: Duke Energy Carolinas, LLC.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): NCMPA1 RS 318 Amendment (2014) to be effective 12/31/2014.

Filed Date: 11/24/14.

Accession Number: 20141124–5201.

Comments Due: 5 p.m. ET 12/15/14.

Take notice that the Commission received the following PURPA 210(m)(3) filings:

Docket Numbers: QM14–3–000.

Applicants: Entergy Arkansas, Inc., Entergy Gulf States Louisiana, L.L.C., Entergy Louisiana, LLC, Entergy Mississippi, Inc., Entergy New Orleans, Inc., Entergy Services, Inc., Entergy Texas, Inc., Entergy Services, Inc.

Description: Motion for Leave to Answer and Answer to Protests of Entergy Services, Inc., et al.

Filed Date: 11/21/14.

Accession Number: 20141121–5265.
Comments Due: 5 p.m. ET 12/19/14.

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 5:00 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 24, 2014.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2014–28471 Filed 12–3–14; 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 corporate filings:

Docket Numbers: EC15–12–000.
Applicants: Catalina Solar 2, LLC.
Description: Supplement to October 17, 2014 Application of Catalina Solar 2, LLC for Authorization under Section 203 of the Federal Power Act.
Filed Date: 11/25/14.
Accession Number: 20141125–5222.
Comments Due: 5 p.m. ET 12/5/14.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–3097–003.
Applicants: Bruce Power Inc.
Description: Supplement to June 27, 2014 Updated Market Power Analysis for the Northeast Region of Bruce Power Inc.
Filed Date: 11/25/14.
Accession Number: 20141125–5211.
Comments Due: 5 p.m. ET 12/16/14.
Docket Numbers: ER11–3697–000.
Applicants: Southern California Edison Company.
Description: Informational Filing of Notice of Revision to Formula Transmission Rate Annual Update of Southern California Edison Company.
Filed Date: 11/25/14.
Accession Number: 20141125–5208.
Comments Due: 5 p.m. ET 12/16/14.
Docket Numbers: ER12–2178–010; ER14–1524–002; ER13–1536–004; ER12–2528–009; ER12–2311–009; ER12–2201–009; ER12–1829–009; ER12–1223–014; ER11–3989–014; ER11–2016–016; ER11–2014–018; ER11–2013–018; ER11–2011–017; ER11–2010–018; ER11–2009–017; ER11–2007–016; ER11–2005–018; ER10–3308–020; ER10–3027–002; ER10–3025–004; ER10–2192–021; ER10–2184–021; ER10–2183–018; ER10–2182–025; ER10–2181–025; ER10–2180–021; ER10–2179–025; ER10–2178–021; ER10–2172–021; ER14–2144–002; ER11–2056–002; ER10–1143–017; ER10–1080–017; ER10–1081–017; ER10–1078–017; ER10–1048–018; ER10–1020–017; ER14–2145–001.
Applicants: AV Solar Ranch 1, LLC, Baltimore Gas and Electric Company, Beebe 1B Renewable Energy, LLC, Beebe Renewable Energy, LLC, Calvert Cliffs Nuclear Power Plant LLC, Cassia Gulch Wind Park, LLC, CER Generation, LLC,CER Generation II, LLC, Commonwealth Edison Company, Constellation Energy Commodities Group Maine, LLC, Constellation Mystic Power, LLC, Constellation NewEnergy, Inc., Constellation Power Source Generation, LLC, Cow Branch Wind Power LLC, CR Clearing, LLC, Criterion Power Partners, LLC, Exelon Framingham, LLC, Exelon Generation Company, LLC, Exelon New Boston, LLC, Exelon West Medway, LLC, Exelon Wind 4, LLC, Exelon Wyman, LLC, Fourmile Wind Energy, LLC, Handsome Lake Energy, LLC, Harvest WindFarm, LLC, Harvest II Windfarm, LLC, High Mesa Energy, LLC, Integrys Energy Services, Inc., Integrys Energy Services of New York, Inc., Michigan Wind 1, LLC, Michigan Wind 2, LLC, Nine Mile Point Nuclear Station, LLC, PECO Energy Company, R.E. Ginna Nuclear Power Plant, LLC, Shooting Star Wind Project, LLC, Tuana Springs Energy, LLC, Wildcat Wind, LLC, Wind Capital Holdings, LLC.
Description: Notice of Non-Material Change in Status of the Integrys and Exelon MBR Entities under ER12–2178, et. al.
Filed Date: 11/24/14.
Accession Number: 20141124–5286.
Comments Due: 5 p.m. ET 12/15/14.
Docket Numbers: ER14–1224–002.
Applicants: Duke Energy Carolinas, LLC.
Description: Tariff Amendment per 35.17(b): Amendment to PMPA NITSA OATT SA 355 to be effective 1/1/2014.
Filed Date: 11/24/14.
Accession Number: 20141124–5224.
Comments Due: 5 p.m. ET 12/15/14.
Docket Numbers: ER14–2399–003.
Applicants: Southwest Power Pool, Inc.
Description: Tariff Amendment per 35.17(b): Amendment in ER14–2399—Attachment AE (MPL) Section 7.1.1 to be effective 9/8/2014.
Filed Date: 11/25/14.
Accession Number: 20141125–5261.
Comments Due: 5 p.m. ET 12/16/14.
Docket Numbers: ER14–2982–001.
Applicants: Millennium Power Partners, L.P.
Description: Compliance filing per 35: Additional Revisions to Change in Stations to be effective 11/26/2014.
Filed Date: 11/25/14.
Accession Number: 20141125–5055.
Comments Due: 5 p.m. ET 12/16/14.
Docket Numbers: ER15–27–001.
Applicants: New Athens Generating Company, LLC.
Description: Tariff Amendment per 35.17(b): Additional Revisions to MBR Tariff to be effective 11/24/2014.
Filed Date: 11/25/14.
Accession Number: 20141125–5171.
Comments Due: 5 p.m. ET 12/16/14.
Docket Numbers: ER15–255–000.
Applicants: Duke Energy Beckjord Storage, LLC.
Description: Amendment to October 31, 2014 Duke Energy Beckjord Storage, LLC tariff filing.
Filed Date: 11/21/14.
Accession Number: 20141121–5160.
Comments Due: 5 p.m. ET 12/12/14.
Docket Numbers: ER15–470–000.
Applicants: New York Independent System Operator, Inc.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): NYISO 205 filing: tariff revisions credit requirement for external transactions to be effective 2/18/2015.
Filed Date: 11/24/14.
Accession Number: 20141124–5225.
Comments Due: 5 p.m. ET 12/15/14.
Docket Numbers: ER15–470–001.
Applicants: New York Independent System Operator, Inc.
Description: Tariff Amendment per 35.17(b): NYISO amendment errata filing to 11/24/14 tariff revision filing to be effective 2/18/2015.
Filed Date: 11/25/14.
Accession Number: 20141125–5201.
Comments Due: 5 p.m. ET 12/16/14.
Docket Numbers: ER15–471–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): 1884R3 Westar Energy, Inc. NITSA and NOA to be effective 8/1/2014.

Filed Date: 11/25/14.
Accession Number: 20141125–5069.
Comments Due: 5 p.m. ET 12/16/14.
Docket Numbers: ER15–472–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): 1885R3 Westar Energy, Inc. (City of Bronson) NITSA and NOA to be effective 8/1/2014.
Filed Date: 11/25/14.
Accession Number: 20141125–5070.
Comments Due: 5 p.m. ET 12/16/14.
Docket Numbers: ER15–473–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): 1886R3 Westar Energy, Inc. (Doniphan) NITSA and NOA to be effective 8/1/2014.
Filed Date: 11/25/14.
Accession Number: 20141125–5086.
Comments Due: 5 p.m. ET 12/16/14.
Docket Numbers: ER15–474–000.
Applicants: Ocean State Power LLC.
Description: Tariff Withdrawal per 35.15: Ocean State Power II Notice of Cancellation to be effective 11/25/2014.
Filed Date: 11/25/14.
Accession Number: 20141125–5120.
Comments Due: 5 p.m. ET 12/16/14.
Docket Numbers: ER15–475–000.
Applicants: Public Service Company of New Mexico.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): Certificate of Concurrence with TEP's Rate Schedule No. 104 to be effective 12/29/2014.
Filed Date: 11/25/14.
Accession Number: 20141125–5133.
Comments Due: 5 p.m. ET 12/16/14.
Docket Numbers: ER15–476–000.
Applicants: Louisville Gas and Electric Company.
Description: Compliance filing per 35: Order 676_H Section 4 Rev to be effective 2/2/2015.
Filed Date: 11/25/14.
Accession Number: 20141125–5136.
Comments Due: 5 p.m. ET 12/16/14.
Docket Numbers: ER15–477–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): 1888R3 Westar Energy, Inc. NITSA and NOA to be effective 8/1/2014.
Filed Date: 11/25/14.
Accession Number: 20141125–5153.
Comments Due: 5 p.m. ET 12/16/14.
Docket Numbers: ER15–478–000.
Applicants: MATL LLP.
Description: Compliance filing per 35: NAESB Compliance Filing to be effective 2/2/2015.
Filed Date: 11/25/14.
Accession Number: 20141125–5164.
Comments Due: 5 p.m. ET 12/16/14.
Docket Numbers: ER15–479–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): 1890R3 Westar Energy, Inc. NITSA and NOA to be effective 8/1/2014.
Filed Date: 11/25/14.
Accession Number: 20141125–5194.
Comments Due: 5 p.m. ET 12/16/14.
Docket Numbers: ER15–480–000.
Applicants: Pacific Gas and Electric Company.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): Shelter Cover Extension Amendment Filing to be effective 12/1/2014.
Filed Date: 11/25/14.
Accession Number: 20141125–5204.
Comments Due: 5 p.m. ET 12/16/14.
Docket Numbers: ER15–481–000.
Applicants: AEP Texas Central Company.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): TCC–EC&R Development PDA to be effective 11/3/2014.
Filed Date: 11/25/14.
Accession Number: 20141125–5248.
Comments Due: 5 p.m. ET 12/16/14.

Take notice that the Commission received the following electric reliability filings:

Docket Numbers: RR14–8–000.
Applicants: North American Electric Reliability Corp.
Description: Errata to September 16, 2014 Petition of the North American Electric Reliability Corporation for Approval of the Bylaws and Reliability Standards Development Procedures of the Western Electricity Coordinating Council.
Filed Date: 11/21/14.
Accession Number: 20141121–5269.
Comments Due: 5 p.m. ET 12/1/14.

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 5:00 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 25, 2014.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2014–28472 Filed 12–3–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP14–555–000]

Dominion Transmission, Inc.; Notice of Intent To Prepare an Environmental Assessment for the Proposed Lebanon West II Project and Request for Comments on Environmental Issues

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the Lebanon West II Project (Project) involving construction, operation, and abandonment of facilities by Dominion Transmission, Inc. (DTI) in Armstrong, Allegheny, and Beaver Counties, Pennsylvania, and Licking, Fayette, Coshocton, Tuscarawas, Harrison, Carroll, and Columbiana Counties, Ohio. The Commission will use this EA in its decision-making process to determine whether the project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies on the project. Your input will help the Commission staff determine what issues they need to evaluate in the EA. Please note that the scoping period will close on December 26, 2014.

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives should notify their constituents of this proposed project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The company would seek to negotiate a mutually acceptable agreement. However, if the Commission approves the project, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings where compensation would be determined in accordance with state law.

DTI provided landowners with a fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' This fact sheet addresses a number of typically-asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. It is also available for viewing on the FERC Web site (*www.ferc.gov*).

Summary of the Proposed Project

DTI proposes to replace 11 segments of 26- and 30-inch-diameter pipeline and install compressor station facilities to transport 130,000 dekatherms per day on behalf of R. E. Gas Development, LLC from DTI's MarkWest Liberty Bluestone Interconnect in Butler County, Pennsylvania to DTI's Lebanon-Texas Gas Interconnect in Warren County, Ohio. DTI also proposes to increase the maximum allowable operating pressure of these pipeline segments from 745 pounds per square inch gauge (psig) to 848 psig.

The Project would consist of the following facilities:

1. Pipeline Facilities—DTI would undertake the following activities on its existing TL–400 Pipeline:

- Segment 14—abandon in-place about 2,647 feet, abandon by removal about 8,420 feet, and construct about 11,067 feet of 26-inch-diameter replacement pipeline in Coshocton and Tuscarawas Counties, Ohio.
- Segment 15—abandon in-place about 664 feet, abandon by removal about 1,434 feet, and construct about 2,098 feet of 26-inch-diameter replacement pipeline in Tuscarawas County.
- Segment 16—abandon in-place about 1,654 feet, abandon by removal about 4,159 feet, and construct about 5,813 feet of 30-inch-diameter replacement pipeline in Tuscarawas County.
- Segment 17—abandon in-place about 6,664 feet, abandon by removal about 3,418 feet, and construction of about 10,082 feet of 30-inch-diameter replacement pipeline in Harrison County, Ohio.
- Segment 19—abandon in-place about 1,805 feet, abandon by removal about 6,243 feet, and construct about 8,048 feet of 30-inch-diameter replacement pipeline in Carroll County.
- Segment 20—abandon in-place about 1,413 feet, abandon by removal about 3,708 feet, and construct about 5,121 feet of 30-inch-diameter replacement pipeline in Carroll County.
- Segment 21—abandon by removal about 1,709 feet, and construct about 1,709 feet of 30-inch-diameter replacement pipeline in Columbiana County, Ohio.
- Segment 22—abandon in-place about 920 feet, abandon by removal about 3,277 feet, and construct about 4,197 feet of 30-inch-diameter replacement pipeline in Columbiana County.
- Segment 24—abandon in-place about 897 feet, abandon by removal about 2,714 feet, and construct about 3,611 feet of 30-inch-diameter replacement pipeline in Columbiana County.
- Segment 25—abandon in-place about 151 feet, abandon by removal about 951 feet, and construct about 1,102 feet of 30-inch-diameter replacement pipeline in Columbiana County.
- Segment 27—abandon by removal about 986 feet, and construct about 986 feet of 30-inch-diameter replacement pipeline in Beaver County, Pennsylvania.

2. Aboveground Facilities—DTI proposes to undertake the following activities on its existing facilities as described below:

- Rural Valley Compressor Station—Install a new 10,915-horsepower Solar Taurus 70S combustion turbine and a 3.5 million British thermal units per hour (MMBtu/hr) boiler that would replace an existing 2.1 MMBtu/hr boiler at the Rural Valley Compressor Station, in Armstrong County, Pennsylvania. In addition, DTI would install one new gas cooler, one new filter separator, a blowdown separator/silencer, new suction/discharge tie-ins, and expand the existing compressor building to accommodate the new compressor unit.
- Newark Compressor Station—Install additional regulation at the existing Newark Compressor Station in Licking County, Ohio to reduce the pressure in the TL–400 Pipeline as the gas flows west from the compressor station.
- Beaver Compressor Station—Install additional regulation at the existing Beaver Compressor Station in Beaver County, Pennsylvania to allow additional gas to flow from the TL–400 Extension 1 Pipeline into the TL–400 Pipeline.
- Washington Compressor Station—Install four new valves and 30-inch diameter steel crossover piping at the existing Washington Compressor Station in Fayette County, Ohio.
- Coxcomb Gate Assembly—Install a new relief valve on the existing LN–25 Pipeline at the existing Coxcomb Gate Site in Allegheny County, Pennsylvania.

The general location of the project facilities is shown in appendix 1.[1]

Land Requirements for Construction

DTI's replacement activities would disturb a total of about 196.4 acres, including 128.6 acres for abandonment of existing pipeline segments and installation of new pipeline, 10.9 acres for 63 additional temporary work spaces, 14.6 acres for use of 28 access roads, 18.7 acres for 10 pipe storage and contractor yards, and 23.6 acres for installation of aboveground facilities. Following construction DTI would maintain a total of about 109.4 acres for permanent operation of the projects facilities, and the remaining acreage would be restored and revert to former uses.

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us [2] to discover and address concerns the public may have about proposals. This process is referred to as ''scoping.'' The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in the EA. We will consider all filed comments during the preparation of the EA.

In the EA we will discuss impacts that could occur as a result of the construction and operation of the proposed project under these general headings:

- Geology and soils;
- land use;
- water resources, fisheries, and wetlands;
- cultural resources;
- vegetation and wildlife;
- air quality and noise;
- endangered and threatened species;
- public safety; and
- cumulative impacts.

We will also evaluate reasonable alternatives to the proposed project or portions of the project, and make

[1] The appendices referenced in this notice will not appear in the **Federal Register**. Copies of appendices were sent to all those receiving this notice in the mail and are available at *www.ferc.gov* using the link called ''eLibrary'' or from the Commission's Public Reference Room, 888 First Street NE., Washington, DC 20426, or call (202) 502–8371. For instructions on connecting to eLibrary, refer to the last page of this notice.

[2] ''We,'' ''us,'' and ''our'' refer to the environmental staff of the Commission's Office of Energy Projects.

recommendations on how to lessen or avoid impacts on the various resource areas.

The EA will present our independent analysis of the issues. The EA will be available in the public record through eLibrary. Depending on the comments received during the scoping process, we may also publish and distribute the EA to the public for an allotted comment period. We will consider all comments on the EA before making our recommendations to the Commission. To ensure we have the opportunity to consider and address your comments, please carefully follow the instructions in the Public Participation section beginning on page 6.

With this notice, we are asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues of this project to formally cooperate with us in the preparation of the EA.[3] Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice.

Consultations Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, we are using this notice to initiate consultation with the applicable State Historic Preservation Offices (SHPOs), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the project's potential effects on historic properties.[4]

We will define the project-specific Area of Potential Effects (APE) in consultation with the SHPOs as the project develops. On natural gas facility projects, the APE at a minimum encompasses all areas subject to ground disturbance (examples include construction right-of-way, contractor/pipe storage yards, compressor stations, and access roads). Our EA for this project will document our findings on the impacts on historic properties and summarize the status of consultations under section 106.

[3] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Part 1501.6.

[4] The Advisory Council on Historic Preservation's regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

Currently Identified Environmental Issues

We have already identified several issues that we think deserve attention based on a preliminary review of the proposed facilities and the environmental information provided by DTI. This preliminary list of issues may be changed based on your comments and our analysis.

- Impacts on federally listed threatened and endangered species
- impacts on wetlands
- impacts on perennial waterbodies

Public Participation

You can make a difference by providing us with your specific comments or concerns about the project. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that your comments are timely and properly recorded, please send your comments so that the Commission receives them in Washington, DC on or before December 26, 2014.

For your convenience, there are three methods which you can use to submit your comments to the Commission. In all instances please reference the project docket number (CP14–555–000) with your submission. The Commission encourages electronic filing of comments and has expert staff available to assist you at (202) 502–8258 or *efiling@ferc.gov*.

(1) You can file your comments electronically using the *eComment* feature on the Commission's Web site (*www.ferc.gov*) under the link to *Documents and Filings.* This is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You can file your comments electronically using the *eFiling* feature on the Commission's Web site (*www.ferc.gov*) under the link to *Documents and Filings.* With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''*eRegister.''* You must select the type of filing you are making. If you are filing a comment on a particular project, please select ''Comment on a Filing''; or

(3) You can file a paper copy of your comments by mailing them to the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project. We will update the environmental mailing list as the analysis proceeds to ensure that we send the information related to this environmental review to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed project.

If we publish and distribute the EA, copies will be sent to the environmental mailing list for public review and comment. If you would prefer to receive a paper copy of the document instead of the CD version or would like to remove your name from the mailing list, please return the attached Information Request (appendix 2).

Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an ''intervenor'' which is an official party to the Commission's proceeding. Intervenors play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene. Instructions for becoming an intervenor are in the User's Guide under the ''e-filing'' link on the Commission's Web site.

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC Web site at *www.ferc.gov* using the ''eLibrary'' link. Click on the eLibrary link, click on ''General Search'' and enter the docket number, excluding the last three digits in the Docket Number field (*i.e.,* CP14–555). Be sure you have selected an appropriate date range. 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. The eLibrary link also provides access to the

texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission now offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/docs-filing/esubscription.asp.*

Finally, public meetings or site visits will be posted on the Commission's calendar located at *www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Dated: November 25, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–28490 Filed 12–3–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of FERC Staff Attendance at the Entergy Regional State Committee Meeting

The Federal Energy Regulatory Commission (Commission) hereby gives notice that members of its staff may attend the meeting noted below. Their attendance is part of the Commission's ongoing outreach efforts.

Entergy Regional State Committee

December 2, 2014 (9:30 a.m.–12:30 p.m. Central)

This meeting will be held at the Hilton Austin, 500 East 4th St., Austin, TX 78701.

The discussions may address matters at issue in the following proceedings:

Docket No. EL01–88, Louisiana Public Service Commission v. Entergy Services, Inc.
Docket No. EL09–50, Louisiana Public Service Commission v. Entergy Services, Inc.
Docket No. EL09–61, Louisiana Public Service Commission v. Entergy Services, Inc.
Docket No. EL10–55, Louisiana Public Service Commission v. Entergy Services, Inc.
Docket No. EL10–65, Louisiana Public Service Commission v. Entergy Services, Inc.
Docket No. EL11–30, Midcontinent Independent System Operator, Inc. v. Southwest Power Pool, Inc.
Docket No. EL11–34, Midwest Independent Transmission System Operator, Inc. v. Southwest Power Pool, Inc.
Docket No. EL11–57, Louisiana Public Service Commission v. Entergy Services, Inc., et al.
Docket No. EL11–63, Louisiana Public Service Commission v. Entergy Services, Inc.
Docket No. EL11–65, Louisiana Public Service Commission v. Entergy Services, Inc.
Docket No. EL13–41, Occidental Chemical Company v. Midwest Independent System Transmission Operator, Inc.
Docket No. EL14–19, Midcontinent Independent System Operator and Entergy Services, Inc.
Docket No. EL14–21, Southwest Power Pool, Inc. v. Midcontinent Independent System Operator, Inc.
Docket No. EL14–46, Ameren Services Co.
Docket No. ER07–956, Entergy Services, Inc.
Docket No. ER08–1056, Entergy Services, Inc.
Docket No. ER09–1224, Entergy Services, Inc.
Docket No. ER10–794 Entergy Services, Inc.
Docket No. ER10–1350, Entergy Services, Inc.
Docket No. ER10–2001, Entergy Arkansas, Inc.
Docket No. ER10–3357, Entergy Arkansas, Inc.
Docket No. ER11–2161, Entergy Texas, Inc.
Docket No. ER11–3658, Entergy Services, Inc.
Docket No. ER12–1384, Entergy Arkansas, Inc.
Docket No. ER12–1385, Entergy Gulf States Louisiana, L.L.C.
Docket No. ER12–1386, Entergy Louisiana, LLC
Docket No. ER12–1387, Entergy Mississippi, Inc.
Docket No. ER12–1388, Entergy New Orleans, Inc.
Docket No. ER12–1390, Entergy Texas, Inc.
Docket No. ER12–1920, Entergy Services, Inc.
Docket No. ER13–432, Entergy Services, Inc.
Docket No. ER13–769, Entergy Arkansas, Inc. and Entergy Mississippi, Inc.
Docket No. ER13–770, Entergy Arkansas, Inc. and Entergy Louisiana, LLC.
Docket No. ER13–948, Entergy Services, Inc.
Docket No. ER13–1195, Entergy Services, Inc.
Docket No. ER13–1317, Entergy Arkansas, Inc.
Docket No. ER13–1508, Entergy Arkansas, Inc.
Docket No. ER13–1509, Entergy Gulf States Louisiana, L.L.C.
Docket No. ER13–1510, Entergy Louisiana, LLC
Docket No. ER13–1511, Entergy Mississippi, Inc.
Docket No. ER13–1512, Entergy New Orleans, Inc.
Docket No. ER13–1513, Entergy Texas, Inc.
Docket No. ER13–1595, Entergy Services, Inc.
Docket No. ER13–1623, Entergy Services, Inc.
Docket No. ER14–73, Entergy Services, Inc.
Docket No. ER14–75, Entergy Arkansas, Inc.
Docket No. ER14–76, Entergy Gulf States Louisiana, L.L.C.
Docket No. ER14–77, Entergy Louisiana, LLC
Docket No. ER14–78, Entergy Mississippi, Inc.
Docket No. ER14–79, Entergy New Orleans, Inc.
Docket No. ER14–80, Entergy Texas, Inc.
Docket No. ER14–89, Entergy Arkansas, Inc.
Docket No. ER14–108, Entergy Services, Inc.
Docket No. ER14–128, Entergy Texas, Inc.
Docket No. ER14–148, Midcontinent Independent System Operator
Docket No. ER14–673, Entergy Arkansas, Inc.
Docket No. ER14–693, Entergy Services, Inc.
Docket No. ER14–694, Entergy Services, Inc.
Docket No. ER14–696, Entergy Services, Inc.
Docket No. ER14–697, Entergy Services, Inc.
Docket No. ER14–700, Entergy Services, Inc.
Docket No. ER14–702, Entergy Services, Inc.
Docket No. ER14–703, Entergy Services, Inc.
Docket No. ER14–704, Entergy Services, Inc.
Docket No. ER14–1174, Southwest Power Pool, Inc.
Docket No. ER14–1263, Entergy Gulf States Louisiana, L.L.C.
Docket No. ER14–1264, Entergy Louisiana, LLC
Docket No. ER14–1265, Entergy Mississippi, Inc.
Docket No. ER14–1266, Entergy New Orleans, Inc.
Docket No. ER14–1267, Entergy Texas, Inc.

Docket No. ER14–1268, Entergy Arkansas, Inc.
Docket No. ER14–1328, Entergy Louisiana, LLC
Docket No. ER14–1329, Entergy Gulf States Louisiana, L.L.C.
Docket No. ER14–2085, Entergy Services, Inc.
Docket No. ER14–2850, Southwest Power Pool, Inc.
Docket No. ER14–2851, Southwest Power Pool, Inc.

These meetings are open to the public.

For more information, contact Patrick Clarey, Office of Energy Market Regulation, Federal Energy Regulatory Commission at (317) 249–5937 or *patrick.clarey@ferc.gov.*

Dated: November 25, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–28491 Filed 12–3–14; 8:45 am]

BILLING CODE 6717–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1030]

Information Collection Being Submitted for Review and Approval to the Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before January 5, 2015. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, OMB, via email *Nicholas_A._Fraser@omb.eop.gov;* and to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** section below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Cathy Williams at (202) 418–2918. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page *http://www.reginfo.gov/public/do/PRAMain*, (2) look for the section of the Web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the OMB control number of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1030.

Title: Service Rules for Advanced Wireless Services (AWS) in the 1.7 GHz and 2.1 GHz Bands.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities; state, local, or tribal government; Federal Government and not for profit institutions.

Number of Respondents: 393 respondents; 83,505 responses.

Estimated Time per Response: 0.25 to 5 hours.

Frequency of Response: Annual, semi-annual, one time, and on occasion reporting requirements, recordkeeping requirement, third-party disclosure requirements, and every ten years reporting requirements.

Obligation To Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in sections 1, 2, 4(i), 201, 301, 302, 303, 307, 308, 309, 310, 316, 319, 324, 332, and 333 of the Communications Act of 1934, as amended, and sections 6003, 6004, and 6401 of the Middle Class Tax Relief Act of 2012, Public Law 112–96, 126 Stat. 156, 47 U.S.C. 151, 152, 154(i), 201, 301, 302(a), 303, 307, 308, 309, 310, 316, 319, 324, 332, 333, 1403, 1404, and 1451.

Total Annual Burden: 24,417 hours.

Total Annual Cost: $508,120.

Privacy Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: The Commission seeks the Office of Management and Budget (''OMB'') approval for a revision to obtain the full three-year clearance for the requirements described below. We are revising the estimates of the currently approved information collections primarily to reflect the issuance of the AWS–3 Report and Order, FCC 14–31, whose information collection requirements for new spectrum bands would increase the number of respondents, responses, hourly burden, and annual costs associated with these bands. We are also updating prior estimates for other related spectrum bands. The following information collection requirements by AWS–3 applicants are not effective until approved by the Office of Management and Budget and apply to the following rule sections:

Section 27.14(k) and (s)—set forth performance requirements for AWS–3 licensees. Section 27.14(s) requires AWS–3 licensees to offer service to 40 percent of the population of their license areas within six years of licensing, and to 75 percent of the population within 12 years (accelerated to 10 years if the interim performance requirement is not met). These performance timeframes are different from those for AWS–4 due to the longer initial AWS–3 license terms (12 years versus 10 years for AWS–4). Section 27.14(k) requires AWS–3 licensees to demonstrate compliance with the performance requirements by filing construction notifications with the Commission within 15 days of the expiration of the applicable benchmark, certifying whether they meet the applicable performance requirements, and including a description and

certification of the areas for which they are providing service. Construction notifications must include electronic coverage maps, supporting technical documentation, and any other information as the Wireless Telecommunications Bureau may prescribe by public notice.

Section 27.14(s)—requires AWS–3 licensees to make a ''renewal showing'' at the time of license renewal—independent of the performance requirements—as a condition of renewal. The showing must include a detailed description of the applicant's provision of service during the entire license period and address: (1) The level and quality of service provided by the applicant (*e.g.,* the population served, the area served, the number of subscribers, the services offered); (2) the date service commenced, whether service was ever interrupted, and the duration of any interruption or outage; (3) the extent to which service is provided to rural areas; (4) the extent to which service is provided to qualifying tribal land as defined in § 1.2110(f)(3)(i); and (5) any other factors associated with the level of service to the public.

Section 27.17(c)—requires that an AWS–3 licensee that permanently discontinues service must notify the Commission of the discontinuance within 10 days by filing FCC Form 601 or 605 requesting license cancellation. It also provides that an authorization will automatically terminate, without specific Commission action, if service is permanently discontinued, even if a licensee fails to file the required form requesting license cancellation. Sections 27.17(a) and (b) define permanent discontinuation of service as 180 days during which a licensee does not provide service to at least one unaffiliated subscriber.

Section 27.50(d)(3)—requires that a licensee operating an AWS–3 base or fixed station utilizing a power greater than 1640 watts EIRP or 1640 watts/MHz EIRP must be coordinated in advance with the following licensees authorized to operate within 120 kilometers (75 miles) of the base or fixed station: All Broadband Radio Service (BRS) licensees authorized in the 2155–2160 MHz band, and all AWS licensees authorized to operate on adjacent frequency blocks in the 2110–2180 MHz band.

Section 27.1131—requires AWS–3 licensees, prior to initiating operations from any base or fixed station, to coordinate their frequency usage with incumbent co-channel and adjacent-channel fixed point-to-point microwave licensees operating in the 2110–2150 MHz and 2160–2200 MHz bands. If coordination does not resolve potential conflicts, an AWS licensee may undertake to relocate the FS stations under Part 101, Subpart B of the Commission's rules. Although AWS–1 licensees have relocated many FS legacy operations, AWS–3 licensees will likely have to relocate some remaining incumbents, resulting in disclosures described below. Under section 101.79 of the Commission's rules, these requirements will sunset ten years after the first AWS license is issued in the band.

Section 27.1132—requires AWS–3 licensees in the 2155–2160/62 MHz band to protect BRS stations from interference or to relocate them prior to initiating operations. Under section 27.1253 of the Commission's rules, these requirements will sunset fifteen years after the first AWS license is issued in the band.

Section 27.1134(c)—requires AWS–3 licensees to coordinate with Federal Government incumbents before commencing operations in the 1695–1710 MHz band. For transmitters operating with a maximum EIRP of 20 dBm, coordination is required inside 27 specific Protection Zones detailed in U.S. note 88 to section 2.106 of the Commission's rules and in the 2014 Joint PN. For higher-powered operations, § 27.1134(c) and U.S. note 88 to § 2.106 both require coordination nationwide unless otherwise specified by FCC rule, order, or notice. The 2014 Joint PN (see below) refined the nationwide default zone for higher-power operations by adding 27 Protection Zones (larger than the zones for operations up to 20 dBm, to account for the higher power).

Section 27.1134(f)—requires AWS–3 licensees to coordinate with Federal Government incumbents before commencing operations in the 1755–1780 MHz band. While the default coordination requirement for this band is nationwide, the 2014 Joint PN (see below) effectively reduced the scope of coordination to specific Protection Zones for many AWS–3 licensees that limit transmitter power to 20 dBm EIRP.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of the Managing Director.

[FR Doc. 2014–28496 Filed 12–3–14; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–xxxx]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before February 2, 2015. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–xxxx.

Title: Certification of TV Broadcast Licensee Technical Information in Advance of Incentive Auction.

Form No.: Form 2100, Schedule 381, Pre-Auction Technical Certification Form.

Type of Review: New information collection.

Respondents: Business or other for profit entities; not for profit institutions.

Number of Respondents and Responses: 2,170 respondents and 2,170 responses.

Estimated Time per Response: 2 hours.

Frequency of Response: One-time reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in Public Law 112–96, §§ 6402 (codified at 47 U.S.C. 309(j)(8)(G)), 6403 (codified at 47 U.S.C. 1452), 126 Stat. 156 (2012) (Spectrum Act).

Total Annual Burden: 2,170 hours.

Annual Cost Burden: $542,500.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: Some assurances of confidentiality are being provided to the respondents. Parties filing Form 2100, Schedule 381 may seek confidential treatment of information they provide pursuant to the Commission's existing confidentiality rules (*See* 47 CFR 0.459).

Needs and Uses: The information gathered in this collection will be used to support the Federal Communications Commission's efforts to hold an incentive auction, as required by the Middle Class Tax Relief and Job Creation Act of 2012 (Spectrum Act) (Pub. L. 112–96, §§ 6402 (codified at 47 U.S.C. 309(j)(8)(G)), 6403 (codified at 47 U.S.C. 1452), 126 Stat. 156 (2012)). In the *Incentive Auction Order,* the Commission directed the Media Bureau to develop a form to be submitted prior to the incentive auction by each full power and Class A broadcast licensee to certify that it has reviewed the technical data on file with the Commission related to its current license authorization and confirm that the technical data is correct with respect to actual operations FCC Form 2100, Schedule 381, Pre-Auction Technical Certification Form. *See* Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions, Report and Order, GN Docket 12–268, Report and Order, 29 FCC Rcd 6567, 6820 (2014) (''*Incentive Auction Order*''). This data collection will also collect from licensees basic data regarding equipment currently in use at each licensed facility to facilitate the channel reassignment process following the completion of the incentive auction. Licensees will submit FCC Form 2100, Schedule 381 one time, at a deadline to be announced by the Media Bureau in advance of the incentive auction.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of the Managing Director.

[FR Doc. 2014–28497 Filed 12–3–14; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

AGENCY: Federal Election Commission.

DATE AND TIME: Tuesday December 9, 2014 at 10:00 a.m.

PLACE: 999 E Street NW., Washington, DC.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 2 U.S.C. § 437g.

Matters concerning participation in civil actions or proceedings or arbitration.

* * * * *

PERSON TO CONTACT FOR INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Shelley E. Garr,

Deputy Secretary of the Commission.

[FR Doc. 2014–28590 Filed 12–2–14; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

Board of Governors of the Federal Reserve System Meeting Notice

TIME AND DATE: 3:00 p.m. on Tuesday, December 9, 2014.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th Street entrance between Constitution Avenue and C Streets NW., Washington, DC 20551.

STATUS: Open.

On the day of the meeting, you will be able to view the meeting via webcast from a link available on the Board's public Web site. *You do not need to register to view the webcast of the meeting.* A link to the meeting documentation will also be available approximately 20 minutes before the start of the meeting. Both links may be accessed from the Board's public Web site at *www.federalreserve.gov.*

If you plan to attend the open meeting in person, we ask that you notify us in advance and provide your name, date of birth, and social security number (SSN) or passport number. You may provide this information by calling 202–452–2474 or you may *register online.* You may pre-register until close of business on December 8, 2014. You also will be asked to provide identifying information, including a photo ID, before being admitted to the Board meeting. The Public Affairs Office must approve the use of cameras; please call 202–452–2955 for further information. If you need an accommodation for a disability, please contact Penelope Beattie on 202–452–3982. For the hearing impaired only, please use the Telecommunication Device for the Deaf (TDD) on 202–263–4869.

PRIVACY ACT NOTICE: The information you provide will be used to assist us in prescreening you to ensure the security of the Board's premises and personnel. In order to do this, we may disclose your information consistent with the routine uses listed in the Privacy Act Notice for BGFRS–32, including to appropriate federal, state, local, or foreign agencies where disclosure is reasonably necessary to determine whether you pose a security risk or where the security or confidentiality of your information has been compromised. We are authorized to collect your information by 12 U.S.C. §§ 243 and 248, and Executive Order 9397. In accordance with Executive Order 9397, we collect your SSN so that we can keep accurate records, because other people may have the same name and birth date. In addition, we use your SSN when we make requests for information about you from law enforcement and other regulatory agency databases. Furnishing the information requested is voluntary; however, your failure to provide any of the information requested may result in disapproval of your request for access to the Board's premises. You may be subject to a fine or imprisonment under 18 U.S.C. § 1001 for any false statements you make in your request to enter the Board's premises.

Matters To Be Considered

Discussion Agenda

1. Proposal to Establish Risk-Based Capital Surcharges for Systemically Important Bank Holding Companies.

Notes: 1. The staff memo to the Board will be made available to the public on the day of the meeting in paper and the background material will be made available on a compact disc (CD). If you require a paper copy of the entire document, please call Penelope Beattie

on 202–452–3982. The documentation will not be available until about 20 minutes before the start of the meeting.

2. This meeting will be recorded for the benefit of those unable to attend. The webcast recording and a transcript of the meeting will be available after the meeting on the Board's public Web site *http://www.federalreserve.gov/about thefed/boardmeetings/* or if you prefer, a CD recording of the meeting will be available for listening in the Board's Freedom of Information Office, and copies can be ordered for $4 per disc by calling 202–452–3684 or by writing to: Freedom of Information Office, Board of Governors of the Federal Reserve System, Washington, DC 20551.

FOR MORE INFORMATION PLEASE CONTACT: Michelle Smith, Director, Office of Board Members at 202–452–2955.

SUPPLEMENTARY INFORMATION: You may access the Board's public Web site at *www.federalreserve.gov* for an electronic announcement. (The Web site also includes procedural and other information about the open meeting.)

Dated: December 2, 2014.

Margaret M. Shanks,

Deputy Secretary of the Board.

[FR Doc. 2014–28559 Filed 12–2–14; 11:15 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Administration for Native Americans; Statement of Organization, Functions, and Delegations of Authority

AGENCY: Administration for Children and Families, HHS.

ACTION: Notice.

SUMMARY: The Administration for Children and Families (ACF) has reorganized the Administration for Native Americans (ANA). This reorganization creates the Division of Policy and makes other technical changes to reflect the current functions within ANA. The realignment of functions better reflects the current work environment and priorities within ANA, manifests ANA's commitment to Federal/Tribal government-to-government relationships, and promotes self-determination for all Native Americans. The statement of mission, organization, functions, and delegations of authority conforms to and carries out the statutory requirements of the Native American Programs Act (NAPA).

FOR FURTHER INFORMATION CONTACT: Lillian Sparks-Robinson, Commissioner, Administration for Native Americans, 901 D Street SW., Washington, DC 20447, 202–401–5590.

This notice amends Part K of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS), Administration for Children and Families (ACF), as follows: Chapter KE, Administration for Native Americans (ANA), as last amended in 74 FR 3053–54, Jan. 16, 2009.

SUPPLEMENTARY INFORMATION:

I. Under Chapter KE, Administration for Native Americans, delete KE in its entirety and replace with the following:

KE.00 MISSION. The mission of the Administration for Native Americans (ANA) is to promote the goal of self-sufficiency and cultural preservation for Native Americans by providing social and economic development opportunities through financial assistance, training, and technical assistance to eligible Tribes and Native American communities, including American Indians, Alaska Natives, Native Hawaiians, and other Native Pacific Islander organizations. ANA provides funding for community-based projects that are designed to improve the lives of Native children and families and reduce long-term dependency on public assistance. Competitive funding authorized under the Native American Programs Act of 1974 (NAPA), as amended, for community-based projects is provided through three competitive discretionary grant programs to eligible Tribes and non-profit Native American organizations: Social and economic development, language preservation, and environmental regulatory enhancement. In carrying out the provisions of NAPA, the Commissioner advises the Secretary, through the Assistant Secretary for Children and Families, on federal policies affecting Native Americans and matters pertaining to Native Americans within the Department of Health and Human Services and with other Departments and agencies of the Federal Government.

KE.10 ORGANIZATION. ANA is headed by a Commissioner who is confirmed by the Senate and reports directly to the Assistant Secretary for Children and Families. ANA is organized as follows:

Office of the Commissioner (KEA)
Intra-Departmental Council on Native American Affairs (KEB)
Division of Program Operations (KEC)
Division of Program Evaluation and Planning (KED)
Division of Policy (KEE)

KE.20 Functions

A. The Office of the Commissioner provides executive leadership, management strategies, and day-to-day operational leadership for all components of ANA. The Commissioner serves as an effective and visible advocate on behalf of Native Americans within the Department, and with other departments and agencies of the Federal Government regarding all federal policies affecting Native Americans. The Commissioner provides policy direction and guidance to ACF Regional Offices with respect to programs for reservation-based Indians, urban Indians, off-Reservation Indians, and other Native American projects in Hawaii and the Pacific Islands. The Commissioner oversees the Native Hawaiian Revolving Loan Fund administered by the Office of Hawaiian Affairs. The Commissioner also ensures training and technical assistance and other resources are allocated and deployed to support and promote ANA's mission.

The Commissioner is the Chair of the Intra-Departmental Council on Native American Affairs (ICNAA) and advises the Secretary on Native American issues. ICNAA staff members provide support to the Commissioner. ICNAA develops and promotes HHS policy to provide greater access and quality services for American Indians, Alaska Natives, and Native Americans (AI/AN/NAs) throughout the Department and where possible, the Federal Government; promotes implementation of HHS policy and agency plans on consultation with AI/AN/NAs and Tribal Governments; identifies and develops legislative, administrative, and regulatory proposals that promotes an effective, meaningful AI/AN/NA policy to improve health and human services for AI/AN/NAs; identifies and develops comprehensive Departmental strategy proposal to promote self-sufficiency and self-determination for all AI/AN/NA people; and promotes the Tribal/Federal government-to-government relationship on a Department-wide basis in accordance with Presidential Executive Order.

The Deputy Commissioner reports to the Commissioner, assists the Commissioner in carrying out the responsibilities of ANA, and performs the duties of the Commissioner when absent. The Deputy Commissioner supervises all three Division Directors. In addition, the Deputy Commissioner provides day-to-day supervision and oversight to the Management Operations

Staff (MOS), coordinates the activities of the ACF Native American Affairs Liaison Workgroup, serves as the ANA liaison to the Inter-Departmental Council on Native American Affairs, provides coordination of ANA's data driven strategic plan, and advises the Commissioner on strategic and operational activities of ANA.

The MOS provides administrative and budget support to ANA. These responsibilities include: (1) Serving as the Executive Secretariat for ANA, including managing correspondence, correspondence systems, and public requests including, but not limited to Freedom of Information Act (FOIA) requests; (2) coordinating human resources activities; (3) developing and executing the budget; (4) providing on-going administrative technical support of ANA contracts; and (5) as appropriate, developing internal policies and procedures relating to these activities.

B. The Division of Program Operations is primarily responsible for the pre-award and post-award administration of discretionary grant programs to eligible Tribes and non-profit Native American organizations. These responsibilities include: (1) Developing ANA's Funding Opportunity Announcements; (2) managing annual grant competitions, including coordination of the panel review process and internal application review; (3) on-going grantee monitoring and support; (4) administering grant award portfolio, including close-out; and (5) providing liaison to the Office of Administration, Divisions of Grants Management and Division of Grants Policy.

C. The Division of Program Evaluation and Planning is responsible for evaluations of grantee effectiveness and impact as well as ANA performance including, but not limited to Government Performance and Results Act measures. These responsibilities include: (1) Oversight of planning and implementation activities related to ANA program evaluation, including development of annual reports, which includes the annual Report to Congress on Impact and Effectiveness; (2) data analyses and special organizational studies to guide programmatic enhancements and inform training and technical assistance efforts; (3) coordination of pre-award and post-award training and technical assistance activities in Alaska, the Pacific Basin, and the lower forty-eight states; (4) coordination of ANA's data and social media tools; and (5) liaison with the Office of Planning, Research and Evaluation.

D. The Division of Policy is responsible for providing support and guidance to define, establish, and disseminate policy affecting Native American communities at large. These responsibilities include: (1) Management of a unified and effective policy formulation process, including coordination of ANA regulations and other policy issuances affecting grantees and Native American communities; (2) formulation of advice on tribal and state legislative, and other activities affecting Native Americans; (3) development of long- and short-term strategies to address issues raised in consultations and collaborations with Native Americans; (4) support of the activities of the ACF Tribal Advisory Committee and other committees, councils, and workgroups affecting Native Americans; and (5) liaison with the Office of the General Counsel and others in the Department on matters involving or affecting Native Americans.

II. Continuation of Policy. Except as inconsistent with this reorganization, all statements of policy and interpretations with respect to organizational components affected by this notice within ACF, heretofore issued and in effect on this date of this reorganization are continued in full force and effect.

III. Delegation of Authority. All delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

IV. Funds, Personnel, and Equipment. Transfer of organizations and functions affected by this reorganization shall be accompanied in each instance by direct and support funds, positions, personnel, records, equipment, supplies, and other resources.

This reorganization will be effective upon date of signature.

Dated: November 24, 2014.

Mark H. Greenberg,

Acting Assistant Secretary for Children and Families.

[FR Doc. 2014–28486 Filed 12–3–14; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Health Information National Trends Survey (HINTS)

Summary: 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 National Cancer Institute (NCI), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) 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; (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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and For Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project contact: Bradford W. Hesse, Ph.D., Health Communication and Informatics Research Branch, 9609 Medical Center Drive, MSC 9761, Room 3E610, Rockville, MD 20850 or call non-toll free number 240–276–6721 or Email your request, including your address, to *hesseb@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: Health Information National Trends Survey (HINTS) 0925–0538, Reinstatement with Change, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: This partnership between NCI and FDA will include assessing the public's knowledge of medical devices, communications related to product recalls, nutritional supplement labeling, and topics to inform FDA's regulatory authority over tobacco, such as risk perceptions about new tobacco products, product pack color gradations, perceptions of product harm, and tobacco product claims and labels. This HINTS survey will couple knowledge-

related questions with inquiries into the communication channels through which understanding is being obtained, and assessment of FDA-regulated material. This survey will extend the information collected and priorities from HINTS which have been to provide a comprehensive assessment of the American public's current access to, and use of, information about cancer across the cancer care continuum from cancer prevention, early detection, diagnosis, treatment, and survivorship.

OMB approval is requested for 1 year. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2,159.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
Individuals	4,318	1	30/60	2,159

Dated: November 24, 2014.

Karla Bailey,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2014–28513 Filed 12–3–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Surveys and Interviews To Support an Evaluation of the Innovative Molecular Analysis Technologies (IMAT) Program (NCI)

SUMMARY: 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 National Cancer Institute (NCI), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) 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; (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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and For Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Anthony Dickherber, NCI Center for Strategic Scientific Initiatives, 31 Center Drive, Rm10A33, Bethesda, MD 20892 or call non-toll-free number 301–547–9980 or Email your request, including your address to: *dickherberaj@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: Surveys and Interviews to Support an Evaluation of the Innovative Molecular Analysis Technologies (IMAT) Program (NCI), 0925–NEW, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of the proposed evaluation is to pursue a comprehensive process and outcome assessment of the 15-year old Innovative Molecular Analysis Technologies (IMAT) program. While the program consistently offers promising indicators of success, the full program has not been evaluated since 2008, and never in as comprehensive a manner as has been formulated in the current evaluation plan. An outcome evaluation of the long-standing National Cancer Institute's (NCI) IMAT program presents a rich and unique opportunity likely to serve institutes across the National Institutes of Health (NIH), and perhaps other federal agencies, considering the costs and benefits of directing resources towards supporting technology development. An award through the NIH Evaluation Set-Aside program to support this evaluation, for which NIH-wide relevance is a principle element of determining merit for support, is testament to this. The evaluation serves as an opportunity to gauge the impact of investments in technology development and also to assess the strengths and weaknesses of phased innovation award mechanisms.

Like all institutes and centers (ICs) of the NIH, NCI seeks opportunities for improving their programs' utility for the broad continuum of researchers, clinicians and ultimately patients. NCI Director Harold Varmus and other leadership across NCI, as well as the NCI Board of Scientific Advisors, will be the primary users of the evaluation results. Findings are primarily intended for considering the long-term strategy to support innovative technology development and how to more efficiently translate emerging capabilities through such technologies into the promised benefits for cancer research and clinical care. Interviews with grantees, program officers, review officers, and other NIH awardees make up a crucial component of the evaluation plan and will largely follow set survey protocols. Specific near-term aims include the use of this information to consider the utility of continued investment through existing solicitations and in strategic planning generally for institute support for innovative technology development.

OMB approval is requested for 1 year. There are no costs to respondents other than their time. The total estimated annualized burden hours are 575.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
IMAT Awardee Interview	IMAT Awardees	100	1	1	100
Evaluation Web-based Survey	IMAT Awardees, and other NIH Awardees (Comparison group).	900	1	30/60	450
Tech End Users Interview	Technology End-Users	50	1	30/60	25

Dated: November 24, 2014.

Karla Bailey,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2014–28498 Filed 12–3–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITF) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); and on April 30, 2010 (75 FR 22809).

A notice listing all currently HHS-certified laboratories and IITFs is published in the **Federal Register** during the first week of each month. If any laboratory or IITF certification is suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at *http://beta.samhsa.gov/workplace.*

FOR FURTHER INFORMATION CONTACT: Giselle Hersh, Division of Workplace Programs, SAMHSA/CSAP, Room 7–1051, One Choke Cherry Road, Rockville, Maryland 20857; 240–276–2600 (voice), 240–276–2610 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71. The ''Mandatory Guidelines for Federal Workplace Drug Testing Programs,'' as amended in the revisions listed above, requires strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on urine specimens for federal agencies.

To become certified, an applicant laboratory or IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory or IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and IITFs in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A HHS-certified laboratory or IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA), which attests that it has met minimum standards.

In accordance with the Mandatory Guidelines dated November 25, 2008 (73 FR 71858), the following HHS-certified laboratories and IITFs meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

HHS-Certified Instrumented Initial Testing Facilities

Gamma-Dynacare Medical Laboratories, 6628 50th Street NW., Edmonton, AB Canada T6B 2N7, 780–784–1190

HHS-Certified Laboratories

ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 585–429–2264

Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615–255–2400, (Formerly: Aegis Sciences Corporation, Aegis Analytical Laboratories, Inc., Aegis Analytical Laboratories)

Alere Toxicology Services, 1111 Newton St., Gretna, LA 70053, 504–361–8989/800–433–3823, (Formerly: Kroll Laboratory Specialists, Inc., Laboratory Specialists, Inc.)

Alere Toxicology Services, 450 Southlake Blvd., Richmond, VA 23236, 804–378–9130, (Formerly: Kroll Laboratory Specialists, Inc., Scientific Testing Laboratories, Inc.; Kroll Scientific Testing Laboratories, Inc.)

Baptist Medical Center-Toxicology Laboratory, 11401 I–30, Little Rock, AR 72209–7056, 501–202–2783, (Formerly: Forensic Toxicology Laboratory Baptist Medical Center)

Clinical Reference Lab, 8433 Quivira Road, Lenexa, KS 66215–2802, 800–445–6917

DrugScan, Inc., 200 Precision Road, Suite 200, Horsham, PA 19044, 800–235–4890

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662–236–2609

Fortes Laboratories, Inc., 25749 SW., Canyon Creek Road, Suite 600, Wilsonville, OR 97070, 503–486–1023

Gamma-Dynacare Medical Laboratories *, A Division of the Gamma-Dynacare Laboratory Partnership, 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519–679–1630

Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713–856–8288/800–800–2387

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908–526–2400/800–437–4986, (Formerly: Roche Biomedical Laboratories, Inc.)

Laboratory Corporation of America Holdings, 1904 Alexander Drive,

Research Triangle Park, NC 27709, 919–572–6900/800–833–3984, (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group)

Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866–827–8042/ 800–233–6339, (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center)

LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927/800–873–8845, (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.)

MedTox Laboratories, Inc., 402 W. County Road D, St. Paul, MN 55112, 651–636–7466/800–832–3244

MetroLab-Legacy Laboratory Services, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295/800–950–5295

Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612–725–2088

National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 661–322–4250/800–350–3515

One Source Toxicology Laboratory, Inc., 1213 Genoa-Red Bluff, Pasadena, TX 77504, 888–747–3774, (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory)

Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800–328–6942, (Formerly: Centinela Hospital Airport Toxicology Laboratory)

Pathology Associates Medical Laboratories, 110 West Cliff Dr., Spokane, WA 99204, 509–755–8991/ 800–541–7891x7

Phamatech, Inc., 10151 Barnes Canyon Road, San Diego, CA 92121, 858–643–5555

Quest Diagnostics Incorporated, 1777 Montreal Circle, Tucker, GA 30084, 800–729–6432, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)

Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610–631–4600/877–642–2216, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)

Quest Diagnostics Incorporated, 8401 Fallbrook Ave., West Hills, CA 91304, 818–737–6370, (Formerly: SmithKline Beecham Clinical Laboratories)

Redwood Toxicology Laboratory, 3700650 Westwind Blvd., Santa Rosa, CA 95403, 800–255–2159

Southwest Laboratories, 4625 E. Cotton Center Boulevard, Suite 177, Phoenix, AZ 85040, 602–438–8507/800–279–0027

STERLING Reference Laboratories, 2617 East L Street, Tacoma, Washington 98421, 800–442–0438

U.S. Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755–5235, 301–677–7085

* The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (**Federal Register**, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on April 30, 2010 (75 FR 22809). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.

Janine Denis Cook,

Chemist, Division of Workplace Programs, Center for Substance Abuse Prevention, SAMHSA.

[FR Doc. 2014–28493 Filed 12–3–14; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–IA–2014–N248; FXIA16710900000–156–FF09A30000]

Endangered Species; Marine Mammals; Issuance of Permits

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of issuance of permits.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), have issued the following permits to conduct certain activities with endangered species, marine mammals, or both. We issue these permits under the Endangered Species Act (ESA) and Marine Mammal Protection Act (MMPA).

ADDRESSES: Brenda Tapia, U.S. Fish and Wildlife Service, Division of Management Authority, Branch of Permits, MS: IA, 5275 Leesburg Pike, Falls Church, VA 22041; fax (703) 358–2281; or email *DMAFR@fws.gov.*

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, (703) 358–2104 (telephone); (703) 358–2281 (fax); *DMAFR@fws.gov* (email).

SUPPLEMENTARY INFORMATION: On the dates below, as authorized by the provisions of the ESA (16 U.S.C. 1531 *et seq.*), as amended, and/or the MMPA, as amended (16 U.S.C. 1361 *et seq.*), we issued requested permits subject to certain conditions set forth therein. For each permit for an endangered species, we found that (1) The application was filed in good faith, (2) The granted permit would not operate to the disadvantage of the endangered species, and (3) The granted permit would be consistent with the purposes and policy set forth in section 2 of the ESA.

Permit No.	Applicant	Receipt of application **Federal Register** notice	Permit issuance date
		Endangered Species	
37543B	Byron Wates	79 FR 39409; July 10, 2014	September 16, 2014.
40316B	Ramon Gonzalez	79 FR 52038; September 2, 2014	September 2, 2014.
39418B	Exotic Feline Breeding Compound Inc.	79 FR 52038; September 2, 2014	November 25, 2014.
43610B	Exotic Feline Breeding Compound Inc.	79 FR 52038; September 2, 2014	November 25, 2014.

Permit No.	Applicant	Receipt of application **Federal Register** notice	Permit issuance date
43611B	Exotic Feline Breeding Compound Inc.	79 FR 52038; September 2, 2014	November 25, 2014.
42019B	Byron Christie	79 FR 52038; September 2, 2014	November 25, 2014.
27473B	Ryan Blakley	79 FR 57968; September 26, 2014	November 17, 2014.
43444B	William Farrar	79 FR 57968; September 26, 2014	November 25, 2014.
43445B	Robert Brocchini	79 FR 57968; September 26, 2014	November 25, 2014.
43448B	Richard Lane	79 FR 57968; September 26, 2014	November 25, 2014.
187330	University of Illinois–Zoological Pathology Program.	79 FR 60182; October 6, 2014	November 10, 2014.
42307B	Lions, Tigers & Bears	79 FR 62662; October 20, 2014	November 20, 2014.
Marine Mammals			
067116	University of Florida, Aquatic Animal Health Program.	79 FR 48244; August 15, 2014	November 10, 2014.

Availability of Documents

Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents to: U.S. Fish and Wildlife Service, Division of Management Authority, Branch of Permits, MS: IA, 5275 Leesburg Pike, Falls Church, VA 22041; fax (703) 358–2281.

Brenda Tapia,

Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2014–28480 Filed 12–3–14; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–IA–2014–N249; FXIA16710900000–156–FF09A30000]

Endangered Species; Marine Mammals; Receipt of Applications for Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications for permit.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct certain activities with endangered species, marine mammals, or both. With some exceptions, the Endangered Species Act (ESA) and Marine Mammal Protection Act (MMPA) prohibit activities with listed species unless Federal authorization is acquired that allows such activities.

DATES: We must receive comments or requests for documents on or before January 5, 2015. We must receive requests for marine mammal permit public hearings, in writing, at the address shown in the **ADDRESSES** section by January 5, 2015.

ADDRESSES: Brenda Tapia, U.S. Fish and Wildlife Service, Division of Management Authority, Branch of Permits, MS: IA, 5275 Leesburg Pike, Falls Church, VA 22041; fax (703) 358–2281; or email *DMAFR@fws.gov.*

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, (703) 358–2104 (telephone); (703) 358–2281 (fax); *DMAFR@fws.gov* (email).

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

A. How do I request copies of applications or comment on submitted applications?

Send your request for copies of applications or comments and materials concerning any of the applications to the contact listed under **ADDRESSES**. Please include the **Federal Register** notice publication date, the PRT-number, and the name of the applicant in your request or submission. We will not consider requests or comments sent to an email or address not listed under **ADDRESSES**. If you provide an email address in your request for copies of applications, we will attempt to respond to your request electronically.

Please make your requests or comments as specific as possible. Please confine your comments to issues for which we seek comments in this notice, and explain the basis for your comments. Include sufficient information with your comments to allow us to authenticate any scientific or commercial data you include.

The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) Those that include citations to, and analyses of, the applicable laws and regulations. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**) or comments delivered to an address other than those listed above (see **ADDRESSES**).

B. May I review comments submitted by others?

Comments, including names and street addresses of respondents, will be available for public review at the street address listed under **ADDRESSES**. The public may review documents and other information applicants have sent in support of the application unless our allowing viewing would violate the Privacy Act or Freedom of Information Act. 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.

II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), along with Executive Order 13576, ''Delivering an Efficient, Effective, and Accountable Government,'' and the President's Memorandum for the Heads of Executive Departments and Agencies of January 21, 2009—Transparency and Open Government (74 FR 4685; January 26, 2009), which call on all Federal agencies to promote openness and transparency in Government by disclosing information to the public, we invite public comment on these permit

applications before final action is taken. Under the MMPA, you may request a hearing on any MMPA application received. If you request a hearing, give specific reasons why a hearing would be appropriate. The holding of such a hearing is at the discretion of the Service Director.

III. Permit Applications

A. Endangered Species

Applicant: Space Wild Animal Farm Inc. Sussex, NJ; PRT–047058

The applicant requests renewal of their captive-bred wildlife registration under 50 CFR 17.21(g) for leopards (*Panthera pardus*) and ring-tailed lemurs (*Lemur catta*) to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: GTWT, LLC, Okeechobee, FL; PRT–48054A

The applicant requests renewal of their captive-bred wildlife registration under 50 CFR 17.21(g) for barasingha (*Rucerus duvaucelii*) to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Toledo Zoo, Toledo, OH; PRT–677660

The applicant requests a renewal of their captive-bred wildlife registration under 50 CFR 17.21(g) for the following families and species, to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Families:

Bovidae
Canidae
Cebidae
Cercopithecidae
Felidae (does not include jaguar, margay or ocelot)
Hominidae
Hylobatidae
Lemuridae
Rhinocerotidae
Columbidae
Psittacidae (does not include thick-billed parrot)
Rallidae
Sturnidae (does not include *Aplonis pelzelni*)
Alligatoridae
Boidae (does not include Mona or Puerto Rican boa)
Chelidae
Crocodylidae (does not include American crocodile)
Emydidae
Gekkonidae
Iguanidae
Sphenodontidae
Testudinidae
Varanidae
Viperidae

Species:

Koala (*Phascolarctos cinereus*)
Jackass penguin (*Spheniscus demersus*)

Applicant: Washington Park Zoo, Michigan City, IN; PRT–694606

The applicant requests renewal of their captive-bred wildlife registration under 50 CFR 17.21(g) for the family Lemuridae or the species white-collared mangabey (*Cercocebus torquatus*) to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Mac Embury, Grants Pass, OR; PRT–37451A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the following species, to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Species:

Golden parakeet (*Guarouba guarouba*)
Cuban parrot (*Amazona leucocephala)*
Vinaceous parrot (*Amazona vinacea*)
Blyth's tragopan (*Tragopan blythii)*
Cabot's tragopan (*Tragopan caboti*)
Red-crowned crane (*Grus japonensis*)
Black-necked crane (*Grus nigricollis*)
White-naped crane (*Grus vipio*)
Hooded crane (*Grus monacha*)
Galapagos tortoise (*Chelonoidis nigra*)
Radiated tortoise (*Astrochelys radiata*)

Applicant: St. Augustine Alligator Farm, St. Augustine, FL; PRT–749207

The applicant requests renewal of their captive-bred wildlife registration under 50 CFR 17.21(g) for the following families and species to enhance their propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Families:

Alligatoridae (does not include the American alligator)
Crocodylidae (does not include the American crocodile)

Species:

Cotton-top tamarin (*Saguinus oedipus*)
Golden parakeet (*Aratinga guarouba*)
Blue-throated macaw (*Ara glaucogularis*)

Applicant: Black Eagle Ranch, Fredericksburg, TX; PRT–52197B

The applicant requests authorization to take up to five Arabian oryx (*Oryx leucoryx*), up to five red lechwe (*Kobus lechwe*), and up to five Barasingha deer (*Cervus duvaucelii*) per year, under their captive-bred wildlife registration 50 CFR 17.21(g). This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Larry Johnson, Boerne, TX; PRT–49080B

The applicant requests a permit to export 51 captive-bred Scimitar-horned oryx (*Oryx dammah*) for the purpose of enhancement of the survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Honolulu Zoo, Honolulu, HI; PRT–48586B

The applicant requests a permit to import one male and two female captive-born Japanese giant salamanders (*Andrias japonicus*) from Asa Zoo, Hiroshima, Japan, for the purpose of enhancement of the survival of the species.

Applicant: Louisiana State University, Baton Rouge, LA; PRT–003005

The applicant requests a permit to export and reimport nonliving museum specimens of endangered and threatened species previously accessioned into the applicant's collection for scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Multiple Applicants

The following applicants each request a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Richard Boyer, Morrison, CO; PRT–46005B

Applicant: Frank Giacalone, Magnolia, TX; PRT–46530B

Applicant: Lee Friend, Loganville, GA; PRT–48426B

Applicant: David L. Bahl, Waukesha, WI; PRT–49174B

Applicant: Robert M. Pirnie, Pike Road, AK; PRT–49743B

B. Endangered Marine Mammals and Marine Mammals

Applicant: Terrie Williams, University of California, Santa Cruz, CA; PRT–45505B

The applicant requests a permit to take southern sea otters (*Enhydra lutris nereis*) for the purpose of scientific research on the physiology of and metabolic demands on female southern sea otters. This notification covers activities to be conducted by the applicant over a 5-year period.

Concurrent with publishing this notice in the **Federal Register**, we are forwarding copies of the above applications to the Marine Mammal Commission and the Committee of Scientific Advisors for their review.

Brenda Tapia,

Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2014–28479 Filed 12–3–14; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[AAK3000000/156A2100DD/A0H501010.999900]

Indian Child Welfare Act; Designated Tribal Agents for Service of Notice

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The regulations implementing the Indian Child Welfare Act (ICWA) provide that Indian tribes may designate an agent other than the tribal chairman for service of notice of proceedings under ICWA. This notice includes the current list of designated tribal agents for service of notice.

FOR FURTHER INFORMATION CONTACT: Ms. Debra Burton, Bureau of Indian Affairs Division of Human Services, 1849 C Street NW., Mail Stop 4513–MIB, Washington, DC 20240; Telephone: (202) 513–7610, Email: *debra.burton@bia.gov.*

SUPPLEMENTARY INFORMATION: The regulations implementing ICWA, 25 U.S.C. 1901 *et seq.,* provide that Indian tribes may designate an agent other than the tribal chairman for service of notice of proceedings under the Act. *See* 25 CFR 23.12. The Secretary of the Interior is required to publish as necessary in the **Federal Register** the names and addresses of the designated tribal agents. This notice is published in exercise of authority delegated by the Secretary of the Interior to the Principal Deputy Assistant Secretary—Indian Affairs by 209 DM 8. In addition to this notice, the updated list of designated tribal agents by Bureau of Indian Affairs (BIA) Region can also be found on the BIA Web site at: *http://www.bia.gov/WhoWeAre/BIA/OIS/HumanServices/IndianChildWelfareAct/index.htm.*

A. List of Regions

1. Alaska Region
2. Eastern Region
3. Eastern Oklahoma Region
4. Great Plains Region
5. Midwest Region
6. Navajo Region
7. Northwest Region
8. Pacific Region
9. Rocky Mountain Region
10. Southern Plains Region
11. Southwest Region
12. Western Region

B. List of Designated Tribal Agents by Region

1. Alaska Region

Alaska Region, Human Services Director, 3601 C Street, Suite 1100 Anchorage, AK 99503 Phone: (907) 271–4111.

A

Afognak, Native Village of, Denise Malutin, ICWA Worker, 323 Carolyn Street Kodiak, AK 99615; Phone: (907) 486–6357; Fax: (907) 486–6529 Email: *denise@afognak.org; taletha@afognak.org;Melissa@afognak.org*

Agdaagux Tribe of King Cove, Tara Bourdukofsky, M.S., Human Services Director, Aleutian/Pribilof Islands Association, 1131 East International Airport Road, Anchorage, AK 99518–1408; Phone: (907) 276–2700; Fax: (907) 279–4351; Email: *taralb@apiai.org*

Akhiok, Native Village of, Cassie Hickey, ICWA Coordinator, 3449 Rezanof Drive East, Kodiak, AK 99615; Phone: (907) 486–9882; Fax: (907) 486–1410 Email: *cassie.hickey@kanaweb.org*

Akiachak Native Community, Georgianna Wassilie, ICWA Worker P.O. Box 51070 Akiachak, AK 99551; Phone: (907) 825–4073; Fax: (907) 825–4029 and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *cofft@avcp.org*

Akiak Native Community, Sheila Williams, Tribal Administrator P.O. Box 52127, Akiak, AK 99552 Phone: (907) 765–7117; Fax: (907) 765–7512

Akutan, Native Village of, Tara Bourdukofsky, M.S., Human Services Director, Aleutian/Pribilof Islands Association, 1131 East International Airport Road, Anchorage, AK 99518–1408; Phone: (907) 276–2700; Fax: (907) 279–4351, Email: *taralb@apiai.org*

Alakanuk, Village of, Charlene Striling, ICWA Worker, Box 149, Alakanuk, AK 99554; Phone: (907) 238–3704; Fax: (907) 238–3705; and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *cofft@avcp.org; cstriling@avcp.org*

Alatna Village, Catherine Henzie, Tribal Family Youth Specialist, P.O. Box 70 Allakaket, AK 99720; Phone: (907) 968–2261; Fax: (907) 968–2305; and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600 Fairbanks, AK 99701; Phone: (907) 452–8251 Ext. 3178; Fax: (907) 459–3953

Aleknagik, Native Village of, Jane Gottschalk, Caseworker II, P.O. Box 115, Aleknagik, AK 99555; Phone: (907) 842–4577; Fax: (907) 842–2229 and Bristol Bay Native Association, Children's Services Program Manager, P.O. Box 310, 1500 Kanakanak Road, Dillingham, AK 99576; Phone: (907) 842–4139; Fax: (907) 842–4106; Email: *cnixon@bbna.com*

Algaaciq Native Village, Theresa Kelly, Box 48, St. Mary's, AK 99658; Phone: (907) 438–2335; Fax: (907) 438–2227 and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *tkelly@avcp.org; cofft@avcp.org*

Allakaket Village, Melanie Wholecheese, Tribal Family Youth Specialist, P.O. Box 50, Allakaket, AK 99720; Phone: (907) 968–2337; Fax: (907) 968–2233; and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600 Fairbanks, AK 99701; Phone: (907) 452–8251 Ext. 3178; Fax: (907) 459–3953

Ambler, Native Village, Lois Sheldon, ICWA Coordinator; or Effie Esenituk, Alternate, P.O. Box 86047 Ambler, AK 99786; Phone: (907) 445–2189/445–

2196/444–3852; Fax: (907) 445–2257; Email: *icwa@ivisaappaat.org*

Anaktuvuk, Village of, Social Services Director, Inupiat Community of the Arctic Slope, P.O. Box 934, Barrow, AK 99723, Phone: (907) 852–5923; Fax: (907) 852–5924; Email: *social@inupiatgov.com*

Andreafski (see Yupiit of Andreafski)

Angoon Community Association, Marcie Kookesh, ICWA Worker, P.O. Box 328, Angoon, AK, 99820 Phone: (907) 788–3411; Fax: (907) 788–3412

Aniak, Village of, Muriel Morgan, ICWA Worker, P.O. Box 349, Aniak, AK 99557; Phone: (907) 675–4349; Fax: (907) 675–4513

Anvik Village, Tami Jerue, Tribal Family Youth Specialist, P.O. Box 22 Anvik, AK 99558; Phone: (907) 663–6378; Fax: (907) 663–6357; and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600 Fairbanks, AK 99701; Phone: (907) 452–8251 Ext. 3178; Fax: (907) 459–3953

Arctic Village, Lisa Frank, Tribal Family Youth Specialist, P.O. Box 22069, Arctic Village, AK 99722; Phone: (907) 587–5523; Fax: (907) 587–5128; and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600 Fairbanks, AK 99701; Phone: (907) 452–8251 Ext. 3178; Fax: (907) 459–3953

Asa'carsarmiut Tribe (formerly Native Village of Mountain Village), Darlene Peterson, Director of Social Services, and Daphne Joe, Social Services, P.O. Box 32107; Mountain Village, AK 99632; Phone: (907) 591–2428; Fax: (907) 591–2934; Email: *atcicwa@gci.net*

Atka, Native Village of, Tara Bourdukofsky, M.S., Human Services Director, Aleutian/Pribilof Islands Association, 1131 East International Airport Road, Anchorage, AK 99518–1408; Phone: (907) 276–2700; Fax: (907) 279–4351, Email: *taralb@apiai.org*

Atmautluak, Village of, Alexie Earl Brown, ICWA Worker & Daniel Waska, Tribal Administrator, P.O. Box 6568, Atmautluak, AK 99559 Phone: (907) 553–5610; Fax: (907) 553–5612

Atqasuk Village, Maude Hopson, ICWA Coordinator, Social Services Department, Arctic Slope Native Association, Ltd., P.O. Box 1232, Barrow, AK 99723; Phone: (907) 852–9374; Fax: (907) 852–9152 Email: *maude.hopson@arcticslope.org*

B

Barrow, Native Village of, Marjorie Solomon, Social Services Director, P.O. Box 1130 Barrow, AK 99723; Phone: (907) 852–4411 Fax: (907) 852–4413 Email: *marjorie.solomon@nvbarrow.net*

Beaver Village, Arlene Pitka, Tribal Family Youth Specialist, P.O. Box 24029, Beaver, AK 99724; Phone: (907) 628–6126; Fax: (907) 628–6185; and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600, Fairbanks, AK 99701; Phone: (907) 452–8251 Ext. 3178; Fax: (907) 459–3953

Belkofski, Native Village of, Tara Bourdukofsky, M.S., Human Services Director, Aleutian/Pribilof Islands Association, 1131 East International Airport Road, Anchorage, AK 99518–1408; Phone: (907) 276–2700 Fax: (907) 279–4351, Email: *taralb@apiai.org*

Bettles Field (see Evansville Village)

Bill Moore's Slough Village, Nancy C. Andrews, ICWA Worker & Rose Cheemuk, Tribal Administrator, P.O. Box 20288, Kotlik, AK 99620; Main Office Phone: (907) 899–4232; Main Office Fax: (907) 899–4461; ICWA Office Phone: (907) 899–4236; ICWA Office Fax: (907) 899–4002

Birch Creek Tribe, Jackie Balaam, Tribal Family Youth Specialist, P.O. Box KBC Fairbanks, AK 99707; Phone: (907) 378–1573; Fax (907) 452–5063; and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600 Fairbanks, AK 99701; Phone: (907) 452–8251 Ext. 3178; Fax: (907) 459–3953

Brevig Mission, Native Village of, Linda M. Divers, Tribal Family Coordinator, P.O. Box 85039, Brevig Mission, AK 99785; Phone: (907) 642–3012; Fax: (907) 642–3042 Email: *linda@kawerak.org* and Ms. Traci McGarry, Program Director, Kawerak, Inc. Children & Family Services, P.O. Box 948 Nome, AK 99762 Phone: (907) 443–4376/4261 Fax: (907) 443–4464/4457; Email: *cfsdir@kawerak.org*

Buckland, Native Village of, Tracey Hadley, ICWA Coordinator, P.O. Box 67 Buckland, AK 99727; Phone: (907) 494–2169; Fax: (907) 494–2168 Email: *icwa@nunachiak.org*

C

Cantwell, Native Village of, Dorothy Slater, ICWA Program, Copper Center Native Association, P.O. Box 206, Copper Center, AK 99573; Phone: (907) 822–5241; Fax: (907) 822–8800 Email: *djslater@crnative.org*

Central Council of the Tlingit and Haida Indian Tribes of Alaska, Amalia Monreal, ICWA Coordinator; 320 W. Willoughby Ave., Suite 300, Juneau, AK 99801; Phone: (907) 463–7169; Fax: (907) 463–7343; Email:*amonreal@ccthita.org* or*icwamail@ccthita.org*

Chalkyitsik Village, Amanda Wright, Tribal Administrator, P.O. Box 57, Chalkyitsik, AK 99788; Phone: (907) 848–8117; Fax: (907) 848–8986; and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600 Fairbanks, AK 99701; Phone: (907) 452–8251 Ext. 3178; Fax: (907) 459–3953

Chanega (aka Chenega), Native Village of, Norma J. Selanoff, ICWA Representative, P.O. Box 8079, Chenega Bay, AK 99574–8079; Phone: (907) 573–5386; Fax: (907) 573–5387

Cheesh-Na- Tribe, Ms. Cecil Sanford, Social Services Coordinator, P.O. Box 241 Gakona, AK 99586; Phone: (907) 822–3503; Fax: (907) 822–5179; Email: *csanford@cheeshna.com*

Chefornak, Native Village of, Edward Kelly, Community Family Services Specialist, P.O. Box 110 Chefornak, AK. 99651; Phone: (907) 867–8808; Fax: (907) 867–8711 and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *cofft@avcp.org; sjenkins@avcp.org* or *mfredricks@avcp.org*

Chevak, Native Village of, Esther Friday, ICWA Worker, Box 140, Chevak, AK 99563; Phone: (907) 858–7918; Fax: (907) 858–7919 and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *cofft@avcp.org; sjenkins@avcp.org; mfredricks@avcp.org*

Chickaloon Native Village, Penny Westing, ICWA Case Manager, P.O. Box 1105, Chickaloon, AK 99674; Phone: (907) 745–0794; Fax: (907) 745–0709; Email: *penny@chickaloon.org*

Chignik Bay Tribal Council, Debbie Carlson, Administrator, Box 50, Chignik, AK 99564; Phone: (907) 749–2445; Fax: (907) 749–2423; Email: *cbaytc@gci.com;* and Bristol Bay Native Association, Children's Services Program Manager, P.O. Box 310, 1500 Kanakanak Road, Dillingham, AK 99576; Phone: (907) 842–4139; Fax: (907) 842–4106; Email: *cnixon@bbna.com*

Native Village of Chignik Lagoon, Nancy Anderson, ICWA, P.O. Box 09, Chignik Lagoon, AK 99565; Phone: (907) 840–2281; Fax: (907) 840–2217; Email: *clagoon@gci.net* and Bristol Bay Native Association, Children's Services Program Manager, P.O. Box 310, 1500 Kanakanak Road, Dillingham, AK 99576; Phone: (907) 842–4139; Fax: (907) 842–4106; Email: *cnixon@bbna.com*

Chignik Lake Village, ICWA Worker, P.O. Box 33, Chignik Lake, AK 99548; Phone (907) 845–2358; Fax: (907) 845–2246 and Bristol Bay Native Association, Children's Services Program Manager, P.O. Box 310, 1500 Kanakanak Road, Dillingham, AK 99576; Phone: (907) 842–4139; Fax: (907) 842–4106; Email: *cnixon@bbna.com*

Chilkat Indian Village, Carrie Durr, ICWA Caseworker, HC 60 Box 2207 Haines, AK 99827; Phone: (907) 767–5505; Fax: (907) 767–5408; Email: *cdurr@chilkat-nsn.gov*

Chilkoot Indian Association, Stella Howard, Family Caseworker/CCTH Field Supervisor, P.O. Box 624, Haines, AK 99827; Phone: (907) 766–2810; Fax: (907) 766–2845; Email: *showard@ccthita.org*

Chinik Eskimo Community (aka Golovin), Kirstie Ione,Tribal Family Coordinator, P.O. Box 62020, Golovin, AK 99762;Phone: (907) 779–3489; Fax: (907) 779–2000; Email: *tfc.glv@kawerak.org* and Ms. Traci McGarry, Program Director, Kawerak, Inc. Children & Family Services, P.O. Box 948 Nome, AK 99762 Phone: (907) 443–4376/4261; Fax: (907) 443–4464/4457; Email: *cfsdir@kawerak.org*

Chistochina (see Cheesh-na Tribe)

Chitina, Native Village of, Tribal President and Tribal Administrator, P.O. Box 31, Chitina, AK. 99566; Phone: (907) 823–2215; FAX: (907) 823–2233.

Chuathbaluk, Native Village of, Tracy Simeon, ICWA Worker, Box CHU, Chuathbaluk, AK 99557 Phone: (907) 467–4313; Fax: (907) 467–4113; and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *cofft@avcp.org; sjenkins@avcp.org; mfredricks@avcp.org*

Chuloonawick, Native Village of, Bambi Akers, Tribal Administrator, P.O. Box 245, Emmonak, AK 99581; Phone: (907) 949–1345; Fax: (907) 949–1346; Email: *coffice@starband.net*

Circle Native Community, Jessica Boyle, Tribal Family Youth Specialist, P.O. Box 89, Circle, AK 99733; Phone: (907) 773–2822; Fax: (907) 773–2823; Email: *Jessica.boyle@tananachiefs.org;* and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600 Fairbanks, AK 99701; Phone: (907) 452–8251 Ext. 3178; Fax: (907) 459–3953

Clarks Point, Village of, Harry Wassily Sr., President, P.O. 9, Clarks Point, AK 99569 Phone: (907) 236–1427; Fax: (907) 236–1428 and Bristol Bay Native Association, Children's Services Program Manager, P.O. Box 310, 1500 Kanakanak Road, Dillingham, AK 99576; Phone: (907) 842–4139; Fax: (907) 842–4106; Email: *cnixon@bbna.com*

Copper Center (see Native Village of Kluti-Kaah)

Cordova (see Eyak)

Council, Native Village of, Rhonda Hanebuth, ICWA Coordinator, P.O. Box 986, Nome, AK 99762; Phone: (907) 443–7649; Fax: (907) 443–5965.

Craig Community Association, Roberta Patten, Family Casework I, P.O. Box 746 Craig, AK 99921 Phone: 907 826–3948 Fax: (907) 826–5526 and Central Council Tlingit and Haida Tribes of Alaska; Email: *rpatten@ccthita.org*

Crooked Creek, Village of, Helen Macar, ICWA Worker & Evelyn Thomas, President, P.O. Box 69, Crooked Creek, AK 99575; Phone: (907) 432–2200 Fax: (907) 432–2201 Email: *bbcc@starband.net*

Curyung Tribal Council (formerly the Native Village of Dillingham), ICWA Case Worker II, P.O. Box 216, Dillingham, AK 99576; Phone: (907) 842–4508; Fax: (907) 842–4508; and Bristol Bay Native Association, Children's Services Program Manager, P.O. Box 310, 1500 Kanakanak Road, Dillingham, AK 99576; Phone: (907) 842–4139; Fax: (907) 842–4106; Email: *cnixon@bbna.com*

D

Deering, Native Village of, ICWA Coordinator and Tribal Administrator, P.O. Box 360, Deering, AK 99736; Phone: (907) 363–2229; Fax: (907) 363–2195 and Maniilaq Association, Family Services, P.O. Box 256, Kotzebue, AK 99752; Phone: (907) 442–7870

Dillingham (see Curyung Tribal Council)

Diomede (aka Inalik) Native Village of, Etta Ahkinga, Tribal Family Coordinator, P.O. Box 948 Nome, AK 99762; Phone: (907) 443–4261; Fax: (907) 443–4464; Email: *tfc.dio@kawerak.org*

Dot Lake, Village of, Clara Perdue, ICWA Worker, P.O. Box 2279 Dot Lake, AK 99737; Phone: (907) 882–2695; Fax: (907) 882–5558; and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600 Fairbanks, AK 99701; Phone: (907) 452–8251 Ext. 3178; Fax: (907) 459–3953

Douglas Indian Association, Loretta Marvin, ICWA Worker, 811 West 12th Street, Suite 200, Juneau, AK 99801; Phone: (907) 364–2983; Fax: (907) 364–2917; Email: *bmarvin-dia@gci.net*

E

Eagle, Native Village, Claire Ashley, Tribal Family Youth Specialist, P.O. Box 19, Eagle, AK 99738; Phone: (907) 547–2271; Fax: (907) 547–2318; Email: *Claire.ashley@tananachiefs.org;* and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600 Fairbanks, AK 99701; Phone: (907) 452–8251 Ext. 3178; Fax: (907) 459–3953

Edzeno (see Nikolai Native Council)

Eek, Native Village, Lillian Cleveland, ICWA Worker, Box 89, Eek, AK 99578; Phone: (907) 536–5572; Fax: (907) 536–5582; and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *cofft@avcp.org; lcleveland@avcp.org*

Egegik Village, Marcia Abalama, Case Worker III–ICWA Team Leader, P.O. Box 154, Egegik, AK 99579; Phone: (907) 233–2207; Fax: (907) 233–2212; and Bristol Bay Native Association, Children's Services Program Manager, P.O. Box 310, 1500 Kanakanak Road, Dillingham, AK 99576; Phone: (907) 842–4139; Fax: (907) 842–4106; Email: *cnixon@bbna.com*

Eklutna, Native Village of, Ms. Jamison M. Cole, LCSW, ICWA Worker, Social Services Director, P.O. Box 670666 Chugiak, AK 99567; Phone: (907) 688–1808 Office (907) 242–6980 cell; Fax: (907) 688–6032; Email: *nve.icwa@eklutna-nsn.gov; nve.socialservice@eklutna-nsn.gov*

Ekuk, Native Village of, Helen Foster, Tribal Administrator and Maria Binkowski, Receptionist/File Clerk, 300 Main St., P.O. Box 530 Dillingham, AK 99576; Phone: (907) 842–4139; Fax: (907) 842–3843 and Bristol Bay Native Association, Children's Services Program Manager, P.O. Box 310, 1500 Kanakanak Road, Dillingham, AK 99576; Phone: (907) 842–4139; Fax: (907) 842–4106; Email: *cnixon@bbna.com*

Ekwok Village, Sandra Stermer, ICWA Case Worker II, P.O. Box 70, Ekwok, AK 99580; Phone: (907) 464–3349; Fax: (907) 464–3350; Email: *sstermer@starband.net* and Bristol Bay Native Association, Children's Services Program Manager, P.O. Box 310, 1500 Kanakanak Road, Dillingham, AK 99576; Phone: (907) 842–4139; Fax: (907) 842–4106; Email: *cnixon@bbna.com*

Elim, Native Village of, Joseph H. Murray, Tribal Family Coordinator, P.O. Box 70, Elim, AK 99739 Phone: (907) 890–2457; Fax: (907) 890–2458 Email: *jmurrayjr@kawerak.org* and Ms. Traci McGarry, Program Director, Kawerak, Inc. Children & Family

Services, P.O. Box 948 Nome, AK 99762 Phone: (907) 443–4376/4261; Fax: (907) 443–4464/4457; Email: *cfsdir@kawerak.org*

Emmonak, Native Village, Priscilla S. Kameroff, ICWA Coordinator and Tribal Administrator, P.O. Box 126, Emmonak, AK 99581; Phone: (907) 949–1720/1820; Fax: (907) 949–1384; Email: *icwa@hughes.net*

English Bay (see Native Village of Nanwalek)

Evansville Village (aka Bettles Field), Naomi Costello, Tribal Family Youth Specialist, P.O. Box 26087, Evansville, AK 99726; Phone: (907) 692–5005; Fax: (907) 692–5006; and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600 Fairbanks, AK 99701; Phone: (907) 452–8251 Ext. 3178; Fax: (907) 459–3953

Eyak, Native Village, Erin Kurz, Tribal Family Services Coordinator, P.O. Box 1388, Cordova, AK 99574; Phone: (907) 424–7738; Fax: (907)424–7809; Email: *erin@eyak-nsn.gov*

F

False Pass, Native Village, Tara Bourdukofsky, M.S., Human Services Director, Aleutian/Pribilof Islands Association, 1131 East International Airport Road, Anchorage, AK 99518–1408; Phone: (907) 276–2700; Fax: (907) 279–4351; Email: *taralb@apiai.org*

Fort Yukon, Native Village (see Gwichyaa Zhee Gwich'in Tribal Government), Kimberly Ansaknok, Tribal Family Youth Specialist, P.O. Box 10 Fort Yukon, AK 99740; Phone: (907) 662–3625; Fax: (907) 662–3118; and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600 Fairbanks, AK 99701; Phone: (907) 452–8251 Ext. 3178; Fax: (907) 459–3953

Fortuna Ledge (see Native Village of Marshall)

G

Gakona, Native Village of, Charlene Nollner, Tribal Administrator, P.O. Box 102, Gakona, AK 99586; Phone: (907) 822–5997; Fax: (907) 822–5997; Email: *gakonaadmin@cvinternet.net*

Galena Village (aka Louden Village), March Runner, Tribal Administrator/Tribal Family Youth Specialist P.O. Box 244 Galena, AK 99741; Phone: (907) 656–1711; Fax: (907) 656–2491; Email: *marchrunner@aol.com*

Gambell, Native Village of, Tyler Campbell, Sr., ICWA, P.O. Box 90, Gambell, AK 99742; Phone: (907) 985–5346 Ext. 4; Fax: (907) 985–5014

Georgetown, Native Village of, Will Hartman, Tribal Administrator, 5313 Arctic Blvd., Suite 104, Anchorage, AK 99518; Phone: (907) 274–2195; Fax: (907) 274–2196; Email: *gtc@gci.net*

Golovin (see Chinik Eskimo Community)

Goodnews Bay, Native Village, Pauline Echuk, ICWA Worker, Box 48, Goodnews Bay, AK 99589 Phone: (907) 967–8929; Fax: (907) 967–8330 and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *cofft@avcp.org; sjenkins@avcp.org; mfredricks@avcp.org*

Organized Village of Grayling, Johanna Hamilton, Tribal Family Youth Specialist, P. O. Box 49, Grayling, AK 99590; Phone: (907) 453–5142; Fax: (907) 453–5146; and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600 Fairbanks, AK 99701; Phone: (907) 452–8251 Ext. 3178; Fax: (907) 459–3953

Gulkana Village Council, Jan Miller, Family Services Specialist, P.O. Box 254 Gakona, AK 99586 Phone: (907) 822–5363; Fax: (907) 822–3976 Email: *icwa@gulkanacouncil.org*

Gwichyaa Zhee Gwich'in Tribal Government (aka Fort Yukon)

H

Haines (see Chilkoot Indian Association)

Hamilton, Native Village of, Tribal Administrator, P.O. Box 20248 Hamilton, AK 99620; Phone: (907) 899–4252; Fax: (907) 899–4202; and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *cofft@avcp.org; sjenkins@avcp.org; mfredricks@avcp.org*

Healy Lake Village, (No tribal contact information at this time. Contact the BIA Human Services, Alaska Region)

Holikachuk (see Grayling)

Holy Cross Village, Rebecca Demientieff, Tribal Family Youth Specialist, P.O. Box 191, Holy Cross, AK 99602; Phone: (907) 476–7249; Fax: (907) 476–7132; Email: *rebecca.demientieff@tananachiefs.org* and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600 Fairbanks, AK 99701; Phone: (907) 452–8251 Ext. 3178; Fax: (907) 459–3953

Hoonah Indian Association, Candy Keown, Human Services Director, P.O. Box 602 Hoonah, AK 99829 Phone: (907) 945–3545; Fax: (907) 945–3530; Email: *ckeown@hiatribe.org*

Hooper Bay, Native Village, Pearl Semaken, ICWA Program, Box 62, Hooper Bay, AK 99604; Phone: (907) 758–4006; Fax: 758–4606 and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *cofft@avcp.org; psemaken@avcp.org*

Hughes Village, Janet Bifelt, Tribal Administrator or Tribal Family Youth Specialist, P.O. Box 45029 Hughes, AK 99745; Phone: (907) 889–2249; Fax: (907) 889–2252

Huslia Village, Cesa Sam, Tribal Family Youth Specialist, P.O. Box 70, Huslia, AK 99746; Phone: (907) 829–2202; Fax: (907) 829–2214; and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600 Fairbanks, AK 99701; Phone: (907) 452–8251 Ext. 3178; Fax: (907) 459–3953

Hydaburg Cooperative Association, Colleen Kashevarof, Human Services Director, P.O. Box 349, Hydaburg, AK 99922; Phone: (907) 285–3662; Fax: (907) 285–3541

I

Igiugig Village, Tanya Salmon, ICWA Worker, P.O. Box 4008, Igiugig, AK 99613; Phone: (907) 533–3211; Fax: (907) 533–3217

Iliamna Village Council, Thomas Hedlund, Tribal President, P.O. Box 286 Iliamna, AK 99606; Phone: (907) 571–1246; Fax: 571–3539; Email: *ivc@iliamnavc.org*

Inupiat Community of the Arctic Slope, Dora Neakok, Social Services Director P.O. Box 934, Barrow, AK 99723; Phone: (907) 852–4227, ext. 234; Fax: (907) 852–4246; Email: *social@inupiatgov.com*

Iqurmuit Traditional Council (aka Russian Mission), Katie Nick, Community Family Services Specialist, P.O. Box 38 Russian Mission, AK 99657; Phone: (907) 584–5594; Fax: (907) 584–5596; and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *cofft@avcp.org; knick@avcp.org*

Ivanoff Bay Village, Edgar Shangin, Tribal President, 7926 Old Seward Hwy, Suite B–5, Anchorage, AK 99518; Phone (907) 522–2263; Fax: (907) 522–2363; Email: *nicole@ivanofbaytribe.org;* and Bristol Bay Native Association, Children's Services Program Manager, P.O. Box 310, 1500 Kanakanak Road, Dillingham, AK 99576; Phone: (907)

842–4139; Fax: (907) 842–4106; Email: *cnixon@bbna.com*

K

Kaguyak Village, Phyllis Amodo, Tribal President, P.O. Box 5078, Akhiok, AK 99615; Phone: (907) 836–2231; Fax: (907) 836–2345

Organized Village of Kake, Ann Jackson, Social Services Director, P. O. Box 316, Kake, AK 99830; Phone: (907) 785–6471; Fax: (907)785–4902

Kaktovik Village (aka Barter Island), Maude Hopson, ICWA Coordinator, Social Services Department, Arctic Slope Native Association, Ltd., P.O. Box 1232, Barrow, AK 99723; Phone: (907) 852–9374; Fax: (907) 852–9152; Email: *maude.hopson@arcticslope.org*

Kalskag, Village of, (aka Upper Kalskag) Bonnie Persson, Tribal Administrator, P.O. Box 50 Kalskag, AK 99607; Phone: (907) 471–2296; Fax: (907) 471–2399; and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *cofft@avcp.org; sjenkins@avcp.org; mfredricks@avcp.org*

Lower Kalskag (See Lower Kalskag)

Kaltag, Village of, Donna Esmailka, Tribal Administrator, P.O. Box 129 Kaltag, AK 99748 Phone: (907) 534–2243; Fax: (907) 534–2264; and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600 Fairbanks, AK 99701; Phone: (907) 452–8251 Ext. 3178; Fax: (907) 459–3953

Kanatak, Native Tribe of, Shawn Shanigan, Tribal Administrator, P.O. Box 876822 Wasilla, AK 99687; Phone: (907) 357–5991; Fax: (907) 357–5992 and Bristol Bay Native Association, Children's Services Program Manager, P.O. Box 310, 1500 Kanakanak Road, Dillingham, AK 99576; Phone: (907) 842–4139; Fax: (907) 842–4106; Email: *cnixon@bbna.com*

Karluk, Native Village of, Kristeen Reft, ICWA Worker, P.O. Box 22, Karluk, AK 99608 Phone: (907) 241–2218; Fax: (907) 241–2208; Email: *karlukiracouncil@aol.com*

Organized Village of Kasaan, Paula Peterson, Tribal Administrator, P.O. Box 26–KXA, Ketchikan, AK 99950; Phone: (907) 542–2230; Fax: (907)542–3006; Email: *paula@kasaan.org*

Kashnumiut Tribe (see Chevak)

Kasigluk Traditional Council, Lucy Kassel, Tribal President, Lena Keene, ICWA Worker, P.O. Box 19, Kasigluk, AK 99609 Phone: (907) 477–6405/6418; Fax: (907) 477–6416

Kenaitze Indian Tribe, Donna Huntington or Kalyn Simpson, Family Case Managers, P.O. Box 988, Kenai, AK 99611; Phone: (907) 335–7243 or (907) 335–7217; Fax: (907) 335–7236; Email: *dhuntington@kenaitze.org ksimpson@kenaitze.org*

Ketchikan Indian Community, Pauline Sena-Edenshaw, ICWA Specialist, 2960 Tongass Ave., Ketchikan, AK 99901 Phone: (907) 228–9404; Fax: 800–865–6310 Email: *psedenshaw@kictribe.org*

Kiana, Native Village, Naomi Chappel, ICWA Coordinator, P.O. Box 69 Kiana, AK 99749 Phone: (907) 475–2226; Fax: (907) 475–2266; Email: *icwa@katyaaq.org*

King Cove (see Agdaagux)

King Island Native Community, Benjamin Payenna, Tribal Family Coordinator, P.O. Box 682 Nome, AK 99762; Phone: (907) 443–2209; Fax: (907) 443–8049; Email: *tfc.ki@kawerak.org* and Ms. Traci McGarry, Program Director, Kawerak, Inc. Children & Family Services, P.O. Box 948, Nome, AK 99762 Phone: (907) 443–4376/4261; Fax: (907) 443–4464/4457; Email: *cfsdir@kawerak.org*

King Salmon Tribe, Ralph Angasan, Jr., Tribal Administrator and Joni O'Domin, Tribal Enrollment Manager, P.O. Box 68 King Salmon, AK 99613 Phone: (907) 246–3553 (907) 246–3447; Fax: (907) 246–3449; Email: *kingsalmon@kstribe.com joni@kstribe.com*

Kipnuk, Native Village of Helen Paul, Community Family Services Specialist, P.O. Box 57, Kipnuk, AK 99614; Phone: (907) 896–5430; Fax: (907) 896–5704; and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *cofft@avcp.org; hpaul@avcp.org*

Kivalina, Native Village of, Stanley Hawley, Tribal Administrator, P.O. Box 50051, Kivalina, AK 99750; Phone: (907) 645–2201; Fax: (907) 645–2193; Email: *tribeadmin@kivaliniq.org* and Maniilaq Association, Family Services, P.O. Box 256, Kotzebue, AK 99752; Phone: (907) 442–7870

Klawock Cooperative Association, Family Caseworker, P.O. Box 173, Klawock, AK 99925; Phone: (907) 755–2325; Fax: (907) 755–2647

Klukwan (see Chilkat Indian Village)

Kluti- Kaah, Native Village of, Dorothy Slater, Copper Center Native Association, P.O. Box 206, Copper Center, AK 99573 Phone: (907) 822–5241; Fax: (907) 822–8800; Email: *djslater@crnative.org*

Knik Tribe, Geraldine Nicoli, ICWA Worker, P.O. Box 871565, Wasilla, AK 99687; Phone: (907) 373–7938; Fax: (907) 373–2153; Email: *gnicoli@kniktribe.org*

Kobuk, Native Village of, Tribal Administrator, P.O. Box 51039, Kobuk, AK 99751; Phone: (907) 948–2007; Fax: (907) 948–2123

Kodiak Tribal Council (see Sun'aq)

Kokhanok Village, Mary Andrew, Caseworker II, P.O. Box 1007 Kokhanok, AK 99606; Phone: (907) 282–2224; Fax: (907) 282–2221 and Bristol Bay Native Association, Children's Services Program Manager, P.O. Box 310, 1500 Kanakanak Road, Dillingham, AK 99576; Phone: (907) 842–4139; Fax: (907) 842–4106; Email: *cnixon@bbna.com*

Koliganek Village (see New Kolignanek)

Kongiganak, Native Village of, Janet Otto, Community Family Services Specialist, P.O. Box 5092, Kongiganak, AK 99545; Phone: (907) 557–5311; Fax: (907) 557–5348; and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *cofft@avcp.org; j_otto@avcp.org*

Kotlik, Native Village of, Ursula Akaran, Community Family ServicesWorker, P.O. Box 20210, Kotlik, AK 99620 Phone: (907) 899–4459 Fax: (907) 899–4202 and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *cofft@avcp.org; sjenkin@avcp.org; mfredricks@avcp.org*

Kotzebue, Native Village of, Clarissa Ballot, Tribal Family Resource Director, P.O. Box 296, Kotzebue, AK 99752; Phone: (907) 442–3467 Ext. 205; Fax: (907) 442–2162; Email: *clarissa.ballot@qira.org*

Koyuk, Native Village of, Leo M. Charles Sr. Supervisor, P.O. Box 53030, Koyuk, AK 99753; Phone: (907)963–2215; Fax: (907)963–2300; Email: *lcharles@kawerak.org* and Ms. Traci McGarry, Program Director, Kawerak, Inc. Children & Family Services, P.O. Box 948 Nome, AK 99762 Phone: (907) 443–4376/4261; Fax: (907) 443–4464/4457; Email: *cfsdir@kawerak.org*

Koyukuk, Native Village of, Sharon Pilot, Tribal Family Youth Specialist, P.O. Box 109, Koyukuk, AK 99754; Phone: (907) 927–2208; Fax: (907) 927–2220; Email: *sharon.pilot@tananachiefs.org;* and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600 Fairbanks, AK 99701; Phone: (907) 452–8251 Ext. 3178; Fax: (907) 459–3953

Kwethluk (see Organized Village of Kwethluk)
Kwigillingok, Native Village of, Andrew Beaver, Tribal Administrator, P.O. Box 90, Kwigillingok, AK 99622; Phone: 588–8117; Fax: (907) 588–8429
Kwinhagak (aka Quinhagak), Native Village of, Grace Friendly, ICWA, P.O. Box 149, Quinhagak, AK 99655; Phone: (907) 556–8165; Fax (907) 556–8340

L

Larsen Bay, Native Village of, Cassie Hickey, ICWA Coordinator, Kodiak Area Native Association, 3449 Rezanof Drive East Kodiak, AK 99615 Phone: (907) 486–9882; Fax: (907) 486–1410; Email: *cassie.hickey@kanaweb.org*
Lesnoi Village (aka Woody Island), Robert Stauffer, 194 Alimaq Dr., Kodiak, AK 99615 Phone: (907) 486–9806.
Levelock Village, Ida Apokedak, President, Box 70, Levelock, AK 99625; Phone: (907) 287–3030; Fax: (907) 287–3032; Email: *levelock@gci.net;* and Bristol Bay Native Association, Children's Services Program Manager, P.O. Box 310, 1500 Kanakanak Road, Dillingham, AK 99576; Phone: (907) 842–4139; Fax: (907) 842–4106; Email: *cnixon@bbna.com*
Lime Village Traditional Council, Jennifer John, Tribal President, P.O. Box LVD- Lime Village VIA McGrath, AK 99627; Phone: (907) 526–5236; Fax: (907) 526–5235
Louden (see Galena)
Lower Kalskag, Village of, Nastasia Evan, ICWA Worker, P.O. Box 27 Lower Kalskag, AK 99626 Phone: (907) 471–2412 Fax: (907) 471–2378 and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *cofft@avcp.org; sjenkins@avcp.org; mfredricks@avcp.org; nevan@avcp.org*

M

Manley Hot Springs Village, Elizabeth Woods, Tribal Family Youth Specialist, P.O. Box 105 Manley Hot Springs, AK 99756; Phone: (907) 672–3177; Fax: (907) 672–3200; and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600 Fairbanks, AK 99701; Phone: (907) 452–8251 Ext. 3178; Fax: (907) 459–3953
Manokotak Village, Diana Gamechuk, Caseworker I, P.O. Box 169, Manokotak, AK 99628; Phone: (907) 289–2074; Fax: (907) 289–1235 and Bristol Bay Native Association, Children's Services Program Manager, P.O. Box 310, 1500 Kanakanak Road, Dillingham, AK 99576; Phone: (907) 842–4139; Fax: (907) 842–4106; Email: *cnixon@bbna.com*
Marshall, Native Village of, ICWA Worker and Tribal Administrator, P.O. Box 110 Marshall, AK 99585; Phone: (907) 679–6302; Fax: (907) 676–6187 2227 and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *cofft@avcp.org*
Mary's Igloo, Native Village of, Dolly Kugzruk, Tribal Family Coordinator; P.O. Box 546, Teller, AK 99778; Phone: (907) 642–2185; Fax: (907) 642–2189; Email: *dkugzruk@kawerak.org;* and Ms. Traci McGarry, Program Director, Kawerak, Inc. Children & Family Services, P.O. Box 948 Nome, AK 99762 Phone: (907) 443–4376; Fax: (907) 443–4464; Email: *cfsdir@kawerak.org*
McGrath Native Village, Helen Vanderpool, Tribal Family Youth Specialist, P.O. Box 134 McGrath, AK 99672; Phone: (907) 524–3023; Fax: (907) 524–3899; Email: *helenvhf@mcgrath.net;* and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600 Fairbanks, AK 99701; Phone: (907) 452–8251 Ext. 3178; Fax: (907) 459–3953
Mekoryuk, Native Village of, Melanie Shavings, ICWA Coordinator & Jobe Weston, Executive Director, P.O. Box 66 Mekoryuk, AK 99630; Main Phone: (907) 827–8828; ICWA Dept. Phone: (907) 827–8827; Fax: (907) 827–8133; Email: *nvmicwa@gci.net*
Mentasta Traditional Council, Andrea David, ICWA Worker, P.O. Box 6019, Mentasta, AK 99780; Phone: (907) 291–2319; Fax: (907) 291–2305
Metlakatla Indian Community, Craig White, Social Services Director, P.O. Box 8, Metlakatla, AK 99926; Phone: (907) 886–6914/6916; Fax: (907) 886–6913; Email: *cwhite@metlakatla.com*
Minto, Native Village of, Lou Ann Williams, Tribal Family Youth Specialist, P.O. Box 26087 Minto, AK 99758; Phone: (907) 798–7007; Fax: (907) 798–7008; Email: *lou.williams@tananachiefs.org;* and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600 Fairbanks, AK 99701; Phone: (907) 452–8251 Ext. 3178; Fax: (907) 459–3953
Mountain Village (see Asa'carsarmiut)

N

Naknek Native Village, Donna Mae Williams, ICWA Worker & Tribal Administrator, P.O. Box 210, Naknek, AK 99633; Phone: (907) 246–4210; Fax: (907) 246–3563; Email: *naknek.icwa@aol.com*
Nanwalek, Native Village of, Alma Moonin, ICWA Advocate, P.O. Box 8028, Nanwalek, AK 99603; Phone: (907) 281–2307; Fax: (907)281–2252.
Napaimute, Native Village of, Sarah Jenkins, and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *sjenkins@avcp.org; mfredricks@avcp.org; cofft@avcp.org*
Napakiak, Native Village of, Julia Andrew, Tribal Administrator, P. O. Box 34114 Napakiak, AK 99634; Phone: (907) 589–2815; Fax: (907) 589–2814; Email: *choward@avcp.org* and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *cofft@avcp.org*
Napaskiak, Native Village of, Elizabeth Steven, ICWA Worker, P.O. Box 6009 Napaskiak, AK 99559; Phone: (907) 737–7364; Fax: (907) 737–7039 Email: *sjenkins@avcp.org; mfredricks@avcp.org* and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *cofft@avcp.org*
Nelson Lagoon, Native Village of, Tara Bourdukofsky, M.S., Human Services Director, Aleutian/Pribilof Islands Association, 1131 East International Airport Road, Anchorage, AK 99518–1408; Phone: (907) 276–2700 Fax: (907) 279–4351, Email: *taralb@apiai.org*
Nenana Native Association, Jo Noble, Tribal Administrator, P.O. Box 369, Nenana, AK 99760; Phone: (907) 832–5461; Fax: (907) 832–5447; and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600 Fairbanks, AK 99701; Phone: (907) 452–8251 Ext. 3178; Fax: (907) 459–3953
New Koliganek Village Council, Herman Nelson, President, P.O. Box 5057, Koliganek, AK 99576; Phone: (907) 596–3434; Fax: (907) 596–3462 and Bristol Bay Native Association, Children's Services Program Manager, P.O. Box 310, 1500 Kanakanak Road, Dillingham, AK 99576; Phone: (907) 842–4139; Fax: (907) 842–4106; Email: *cnixon@bbna.com*
New Stuyahok Village, Bristol Bay Native Association, Cynthia Nixon, Children's Services Program Manager, P.O. Box 310, 1500 Kanakanak Road, Dillingham, AK 99576; Phone:

(907)842–4139; Fax: (907)842–4106; Email: *cnixon@bbna.com.*

Newhalen Village, Maxine Wassillie, ICWA Worker; P.O. Box 207, Newhalen, AK 99606; Phone: (907) 571–1410; Fax: (907) 571–1537.

Newtok Village, Walter Kassaiuli, Vice-President, P.O. Box 5545 Newtok, AK 99559; Phone: (907) 237–2314; Fax: (907) 237–2428; Email: *newtoktc@gci.net.*

Nightmute, Native Village of, Sarah Jenkins, and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *sjenkins@avcp.org; mfredricks@avcp.org; cofft@avcp.org*

Nikolai Village (Edzeno'), Balassa Alexie, Tribal Administrator, P.O. Box 9107 Nikolai, AK 99691; Phone: (907) 293–2210; Fax: (907) 293–2216; and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600 Fairbanks, AK 99701; Phone: (907) 452–8251 Ext. 3178; Fax: (907) 459–3953

Nikolski, Native Village, Tara Bourdukofsky, M.S., Human Services Director, Aleutian/Pribilof Islands Association, 1131 East International Airport Road, Anchorage, AK 99518–1408; Phone: (907) 276–2700; Fax: (907) 279–4351, Email: *taralb@apiai.org*

Ninilchik Village, Bettyann Steciw, ICWA Specialist, P.O. Box 39444, Ninilchik, AK 99639; Phone: (907) 567–3313; Fax: (907) 567–3354; Email: *bettyann@ninilchiktribe-nsn.gov*

Noatak, Native Village of, Audrey Arey, ICWA Coordinator, P.O. Box 89 Noatak, AK 99761; Phone: (907) 485–2173; Fax: (907) 485–2137; Email: *icwa@nautaaq.org*

Nome Eskimo Community, Lola Stepetin, Family Services Director, 3600 San Jeronimo, Suite 138, Anchorage, AK 99508; Phone: (907) 793–3145; Fax: (907) 793–3127; Email: *lstepetin@gci.net*

Nondalton Village, Susan Bobby, Social Service/ICWA Worker P.O. Box 49 Nondalton, AK 99640; Phone: (907) 294–2257; Fax: (907) 294–2271.

Noorvik Native Community, ICWA Coordinator, P.O. Box 209 Noorvik, AK 99763 Phone: (907) 636–2144; Fax: (907) 636–2284; and Maniilaq Association, Family Services, P.O. Box 256, Kotzebue, AK 99752; Phone: (907) 442–7870

Northway Village, Tasha Demit, ICWA Worker, P.O. Box 516, Northway, AK 99764; Phone: (907)778–2311; Fax: (907) 778–2220.

Nuiqsut, Native Village of, Maude Hopson, ICWA Coordinator, Social Services Department, Arctic Slope Native Association, Ltd., P.O. Box 1232, Barrow, AK 99723; Phone: (907) 852–9374; Fax: (907) 852–9152; Email: *maude.hopson@arcticslope.org*

Nulato Village, Brittany Smith, Director of Human Services, P.O. Box 65049, Nulato, AK 99765 Phone: (907) 898–2329; Fax: (907) 898–2296; Email: *paul.mountain@tananachiefs.org*

Nunakauyarmiut Tribe (formerly Toksook Bay Native Village), Tribal Administrator and Marcella White, ICWA Worker, P.O. Box 37048, Toksook Bay, AK 99637; Phone: (907) 427–7114/7615; Fax: (907) 427–7714

Nunam Iqua (formerly Sheldon's Point), Sarah Jenkins and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *sjenkins@avcp.org; mfredricks@avcp.org; cofft@avcp.org*

Nunapitchuk, Native Village of, Aldine Simon, Community Family Service Specialist, P.O. Box 104 Nunapitchuk, AK 99641; Phone: (907) 527–5731; Fax: (907) 527–5740; Email: *icwa@yupik.org*

O

Ohagamiut, Village of, Gabriel Evan, Tribal Administration, P.O. Box 49, Marshall, AK 99585; Phone: (907) 679–6517/6598; Fax: (907) 679–6516; Email: *gabe@ohogtc.org*

Old Harbor Tribal Council, Bobbi Anne Barnowsky, Tribal Administrator; Jim Cedeno, ICWA Worker, P.O. Box 62, Old Harbor, AK 99643 Phone: (907) 286–2215; Fax: (907) 286–2350; Email: *jim.cedeno@ohtcmail.org*; *bobbi.barnowsky@ohtcmail.org*

Organized Village of Kwethluk, Chariton Epchook, ICWA Coordinator, P.O. Box 130 Kwethluk, AK 99621–0130; Phone: (907) 757–6714/6715; Fax: (907) 757–6328

Organized Village of Saxman, Family Caseworker or Tribal Administrator, Route 2, Box 2, Ketchikan, AK 99901; Phone: (907) 247–2502; Fax: (907) 247–2504

Orutsararmuit Native Village, Marilyn Johnston, ICWA Program, P.O. Box 971, Bethel, AK 99559 Phone: (907) 543–2608; Fax: (907) 543–2639; Email: *mjohnston@nativecouncil.org*

Oscarville Traditional Village, Andrew J. Larson Jr., Community Family Services Specialist, P.O. Box 6129, Oscarville, AK 99559; Phone: (907) 737–7100; Fax: (907) 737–7101; and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *cofft@avcp.org*

Ouzinkie, Native Village of, Robert Katelnikoff, Tribal Administrator, P.O. Box 130, Ouzinkie, AK 99644; Phone (907) 680–2259; Fax: (907) 680–2359; and Cassie Hickey, ICWA Coordinator, Kodiak Area Native Association, 3449 Rezanof Drive East Kodiak, AK 99615 Phone: (907) 486–9882; Fax: (907) 486–1410; Email: *cassie.hickey@kanaweb.org*

P

Paimiut, Native Village of, Tribal President or Tribal Administrator, P.O. Box 230, Hooper Bay, AK 99604; Phone: (907) 758–4002; Fax: (907) 758–4024

Pauloff Harbor Village, Tara Bourdukofsky, M.S., Human Services Director, Aleutian/Pribilof Islands Association, 1131 East International Airport Road, Anchorage, AK 99518–1408; Phone: (907) 276–2700; Fax: (907) 279–4351, Email: *taralb@apiai.org*

Pedro Bay Village, Verna Kolyaha, Program Specialist, P.O. Box 47020, Pedro Bay, AK 99647 Phone: (907) 850–2341; Fax: (907) 850–2221

Perryville, Native Village of, Bernice O'Domin, Case Manager II (ICWA), P.O. Box 97, Perryville, AK 99648; Phone: (907) 853–2242; Fax: (907) 853–2229; and Bristol Bay Native Association, Children's Services Program Manager, P.O. Box 310, 1500 Kanakanak Road, Dillingham, AK 99576; Phone: (907) 842–4139; Fax: (907) 842–4106; Email: *cnixon@bbna.com*

Petersburg Indian Association, Jeanette Ness, Caseworker, P.O. Box 1410 Petersburg, AK 99833 Phone: (907) 772–3637; Fax: (907) 772–3686 Email: *jeanetteness@piatribal.org*

Pilot Point, Native Village of, Suzanne Evanoff, Village Administrator, P.O. Box 449, Pilot Point, AK 99649; Phone: (907) 797–2208; Fax: (907) 797–2258 and Bristol Bay Native Association, Children's Services Program Manager, P.O. Box 310, 1500 Kanakanak Road, Dillingham, AK 99576; Phone: (907) 842–4139; Fax: (907) 842–4106; Email: *cnixon@bbna.com*

Pilot Station Traditional Village, Olga Xavier, Community Family Services Specialist, P.O. Box 5119, Pilot Station, AK 99650; Phone: (907) 549–3550; Fax: (907) 549–3551; and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *cofft@avcp.org; oxavier@avcp.org*

Pitka's Point, Native Village of, Tribal Administrator, P.O. Box 8 Platinum, AK 99651 and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *sjenkins@avcp.org*; *mfredricks@avcp.org; cofft@avcp.org*

Platinum Traditional Village, Tribal Administrator, P.O. Box 8 Platinum, AK 99651; Phone: (907) 979–8220; Fax: (907) 979–8178 and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *cofft@avcp.org; sjenkins@avcp.org; mfredricks@avcp.org*

Point Hope, Native Village, Martha Douglas, Family Caseworker, P.O. Box 109 Point Hope, AK 99766; Phone: (907) 368–3122; Fax: (907) 368–2332; Email: *martha.douglas@tikigaq.org*

Point Lay, Native Village, Social Services Director, Inupiat Community of the Arctic Slope, P.O. Box 934, Barrow, AK 99723, Phone: (907) 852–5923; Fax: (907) 852–5924; Email: *social@inupiatgov.com*

Port Graham, Native Village, Patrick Norman, Chief, and James Miller, ICWA Representative, P.O. Box 5510 Port Graham, AK 99603; Phone: (907) 284–2227; Fax: (907) 284–2222

Port Heiden, Native Village, (Native Council of Port Heiden), Larissa Orloff, Tribal Children Service Worker, P.O. Box 49007, Port Heiden, AK 99549; Phone: (907) 837–2291/2296; Fax: (907) 837–2297; Email: *gkosbruk@starband.net*

Port Lions, Native Village, Susan Boskofsky, Tribal Administrator and Yvonne Mullan, Tribal Services Coordinator, P.O. Box 69, Port Lions, AK 99550; Phone: (907) 454–2234; Fax: (907) 454–2434;

Portage Creek Village (aka Ohgensakale), Eva Kapotak, Caseworker, 1327 E. 72nd Ave., Unit B, Anchorage, AK 99518; Phone: (907) 277–1105; Fax: (907) 277–1104 and Bristol Bay Native Association, Children's Services Program Manager, P.O. Box 310, 1500 Kanakanak Road, Dillingham, AK 99576; Phone: (907) 842–4139; Fax: (907) 842–4106; Email: *cnixon@bbna.com*

Q

Qagan Tayaguyngin Tribe of Sand Point Village, Tara Bourdukofsky, M.S., Human Services Director, Aleutian/Pribilof Islands Association, 1131 East International Airport Road, Anchorage, AK 99518–1408; Phone: (907) 276–2700; Toll-Free: 1–800–478–2742; Fax: (907) 279–4351, Email: *taralb@apiai.org*

Qawalangin Tribe of Unalaska, Tara Bourdukofsky, M.S., Human Services Director, Aleutian/Pribilof Islands Association, 1131 East International Airport Road, Anchorage, AK 99518–1408; Phone: (907) 276–2700; Fax: (907) 279–4351, Email: *taralb@apiai.org*

Quinhagak (see Kwinhagak)

Qissunaimut Tribe (see Chevak)

R

Rampart Village, Tribal Administrator, P.O. Box 29 Rampart, AK 99767; Phone: (907) 358–3312; Fax: (907) 358–3115; and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600 Fairbanks, AK 99701; Phone: (907) 452–8251 Ext. 3178; Fax: (907) 459–3953

Red Devil Village, Tribal Administrator, P.O. Box 8 Platinum, AK 99651; and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *sjenkins@avcp.org*; *mfredricks@avcp.org*; *cofft@avcp.org*

Ruby, Native Village of, Elaine Wright, Tribal Family Youth Specialist, P.O. Box 68117 Ruby, AK 99768; Phone: (907) 468–4400; Fax: (907) 468–4500; and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600 Fairbanks, AK 99701; Phone: (907) 452–8251 Ext. 3178; Fax: (907) 459–3953

Russian Mission (see Iqurmuit Traditional Council)

S

Saint George Island, Native Village of, Tara Bourdukofsky, M.S., Human Services Director, Aleutian/Pribilof Islands Association, 1131 East International Airport Road, Anchorage, AK 99518–1408; Phone: (907) 276–2700; Fax: (907) 279–4351, Email: *taralb@apiai.org*

Saint Michael (see St. Michael)

Salamatoff, Village of, Jeannine Vasillie or Donna Huntington, ICWA Workers, Kenaitze Indian Tribe, P.O. Box 988, Kenai, AK 99611; Phone: (907) 335–7200; Fax: (907) 335–7236; Email: *jvasillie@kenaitze.org*; *dhuntington@kenaitze.org*

Sand Point (see Qagan Tayaguyngin Tribe of Sand Point Village)

Savoonga, Native Village of, Ruthie Okoomealingok, Tribal Family Coordinator, P.O. Box 34 Savoonga, AK 99769; Phone: (907) 984–6758; Fax: (907) 984–6759 and Ms. Traci McGarry, Program Director, Kawerak, Inc. Children & Family Services, P.O. Box 948 Nome, AK 99762; Phone: (907) 443–4376/4261; Fax: (907) 443–4464/4457; Email: *cfsdir@kawerak.org*; *tfc.sva@kawerak.org*

Saxman (see Organized Village of Saxman)

Scammon Bay, Native Village of, Michelle Akerealrea, Community Family Services Specialist, P.O. Box 110, Scammon Bay, AK 99662; Phone: (907) 558–5078; Fax: (907) 558–5079; and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *cofft@avcp.org*; *makerelrea@avcp.org*

Selawik, Native Village of, Jessie Hingsbergen, ICWA Coordinator, P.O. Box 59, Selawik, AK 99770; Phone: (907) 484–2165 Ext. 12; Fax: (907) 424–2001; Email: *icwa@akuligaq.org* and Maniilaq Association, Family Services, P.O. Box 256, Kotzebue, AK 99752; Phone: (907) 442–7870

Seldovia Village Tribe Laurel Hilts, ICWA Representative, P.O. Drawer L, Seldovia, AK 99663 Phone: (907) 234–7898 or (907) 435–3252; Fax: (907) 234–7865; Email: *svt@svt.org* or *lhilts@svt.org*

Shageluk Native Village, Sheila Workman, Tribal Family Youth Specialist, P.O. Box 69, Shageluk, AK 99665; Phone: (907) 473–8229; Fax: (907) 473–8275; and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600 Fairbanks, AK 99701; Phone: (907) 452–8251 Ext. 3178; Fax: (907) 459–3953

Shaktoolik, Native Village, Gail L. Evan, Tribal Family Coordinator, P.O. Box 100, Shaktoolik, AK 99771; Phone: (907) 955–2444; Fax: (907) 955–2443; and Ms. Traci McGarry, Program Director, Kawerak, Inc. Children & Family Services, P.O. Box 948 Nome, AK 99762; Phone: (907) 443–4376/4261; Fax: (907) 443–4464/4457; Email: *cfsdir@kawerak.org*; *tfc.skk@kawerak.org*

Sheldon's Point (see Nunam Iqua)

Shishmaref, Native Village of, Karla Nayokpuk, Tribal Family Coordinator, P.O. Box 72110, Shishmaref, AK 99772; Phone: (907) 649–3078; Fax: (907) 649–2278; and Ms. Traci McGarry, Program Director, Kawerak, Inc. Children & Family Services, P.O. Box 948 Nome, AK 99762; Phone: (907) 443–4376/4261; Fax: (907) 443–4464/4457; Email: *cfsdir@kawerak.org*; *knayokpuk@kawerak.org*

Shungnak, Native Village of, Sally Custer, ICWA Worker, P.O. Box 64 Shungnak, AK 99773 Phone: (907) 432–2138; Fax: (907) 437–2183; Email: *sally.custer@maniilaq.org* and Maniilaq Association, Family

Services, P.O. Box 256, Kotzebue, AK 99752; Phone: (907) 442–7870

Sitka Tribe of Alaska, Glade Morales, Social Services Director Mindy Lowrance, ICWA Caseworker,, 456 Katlian Street, Sitka, AK 99835; Phone: (907) 747–7293 & (907) 747–3207; Fax: (907) 747–7643; Email: *mindy.lowrance@sitkatribe-nsn.gov*; *glade.morales@sitkatribe-nsn.gov*

Skagway Village, Delia Commander, Tribal President/Administrator, P.O. Box 1157, Skagway, AK 99840–1157; Phone: (907) 983–4068; Fax: (907) 983–3068 Email: *dcommander@skagwaytraditonal.org*

Sleetmute, Village of, Cheryl Mellick, ICWA Worker, P.O. Box 109, Sleetmute, AK 99668 Phone: (907) 449–4263; Fax: (907) 449–4265

Solomon, Native Village of, Elizabeth Johnson, Tribal Coordinator, P.O. Box 2053, Nome, AK 99762; Phone: (907) 443–4985; Fax: (907) 443–5189; Email: *tc.sol@kawerak.org*

South Naknek Village, Lorianne Rawson, Tribal Administrator, 1830 E. Parks Highway, Ste. A113, PMB 388, Wasilla, AK 99654; Phone: (907) 631–3648; Fax: (907) 631–0949 and Bristol Bay Native Association, Children's Services Program Manager, P.O. Box 310, 1500 Kanakanak Road, Dillingham, AK 99576; Phone: (907) 842–4139; Fax: (907) 842–4106; Email: *cnixon@bbna.com*

St. Mary's (see Algaaciq)

St. Mary's Igloo (see Teller)

St. George (see Saint George)

St. Michael, Native Village of, Shirley Martin, Tribal Family Coordinator, P.O. Box 59050, St. Michael, AK 99659; Phone: (907) 923–2546; Fax: (907) 923–2474; and Ms. Traci McGarry, Program Director, Kawerak, Inc. Children & Family Services, P.O. Box 948 Nome, AK 99762 Phone: (907) 443–4376/4261; Fax: (907) 443–4464/4457; Email: *cfsdir@kawerak.org*; *tfc.smk@kawerak.org*

St. Paul, Charlene Naulty, MS, Department of Health and Human Services, 1500 W. 33rd Street, Suite 100 Anchorage, AK 99503; and P.O. Box 86 St. Paul Island, AK 99660; Phone: (907) 762–8426; Fax: (907) 770–0540 & (907) 546–3254; Email: *cjnaluty@aleu.com*

Stebbins Community Association, Anna Nashoanak, Tribal Family Coordinator, P.O. Box 71002, Stebbins, AK 99671, Phone: (907) 934–2334; Fax: (907) 934–2675; Email: *a.nashoanak@kawerak.org; tfc.wbb@kawerak.org* and Ms. Traci McGarry, Program Director, Kawerak, Inc. Children & Family Services, P.O. Box 948, Nome, AK 99762; Phone: (907) 443–4376/4261; Fax: (907) 443–4464/4457; Email: *cfsdir@kawerak.org*

Stevens, Native Village of, Harold Simon, 1st Chief, P.O. Box 74016, Stevens Village, AK 99774; Phone: (907) 478–7228; Fax: (907) 478–7229. Cheryl Mayo-Kriska, Indian Child Welfare Case Manager.

Stony River, Village of, Tribal Administrator, P.O Box SRV, Stony River, AK 99557 and ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *sjenkins@avcp.org; mfredricks@avcp.org*

Sun'aq Tribe of Kodiak, Linda Resoff, Social Services Director, 312 West Marine Way, Kodiak, AK 99615 Phone: (907) 486–4449; Fax: (907) 486–3361; Email: *socialservices@sunaq.org*

T

Takotna Village, Janice Newton, P.O. Box 7529, Takotna, AK 99675; Phone: (907) 298–2212; Fax: (907) 298–2314; and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600, Fairbanks, AK 99701; Phone: (907) 452–8251 Ext. 3178; Fax: (907) 459–3953

Tanacross, Native Village of, Colleen Denny, Tribal Family Youth Specialist, P.O. Box 76009, Tanacross, AK 99776; Phone: (907) 883–5024; Fax: (907) 883–4497; and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600, Fairbanks, AK 99701; Phone: (907) 452–8251; Ext. 3178; Fax: (907) 459–3953

Tanana, Native Village of, Donna May Folger, ICWA Worker, Box 130, Tanana, AK 99777; Phone: (907) 366–7170; Fax: (907) 366–7246; and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600, Fairbanks, AK 99701; Phone: (907) 452–8251, Ext. 3178; Fax: (907) 459–3953

Tatitlek, Native Village of, Victoria Vlasoff, Administrator, P.O. Box 171, Tatitlek, AK 99677; Phone: (907) 325–2311; Fax: (907) 325–2298

Tazlina, Native Village of, Marce Simeon, ICWA Coordinator, P.O. Box 87, Glennallen, AK 99588; Phone: (907) 822–4375; Fax: (907) 822–5865; Email: *marce@cvinternet.net*

Telida Village, Josephine Royal, Tribal Administrator/Tribal Family Youth Specialist, P.O. Box 84771, Fairbanks, AK 99708; Phone: (907) 864–0629; Fax: (907) 376–3540; and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600, Fairbanks, AK 99701; Phone: (907) 452–8251 Ext. 3178; Fax: (907) 459–3953

Teller, Native Village of, Dolly Kugzruk, Tribal Family Coordinator; P.O. Box 546, Teller, AK 99778; Phone: (907) 642–2185; Fax: (907) 642–2189; and Ms. Traci McGarry, Program Director, Kawerak, Inc. Children & Family Services, P.O. Box 948, Nome, AK 99762 Phone: (907) 443–4376; Fax: (907) 443–4464; Email: *cfsdir@kawerak.org; dkugzruk@kawerak.org*

Tetlin, Native Village of, Nettie Warbelow, Tribal Family Youth Specialist, 2763 Mack Blvd. Apt. 2, Fairbanks, AK 99709; Phone: (907) 378–3608; Fax: N/A; and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600, Fairbanks, AK 99701; Phone: (907) 452–8251 Ext. 3178; Fax: (907) 459–3953

Tlingit & Haida Indian Tribes of Alaska (see Central Council Tlingit and Haida Tribes)

Togiak, Traditional Council of, Tribal Administrator and Emma Wasillie, ICWA Worker, P.O. Box 310, Togiak, AK 99678; Phone: (907) 493–5003; Fax: (907) 493–5005; Email: *tuyuryak@starband.net;* and Bristol Bay Native Association, Children's Services Program Manager, P.O. Box 310, 1500 Kanakanak Road, Dillingham, AK 99576; Phone: (907) 842–4139; Fax: (907) 842–4106; Email: *cnixon@bbna.com*

Toksook Bay (see Nunakauyarmiut Tribe)

Tuluksak Native Community, Agatha Fly, Community Family Services Specialist, P.O. Box 93, Tuluksak, AK 99679; Phone: (907) 695–6902; Fax: (907) 695–6903; Email: *sjenkins@avcp.org; mfredricks@avcp.org* and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *cofft@avcp.org*

Tuntutuliak, Native Village of, Samantha White, Community Family Services Specialist, P.O. Box 8086, Tuntutuliak, AK 99680; Phone: (907) 256–2311; Fax: (907) 256–2080; and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK 99559; Phone: (907) 543–7400; Fax: (907) 543–5759; Email: *cofft@avcp.org swhite1@avcp.org;*

Tununak, Native Village of, Richard Lincoln III, Community Family Services Specialist, P.O. Box 77, Tununak, AK 99681; Phone: (907) 652–6220; Fax: (907) 652–6011; and Cheryl Offt, ICWA Director, Association of Village Council Presidents, P.O. Box 219, Bethel, AK

99559; Phone: 907 543–7400; Fax: (907) 543–5759; Email: *cofft@avcp.org; rlincoln@avcp.org*

Twin Hills Village, John W. Sharp, President, P.O. Box TWA, Twin Hills, AK 99576; Phone: (907) 525–4821; Fax: (907) 525–4822; and Bristol Bay Native Association, Children's Services Program Manager, P.O. Box 310, 1500 Kanakanak Road, Dillingham, AK 99576; Phone: (907) 842–4139; Fax: (907) 842–4106; Email: *cnixon@bbna.com; william15@starband.net*

Tyonek, Native Village of, Frank Standifer, III, Tribal President and Arthur Standifer, ICWA Worker, P.O. Box 82009, Tyonek, AK 99682–0009; Phone: 907 227–3574; Fax: (907) 583–2442; Email: *arthur_S@tyonek.net*

U

Ugashik Village, Irma Joyce Rhodes King, ICWA Worker, 2525 Blueberry Road, Suite 205, Anchorage, AK 99503; Phone: (907) 338–7611; Fax: (907) 338–7659; Email: *icwa@ugashikvillage.com*

Umkumiut Native Village, Joseph Tony, Council President, P.O. Box 90062, Nightmute, AK; Phone: (907) 647–6145; Fax: (907) 647–6146

Unalakleet, Native Village of, Marie Ivanoff, Tribal Family Coordinator, P.O. Box 270, Unalakleet, AK 99684; Phone: (907) 624–3526; Fax: (907) 624–5104; and Ms. Traci McGarry, Program Director, Kawerak, Inc. Children & Family Services, P.O. Box 948, Nome, AK 99762; Phone: (907) 443–4376/4261; Fax: (907) 443–4464/4457; Email: *cfsdir@kawerak.org; tfc.unk@kawerak.org;*

Unalaska (see Qawalangin Tribe of Unalaska)

Unga, Native Village of, Tara Bourdukofsky, M.S., Human Services Director, Aleutian/Pribilof Islands Association, 1131 East International Airport Road, Anchorage, AK 99518–1408; Phone: (907) 276–2700; Fax: (907) 279–4351, Email: *taralb@apiai.org*

Upper Kalskag Native Village (see Kalskag),

V

Village of Venetie, Larry Williams, Tribal Family Youth Specialist, P.O. Box 119, Venetie, AK 99781; Phone: (907) 849–8212; Fax: (907) 849–8149/8216; and Tanana Chiefs Conference, Legal Department, 122 First Avenue, Suite 600, Fairbanks, AK 99701; Phone: (907) 452–8251 Ext. 3178; Fax: (907) 459–3953

W

Village of Wainwright, Maude Hopson, ICWA Coordinator, Social Services Department, Arctic Slope Native Association, Ltd., P.O. Box 1232, Barrow, AK 99723; Phone: (907) 852–9374; Fax: (907) 852–9152; Email: *maude.hopson@arcticslope.org*

Wales, Native Village of, Linda Divers, Tribal Family Coordinator, P.O. Box 85039, Brevig Mission, AK 99785; Phone: (907) 642–3012 Fax: (907) 642–3042; Email: *linda@kawerak.org*

White Mountain, Native Village of, Carol Smith, Tribal Family Coordinator, P.O. Box 549, White Mountain, AK 99784; Phone: (907) 638–2008; Fax: (907) 638–2009; Email: *tfc.wmo@kawerak.org*

Woody Island (see Lesnoi Village)

Wrangell Cooperative Association, Elizabeth Newman, Family Caseworker II, P.O. Box 1198, Wrangell, AK 99929; Phone: (907) 874–3482; Fax: (907) 874–2982 Email: *bnewman@ccthita.org*

Y

Yakutat Tlingit Tribe, Gloria A. Benson, ICWA Director, P.O. Box 387, Yakutat, AK 99689; Phone: (907) 784–3368; Fax: (907) 784–3664; Email: *gbenson@ytttribe.org*

Yupiit of Andreafski, Geraldine Beans, ICWA Director, P.O. Box 88, St. Mary's, AK 99658; Phone: (907) 438–2572; Fax: (907) 438–2573

2. Eastern Region

Eastern Region Director, 545 Marriott Drive, Suite 700, Nashville, TN 37214; Telephone: (615) 564–6500; Fax: (615) 564–5701

A

Aroostook Band of Micmac Indians, Tania M. Morey Paul, Child Welfare Director, 7 Northern Road, Presque Isle, Maine 04769; Telephone: (207) 764–1972; Fax: (207) 764–7667; Email: *tmorey@micmac-nsn.gov*

C

Catawba Indian Nation, Carla Hudson, ICWA Representative and Linda Love, MSW, LMSW, Social Services Director, Catawba Indian Nation, 996 Avenue of Nations, Rock Hill, South Carolina 29730; Telephone: (803) 366–4792 Ext: 245; Fax: (803) 325–1242; Email: *carla.hudson@catwbaindian.net* and *linda.love@catawbaindian.net*

Cayuga Nation of New York, Sharon Leroy, Assistant Administration, P.O. Box 803, Seneca Falls, NY 13148, Phone: (315) 568–0750, Fax: (315) 568–0752, Email: *sharon.leroy@nsncayuganation-nsn.gov*

Chitimacha Tribe of Louisiana, Karen Matthews, MSW, LMSW, Director of Health & Human Services, P.O. Box 520, Charenton, LA 70523; Telephone: (337) 923–7000; (337) 923–9955 (Health Clinic), Fax: (337) 923–2475

Coushatta Tribe of Louisiana, Milton Hebert, MSW, CADC, CGAC, Social Service Director, 2003 CC Bel Road, Elton, LA 70532; Telephone: (337) 584–1439; Fax: (337) 584–1473; Email: *mhebert@coushattatribela.org*

E

Eastern Band of Cherokee Indians, Barbara Jones, Program Manager, 134 Boys Club Loop, P.O. Box 666, Cherokee, NC 28719; Telephone: (828) 497–6092; Fax: (828) 497–3322; Email: *barbjone@nc-cherokee.com*

H

Houlton Band of Maliseet Indians, Tiffany Randall, ICWA Director, 13–2 Clover Court, Houlton, ME 04730; Telephone: (207) 694–0213; Fax: (207) 532–7287; Email: *icwa.director@maliseets.com*

J

Jena Band of Choctaw Indians, Mona Maxwell, Social Services Director, P.O. Box 14, Jena, LA 71342; Telephone: (318) 992–0136; Cell: (318) 419–8432; Fax: (318) 992–4162

M

Mashantucket Pequot Tribal Nation, Valerie Burgess, Director Child Protective Services, 102 Muhshee Mahchaq, P.O. Box 3313, Mashantucket, CT 06338; Telephone: (860) 396–2007; Fax: (860) 396–2144; Email: *vburgess@mptn-nsn.gov*

Mashpee Wampanoag Tribe, Catherine Hendricks, Director, ICWA & Human and Social Services, 483 Great Neck Road, South Mashpee, MA 02649; Phone: (508) 419–6017 Ext: 604; Cell: (774) 255–0119–604; Fax: (508) 477–1652; Email: *catherinehendricks@mwtribe.com*

Miccosukee Tribe of Indians of Florida, Colley Billie, Tribal Chairman, P.O. Box 440021, Miami, FL 33144; Telephone: (305) 223–8380 Ext. 2377/2386; Fax: (305) 223–1011; Email: *Patriciak@miccosukeetribe.com* or *Hopel@miccosukeetribe.com*

Mississippi Band of Choctaw Indians, Kirsten L. Clegg, Child Welfare Supervisor, Department of Family & Community Services, Children & Family Services Program; P.O. Box 6050, Choctaw, MS 39350; Telephone: (601) 650–1741; Fax: (601) 656–8817; Email: *kirstin.clegg@choctaw.org*

Mohegan Indian Tribe, Irene Miller, APRN, Director, Family Services, 5 Crow Hill Road, Uncasville, CT 06382; Telephone: (860) 862–6236; Fax: (860) 862–6324

N

Narragansett Indian Tribe, Wenonah Harris, Director, Tribal Child and Family Services, 4375B South County Trail or P.O. Box 268, Charlestown, RI 02813; Telephone: (401) 364–1100 Ext: 233; Cell: (401) 862–8863; Fax: (401) 364–1104: Email: *Wenonah@nithpo.com*

O

Oneida Indian Nation, Kim Jacobs, Nation Clerk, Box 1 Vernon, NY 13476; Telephone: (315) 829–8337; Fax: (315) 829–8392; Email: *kjacobs@oneida.nation.org*

Onondaga Nation of New York, Mr. Laverne Lyons, 104 W. Conklin Ave, Nedrow, NY 13120; Phone: (315) 469–9196; Fax: (315) 469–3250; Email: *lglyons@syr.edu*

P

Passamaquoddy Indian Township, Dolly Barnes, LCSW, Director Child and Family Services, P.O. Box 301, Princeton, ME 04668; Telephone: (207) 796–6134; Fax: (207) 796–5606

Passamaquoddy Tribe-Pleasant Point, Molly Newell, Sipayik, Human Services Director, P.O. Box 343 Perry, ME 04667, Telephone: (207) 853–2600 Ext: 258; Fax: (207) 853–9618; Email: *molly@wabanaki.com*

Penobscot Indian Nation of Maine, Sonya LaCoute-Dana, Director of Social Services, P.O. Box 446, Old Town, ME 04468; Telephone: (207) 817–3164; Fax: (207) 817–3166; Email: *Sonya.lacoute-dana@penobscotnation.org*

Poarch Band of Creek Indians, Martha Gookin, Family Services Director, 5811 Jack Springs Rd., Atmore, AL 36502; Telephone: (251) 368–9136 Ext. 2600; Fax: (251) 368–0828; Email: *mgookin@pci-nsn.gov*

S

Saint Regis Mohawk Tribe, Haley Cree, ICWA program Coordinator, 412 State, Route 37, Akwesasne, NY 13655; Telephone: (518) 358–2728; Fax: (518) 358–9258; Email: *haley.cree@srmt-msn.gov*

Seminole Tribe of Florida, Kristi Hill, Family Preservation Administrator, 3006 Josie Billie Avenue, Hollywood, FL 33024; Telephone: (954) 965–1314; Fax: (954) 965–1304; Email: *kristihill@semtribe.com*

Seneca Nation of Indians, Tracy Pacini, Child and Family Services Program Coordinator, 987 RC Hoag Drive or P.O. Box 500, Salamanca, NY 14779; Telephone: (716) 945–5894; Fax: (716) 945–7881; Email: *tracy.pacini@senecahealth.org*

Shinnecock Indian Nation, Paula Collins, Shinnecock Health Services, P.O. Box 1268, Southhampton, NY 11969 Attn: CHWP; Telephone: (631) 287–6476; Email: *ndnpc@hotmail.com*

T

Tonawanda Band of Seneca, Darwin Hill, Chief, Council of Chiefs, 7027 Meadville Road, Basom, NY 14013; Telephone: (716) 542–4244; Fax: (716) 542–4008 Email: *Tonseneca@aol.com*

Tunica Biloxi Indian Tribe of Louisiana, Betty Pierite Logan, Registered Social Worker, P.O. Box 493, Marksville, LA 71351 Telephone: (318) 240–6442; Fax: (318) 253–9791; Email: *blogan@tunica.org*

Tuscarora Nation of New York, Chief Leo Henry, Clerk, 206 Mount Hope Road, Lewistown, NY 14092; Telephone: (716) 297–1148; Fax: (716)297–7355

W

Wampanoag Tribe of Gay Head (Aquinnah), Bonnie Chalifoux, Director Human Services, 20 Black Brook Road, Aquinnah, MA 02535; Telephone: (508) 645–9265 Ext. 133; Fax: (508) 645–2755; Email: *bonnie@wampanoagtribe.net*

3. Eastern Oklahoma Region

Eastern Oklahoma Region Director, P.O. Box 8002, Muskogee, OK 74402–8002; Telephone: (918) 781–4600; Fax (918) 781–4604

A

Alabama-Quassarte Tribal Town, Annie Merritt, ICWA Director, P.O. Box 187, Wetumka, OK 74883; Telephone: (405) 452–3881; Fax: (405) 452–3889; Email: *amerritt@alabama-quassarte.org*

C

Cherokee Nation, Nikki Baker-Limore, Director Division of Children Youth and Family Services, P.O. Box 948, Tahlequah, OK 74465, Telephone: (918) 458–6939, Fax: (918) 458–6146, Email: *Nikki-baker-limore@Cherokee.org*

The Chickasaw Nation, Angela Connor, Division of Family Support, 231 Seabrook Road, Ada, OK 74820; Telephone: (580) 272–5580, Fax: (580) 272–5590; Email: *Angela.Connor@chickasaw.net*

Choctaw Nation of Oklahoma, Alison Wolfe, ICW Supervisor, P.O. Box 1210, Durant, OK 74702; Telephone: (580) 924–8280; Fax: (580) 920–3197; Email: *awolfe@choctawnation.com*

D

Delaware Tribe of Indians, Allan Barnes, ICW Coordinator, 170 NE Barbara, Bartlesville, OK 74006; Telephone: (918) 336–6590; Fax: (918) 337–6591, Email: *abarnes@delawaretribe.org*

E

Eastern Shawnee Tribe of Oklahoma, Faye Woods, ICW Coordinator, 10100 S. Bluejacket Rd. #3, Wyandotte, OK 74370; Telephone: (918) 666–7710 ext. 1123; Fax: (918) 666–7717; Email: *fwoods@estoo.net*

K

Kialegee Tribal Town, Angie Beaver, ICW Coordinator, P.O. Box 332, Wetumka, OK 74883; Telephone: (405) 452–5388; Fax: (405) 452–3413; Email: *angie.beaver@kialegeetribe.net*

M

Miami Tribe of Oklahoma, Callie Lankford, Social Services Director, P.O. Box 1326, Miami, OK 74355; Telephone: (918) 541–1445; Fax: (918) 540–2814; Email: *clankford@miamination.com*

Modoc Tribe of Oklahoma, Regina Shelton, Child Protection, 625 6th SE., Miami, OK 74354; Telephone: (918) 542–7890; Fax: (918) 542–7878; Email: *modoc.ccdf@yahoo.com*

Muscogee (Creek) Nation, Carmin Tecumseh-Williams, Director of Child & Family Services, P.O. Box 580, Okmulgee, OK 74447; Telephone: (918) 732–7859 and 1–800–482–1979; Fax: (918) 732–7855

O

Osage Nation, Ann Davis, Social Work Supervisor, 255 Senior Drive, Pawhuska, OK 74056; Telephone: (918) 287–5218; Fax: (918) 287–5231; Email: *edavis@osagetribe.org*

Ottawa Tribe of Oklahoma, Roy A. Ross, Social Services/CPS Director, P.O. Box 110, Miami, OK 74355; Telephone: (918) 540–1536; Fax: (918) 542–3214; Email: *rross.oto@gmail.com*

P

Peoria Tribe of Indians of Oklahoma, Doug Journeycake, Indian Child Welfare Director, P.O. Box 1527, Miami, OK 74355; Telephone: (918) 540–2535; Fax: (918) 540–4370; Email: *djourneycake@peoriatribe.com*

Q

Quapaw Tribe of Oklahoma, Dee Killion, ICW Director, P.O. Box 765,

Quapaw, OK 74363; Telephone: (918) 674–2522; Fax: (918) 674–2581; Email: *dkillion@quapawtribe.com*

S

Seminole Nation of Oklahoma, Tracy Haney, Director of Indian Child Welfare, P.O. Box 1498, Wewoka, OK 74884; Telephone: (405) 257–9038; Fax: (405) 257–9036; Email: *haney.t@sno-nsn.gov*

Seneca-Cayuga Tribe of Oklahoma, Janet Grant, ICWA Director, 23701 S 655 Road, Grove, OK 74344; Telephone: (918) 786–3508; Fax: (918) 516–0248; Email: *jgrant@sctribe.com*

Shawnee Tribe, Jodi Hayes, Tribal Administrator, P.O. Box 189 Miami, Oklahoma 74354; Telephone: (918) 542–2441; Fax: (918) 542–2922; Email: *shawneetribe@shawneetribe.com*

T

Thlopthlocco Tribal Town, Stephanie Rogers, Program Manager, P.O. Box 188, Okemah, OK 74859; Telephone: (918) 560–6198; Fax: (918) 623–3023; Email: *srogers@tttown.org*

U

United Keetoowah Band of Cherokee Indians in Oklahoma, Joyce Hawk, Tribal Secretary, P.O. Box 746, Tahlequah, OK 74464; Telephone: (918) 453–9375; Fax: (918) 453–9345; *jfourkiller@unitedkeetoowahband.org*

Wyandotte Nation, Kate Randall, Director of Family Services, 64700 E. Hwy 60, Wyandotte, OK 74370; Telephone: (918) 678–2297; Fax: (918) 678–3087; Email: *krandall@wyandotte-nation.org*

4. Great Plains Region

Great Plains Region Director, 115 4th Avenue SE, Aberdeen, SD 57401; Telephone: (605) 226–7343; Fax: (605) 226–7443

C

Cheyenne River Sioux Tribe, Ms. Diane Garreau, Indian Child Welfare Act Program Director, P.O. Box 590, Eagle Butte, SD 57625; Telephone: (605) 964–6460; Fax: (605) 964–6463

Crow Creek Sioux Tribe, Crow Creek Sioux Tribal Court, P.O. Box 247, Fort Thompson, SD 57339; Telephone: (605) 245–2325/2326; Fax: (605) 245–2401

F

Flandreau Santee Sioux Tribe-Dakota, Celeste Honomichl, ICWA Administrator, Flandreau Santee Sioux Tribal Social Services, P.O. Box 283, Flandreau, SD 57028; Telephone: (605) 997–5055; Fax: (605) 997–3694

L

Lower Brule Sioux Tribe, L. Greg Miller, LBST Counseling Service Director, 187 Oyate Circle, Lower Brule, SD 57528; Telephone: (605) 473–5584; Fax: (605) 473–8051; Email: *greg.miller@lbst.org*

O

Oglala Sioux Tribe, Juanita Sherick, Director ONTRAC, P.O. Box 2080 Pine Ridge, SD 57752; Telephone: (605) 867–5805; Fax: (605) 867–1893; Email: *ontrac@qwtc.net*

Omaha Tribe of Nebraska, Deanna Parker, ICWA Specialist, P.O. Box 368, Macy, NE 68039; Telephone: (402) 837–5331; Fax: (402) 837–5362

P

Ponca Tribe of Nebraska, Jill Holt, ICWA Specialist, 2602 J Street, Omaha, NE 68107; Telephone: (402) 734–5275; Fax: (402) 734–5708

R

Rosebud Sioux Tribe, Shirley J. Bad Wound, ICWA Specialist, Rosebud Sioux Tribe ICWA Program, P.O. Box 609 Mission, SD 57555; Telephone: (605) 856–5270; Fax: (605) 856–5268

S

Santee Sioux Nation, Clarissa LaPlante, ICWA Specialist, Dakota Tiwahe Service Unit, Route 2, Box 5191, Niobrara, NE 68760; Telephone: (402) 857–2342; Fax: (402) 857–2361; Email: *clarissa.laplante@nebraska.gov*

Sisseton-Wahpeton Oyate, Evelyn Pilcher, ICWA Specialist, P.O. Box 509 Agency Village, SD 57262; Telephone: (605) 698–3992; Fax: (605) 698–3999; Email: *evelynp@swo-nsn.gov@state.sd.us*

Spirit Lake Tribe, ICWA Director, P.O. Box 356, Fort Totten, ND 58335; Telephone: (701) 766–4855; Fax: (701) 766–4273; Email: *icwadirector@spiritlakenation.com*

Standing Rock Sioux Tribe, Terrance Yellow Fat, Director, Indian Child Welfare Program, P.O. Box 770, Fort Yates, ND 58538; Telephone: (701) 854–3095; Fax: (701) 854–5575; Email: *tyellowfat@standingrock.org*

T

Three Affiliated Tribes (Mandan, Arikara & Hidatsa), Katherine Felix, ICWA Specialist, 404 Frontage Road, New Town, ND 58763; Telephone: (701) 627–4781; Fax: (701) 627–5550; Email: *kfelix@mhanation.com*

Turtle Mountain Band of Chippewa Indians, Marilyn Poitra, Indian Child Welfare Specialist, Child Welfare and Family Services, P.O. Box 900, Belcourt, ND 58316; Telephone: (701) 477–5688; Fax: (701) 477–5797; Email: *marilynp@tmcwfs.net*

W

Winnebago Tribe of Nebraska, Barbara Eagle, ICWA Specialist, #1 Mission Drive Box 723, Winnebago, NE 68071; Telephone: (402) 878–2378; Fax: (402) 878–2228; Email: *baeagleW@winnebagotribe.com*

Y

Yankton Sioux Tribe, Raymond Cournoyer, ICWA Director, P.O. Box 1153, 108 East Avenue South East, Wagner, SD 57380; Telephone: (605) 384–5712; Fax: (605) 384–5014; Email *mmedicinebear1@gmail.com*

5. Midwest Region

Midwest Regional Director, 5600 West American Blvd., Suite 500, Norman Pointe II Building, Bloomington, MN 55437; Telephone: (612) 713–4400; Fax: (612) 713–4453

B

Bad River Band of Lake Superior Chippewa, Esie Leoso-Corbine, Director, Family and Social Services, P.O. Box 55, Odanah, WI 54861; Telephone: (715) 682–7135 Ext: 3; Fax: (715) 682–7883; Email: *bricw2@badriver-nsn.gov*

Bay Mills Indian Community, Phyllis Kinney, Tribal Court Administrator, 12140 W. Lakeshore Dr., Brimley, MI 49715; Phone: (906) 248–3241, (906) 8811; Fax: (906) 248–5817; Email: *phyllisk@baymills.org*

Bois Forte Reservation Business Committee, Angela Wright, Indian Child Welfare Supervisor, 13071 Nett Lake Road Suite A, Nett Lake, MN 55771; Telephone: (218) 757–3295 or (218) 757–3916; Fax: (218) 757–3335; Email: *amwright@boisforte.nsn.gov*

F

Fond du Lac Reservation Business Committee, Karen Diver, Chairwoman, 1720 Big Lake Road, Cloquet, MN 55720; Telephone: (218) 879–4593; Fax: (218) 878–2189; Email: *karendiver@fdlrez.com*

Forest County Potawatomi Community of Wisconsin, Abbey Lukowski, Family Services Division Director, 5415 Everybody's Road, Crandon, WI 54520; Telephone: (715) 478–4812; Fax: (715) 478–7442; Email: *Abbey.lukowski@fcpotawatomi-nsn.gov*

G

Grand Portage Reservation Business Committee, Patti Foley, Social Worker, P.O. Box 428, Grand Portage, MN 55605; Telephone: (218) 475–

2169; Fax: (218) 475–2455; Email: *pfoley@grandportage.com*

Grand Traverse Band of Ottawa and Chippewa Indians, Helen Cook, Anishinaabek Family Services Supervisor, 2605 N. West Bayshore Drive, Peshawbestown, MI 49682–9275; Telephone: (231) 534–7681; Fax: (231) 534–7706; Email: *helen.cook@gtbindians.com*

H

Hannahville Indian Community of Michigan, Jessica Brock, ICWA Worker, N15019 Hannahville B1 Road, Wilson, MI 49896; Telephone: (906) 723–2514; Fax: (906) 466–7397; Email: *Jessica.brock@hichealth.org*

The Ho-Chunk Nation, Stephanie Lozano, ICWA Supervisor, P.O. Box 40, Black River Falls, WI 54615; Telephone: (715) 284–2622; Fax: (715) 284–0097; Email: *stephanie.Lozano@ho-chunk.com*

Nottawaseppi Huron Band of the Potawatomi, Meg Fairchild, LMSW, CAAC, Clinical Social Worker, 1474 Mno Bmadzewen Way, Fulton, MI 49052; Telephone: (269) 729–4422; Fax: (269) 729–4460; Email: *mfairchild@nhbp.org*

K

Keweenaw Bay Indian Community, Judy Heath, Director Social Service, 16429 Beartown Road, Baraga, MI 49908; Telephone: (906) 353–4201; Fax: (906) 353–8171; Email: *judy@kbic-nsn.gov*

L

Lac Courte Oreilles, LuAnn Kolumbus, Tribal Social Services Director, 13394 W. Trepania Road, Hayward, WI 54843; Telephone: (715) 634–8934 ext. 7435; Fax: (715) 634–2981 Email: *lcoicw@nsn.gov*

Lac du Flambeau, Kristin Allen, ICW Director, P.O. Box 216, Lac du Flambeau, WI 54538; Telephone: (715) 588–4275; Fax: (715) 588–3855; Email: *ldficw@ldftribe.com*

Lac Vieux Desert, Dee Dee McGeshick, Social Services Director, P.O. Box 249, Watersmeet, MI 49969; Telephone: (906) 358–4940; Fax: (906) 358–4900; Email: *dee.mcgeshick@lvdtribal.com*

Leech Lake Band of Ojibwe, Victoria White, Child Welfare Director, 115 Sixth Street NW., Suite E, Cass Lake, MN 56633; P.O. Box 967, Cass Lake, MN 56633; Telephone: (218) 335–8270; Fax: (218) 335–3768; Email: *Vicki.white@llojibwe.com*

Little River Band of Ottawa Indians, William Gregory, Tribal Prosecutor, 3031 Domres Road, Manistee, MI 49660; Telephone: (213) 398–2242; Fax: (231) 398–3404; Email: *bgregory@lrboi.com*

Little Traverse Bay Bands, Denneen Smith, Human Services Director, 7500 Odawa Circle, Harbor Springs, MI 49740; Telephone: (231) 242–1620; Fax: (213) 242–1635; Email: *dmsmith@ltbbodawa-nsn.gov*

Lower Sioux, Reanna Jacobs, ICWA Advocate, Darin Prescott, Director, 39568 Reservation Highway 1, Morton, MN 56270; Telephone: (507) 697–9108; Fax: (507) 697–9111; Email: *reanna.jacobs@lowersioux.com*

M

Match-E-Be-Nash-She-Wish Band of Potawatomi Indians of Michigan (Gun Lake Tribe), Leslie Pigeon, Behavior Health/Human Services Coordinator, P.O. Box 306, Dorr, MI 49323; Telephone: (616) 681–0360 Ext: 316; Fax: (616) 681–0380

Menominee Indian Tribe of Wisconsin, Mary Husby, Director of Social Services, P.O. Box 910 Keshena, WI 54135; Telephone: (715) 799–5161; Fax: (715) 799–6061; Email: *mhusby@mitw.org*

Mille Lacs Band of Ojibwe, Ted Waukey, Director of Family Services, Mille Lacs Band Government Center, 43408 Oodena Drive, Onamia, MN 56359; Telephone: (320) 532–7778; Fax: (320) 532–7583; Email: *Ted.Waukey@millelacsband.com*

Minnesota Chippewa Tribe, Linda Johnston, Human Services Director, P.O. Box 217, Cass Lake, MN 56633; Telephone: (218) 335–8585; Fax: (218) 335–8080; Email: *ljohnston@mnchippewatribe.org*

O

Oneida Tribe of Indians of Wisconsin, Attn: Children and Family Services, P.O. Box 365, Oneida, WI 54155; Telephone: (920) 490–3724; Fax: (920) 490–3820; Email: *icw@oneidanation.org*

P

Pokagon Band of Potawatomi Indians, Mark Pompey, Social Services Director, 58620 Sink Road, Dowagiac, MI 49047; Telephone: (269) 782–8998; Fax: (269) 782–4295; Email: *mark.pompey@pokagonband-nsn.gov*

Prairie Island Indian Community, Nancy Anderson, Family Service Manager, 5636 Sturgeon Lake Road, Welch, MN 55089; Telephone: (651) 385–4185; Fax: (651) 385–4183; Email: *nanderson@piic.org*

R

Red Cliff Band of Lake Superior Chippewa, Lorna Gamble, Indian Child Welfare Department Director, 88385 Pike Road, Highway 13, Bayfield, WI 54814; Telephone: (715) 779–3785; Fax: (715) 779–3783; Email: *lorna.gamble@redcliff-nsn.gov*

Red Lake Band of Chippewa Indians, Paula Woods, Executive Director—Family & Children Services, P.O. Box 427 Red Lake, MN 56671; Telephone: (218) 679–2122; Fax: (218) 679–2929; Email: *pwoods@redlak enation.org*

S

Sac & Fox Tribe of the Mississippi in Iowa—Meskwaki, Mylene Wanatee, Meskwaki Family Services Director, P.O. Box 245, 349 Meskwaki Road, Tama, IA 52339; Telephone: (641) 484–4444 Fax: (641) 484–2103; Email: *recruiter.mfs@meskwaki-nsn.gov*

Saginaw Chippewa Indians of MI, Attn: ICWA Director, 7070 East Broadway, Mt. Pleasant, MI 48858; Telephone: (989) 775–4909; Fax: (989) 775–4912

Sault Ste. Marie Tribe of Chippewa Indians, Juanita Bye, ACFS Division Director, 2218 Shunk Rd, Sault Ste. Marie, MI 49783; Telephone: (906) 632–5250; Fax: (906) 632–5266; Email: *jbye@saulttribe.net*

Shakopee Mdewakanton Sioux Community, Karen Ross—ICWA Representative, 2330 Sioux Trail NW., Prior Lake, MN 55372; Telephone: (952) 445–8900 or (952) 496–6112; Fax: (952) 445–8906

Sokaogon Chippewa Community of Wisconsin, Angela Vanzile, Director, Family Services, 10808 Sokaogon Drive, Crandon, WI 54520; Telephone: (715) 478–3265; Fax: (715) 478–7618; Email: *angela.vanzile@scc-nsn.gov*

St. Croix Chippewa Indians of Wisconsin, Erin Fowler, Indian Child Welfare Director, 24670 State Road 35/70, Suite 800, Siren, WI 54872; Telephone: (715) 349–2195; Fax: (715) 349–8665; Email: *erinf@stcroixtribalcenter.com*

Stockbridge Munsee Community, Stephanie Bowman, ICWA Manager, Stockbridge Munsee Health and Wellness Center, W12802 County A, Bowler, WI 54416; Telephone: (715) 793–4580; Fax: (715) 793–1312; Email: *Stephanie.bowman@mohican.com*

U

Upper Sioux Community of Minnesota, Linette Tellinghuisen, ICWA Manager, P.O. Box 147, 5744 Hwy. 67, Granite Falls, MN 56241; Telephone: (320) 564–6315; Fax: (320) 564–2550; Email: *linettet@uppersiouxcommunity-nsn.gov*

W

White Earth Indian Child Welfare, Jeri Jasken, Program Director, P.O. Box

358, White Earth, MN 56591; Telephone: (218) 983–4647; Fax: (218) 983–3712; Email: *jeri.jasken@whiteearth.com*

6. Navajo Region

Navajo Region Director, Navajo Regional Office, P.O. Box 1060, Gallup, NM 87301; Telephone: (505) 863–8314; Fax: (505) 863–8324

N

Navajo Nation, Regina Yazzie, MSW, Director, Navajo Children and Family Services (ICWA), P.O. Box 1930, Window Rock, AZ 86515; Telephone: (928) 871–6806; Fax: (928) 871–7667; Email: *reginayazzie@navajo-nsn.gov*

7. Northwest Region

Northwest Regional Director, 911 NE 11th Avenue, Portland, OR 97232; Telephone: (503) 231–6702; Fax (503) 231–2201

B

Burns Paiute Tribe, Michelle Bradach, Social Service Director, 100 Pasigo Street, Burns, OR 97720; Telephone: (541) 573–7312 Ext. 230; Fax: (541) 573–4217; Email: *bradachma@burnspaiute-nsn.gov*

C

Confederated Tribes of the Chehalis Reservation, Nancy Dufraine, Director of Social Services, P.O. Box 536, Oakville, WA 98568; Telephone: (360) 709–1768; Fax: (360) 273–5207; Email: *ndufraine@chehalistribe.org*

Confederated Tribe of the Coville Reservation, Michael Humiston, Office of the Reservation Attorney, P.O. Box 150, Nespelem, WA 99155–011; Telephone: (509) 634–2382; Fax: (509) 634–2387

Coeur d'Alene Tribal Council Social Worker Lead, P.O. Box 408, Plummer, ID 83851; Telephone: (208) 686–8106; Fax: (208) 686–4410

Confederated Salish & Kootenai Tribes of the Flathead Reservation, Charlene Petet, Contract Specialist, P.O. Box 278, Pablo, MT 59855; Telephone: (406) 675–2700 Ext. 1120, Fax: (406) 275–2898; Email: *charlenep@cskt.org*

Confederated Tribes of Coos, Lower Umpqua, & Siuslaw Indians, Dottie Garcia, Family Service Coordinator, P.O. Box 3279, Coos Bay, OR 97420; Telephone: (541) 888–3012; Cell: (541) 297–0370; Fax: (541) 888–1027; Email: *dgarcia@ctclusi.org*

Confederated Tribes of the Grande Ronde Community of Oregon, Dana Ainam, ICWA Contact, 9615 Grand Ronde Road, Grand Ronde, OR 97347–0038; Telephone: (503) 879–2034; Fax: (503) 879–2142

Confederated Tribes of the Umatilla Indian Reservation, M. Brent Leonhard, Deputy Attorney General, 46411 Timine Way, Pendleton, OR 97801; Telephone/Fax: (541) 429–7406; Email: *brentleonhard@ctuir.org*

Coquille Indian Tribe, Bridgett Wheeler, ICWA Worker, 3050 Tremont St., North Bend, OR 97459; Telephone: (541) 888–9494; Fax: (541) 888–6701; Email: *bridgett@uci.net*

Cow Creek Band of Umpqua Tribe of Indians, Andrea Davis, Human Services Director, 2371 NE Stephens Street, Roseburg, OR 97470; Telephone: (541) 677–5575 Ext: 5513; Fax: (541) 677–5574

Cowlitz Indian Tribe, Jim Sherrill, Health and Human Services, P.O. Box 2429, Longview, WA 98632–8594; Telephone: (360) 577–3307; Fax: (360) 577–1948

H

Hoh Indian Tribe, Annette Penn, ICW, P.O. Box 2196, Forks, WA 98331; Telephone: (360) 374–5022; Fax: (360) 374–5039; Email: *milab@hohtribe-nsn.org*

J

Jamestown Skallam Tribal Council, ICWA Specialist, 1033 Old Blyn Hwy, Sequim, WA 98382; Telephone: (360) 681–4639; Fax: (360) 681–3402

K

Kalispel Tribe of Indians, Wendy L. Thomas, MSW, Support Services Director, 934 S Gargeld Road, Airway Heights, WA 99001; Telephone: (509) 789–7634/Cell (509) 671–6972; Fax: (509) 789–7659; Email: *wthomas@camashealth.com*

The Klamath Tribes, Misty Barney, Child Welfare Program Manager; Candi Crume, Child Protective Specialist; Jim Collins, ICW Specialist; Lisa Ruiz, Child Welfare Caseworker; P.O. Box 436, Chiloquin, OR 97624; Telephone: (541) 783–2219; Fax: (541) 783–7783; Email: *misty.barney@klamathtribes.com; Candi.kirk@klamathtribes.com; jim.collins@klamathtribes.com; Lisa.ruiz@klamathtribes.com.*

Kootenai Tribe of Idaho, Jennifer Porter, Vice-Chairwoman, P.O. Box 1269, Bonners Ferry, ID 83805–1269; Telephone: (208) 267–3519; Fax: 208–267–2960

L

Lower Elwha Tribal Community Council, Becca Weed, ICWA Contact, 3080 Lower Elwha Road, Port Angeles, WA 98363–9518; Telephone: (360) 565–7257, ext. 7456; Fax: (360) 457–8429

Lummi Nation, Amy Finkbonner, Lummi Children's Services Manager, P.O. Box 1024 Ferndale, WA 98248; Telephone: (360) 384–2324; Fax: (360) 380–2157; Email: *amyf@lummi-nsn.gov*

M

Makah Indian Tribal Council, Robin Denney, Social Service Manager, P.O. Box 115, Neah Bay, WA 98357; Telephone: (360) 645–3251/3257; Fax: (360) 645–2806

Metlakatla Indian Community, Metlakatla Indian Community (Northwest Region), Marge Edais-Yeltatzie, Director, Social Services Children's Mental Health & ICW, P.O. Box 85, Metlakatla, AK 99926; Telephone: (907) 886–6911; Fax: (907) 886–6913; Email: *marge@msscmh.org*

Muckleshoot Indian Tribe, Human Services Division Director, 39015 172nd Avenue SE., Auburn, WA 98092; Telephone: (253) 939–3311; Fax: (253) 876–2855

N

Nez Perce Tribe, Jeanette Pinkham, ICWA Supervisor, P.O. Box 365, Lapwai, ID 83540; Telephone: (208) 843–7302; Fax: (208) 843–9401; Email: *Jeanettep@nezperce.org*

Nisqually Indian Community, Cynthia Orie, ICWA Contact, 4820 She- Nah-Num Drive SE., Olympia, WA 98513; Telephone: (360) 456–5221; Fax: (360) 486–9555

Nooksack Indian Tribe of Washington, ICW Program Manager, P.O. Box 157, Deming, WA 98244; Telephone: (360) 306–5090; Fax: (360) 592–0167

Northwestern Band of Shoshoni Nation, Jason S. Walker, Chairman, 505 Pershing Ave. Suite 200, Pocatello, ID 83201; Telephone: (208) 478–5712; Fax: (208) 478–5713

P

Port Gamble S'Klallam, David Delmendo, ICWA Program Manager, 31912 Little Boston Road NE., Kingston, WA 98346; Telephone: (360) 297–9672; Fax: (360) 297–9666; Email: *davidd@pgst.nsn.us*

Puyallup Tribe, Sandra Cooper, ICWA Liaison, 3009 E. Portland Avenue, Tacoma, WA 98404; Telephone: (253) 405–7544; Fax: (253) 680–5998

Q

Quileute Tribal Council, Jessica Smith, ICWA Program Manager, P.O. Box 279, LaPush, WA 98331; Telephone: (360) 374–4340; Fax: (360) 374–7796; Email: *jessica.smith@quileutenation.org*

Quinault Indian Nation Business Committee, William (Bill) Lay,

Quinault Family Services Supervisor, P.O. Box 189, Taholah, WA 98587; Telephone: (360) 276–8215 Ext. 355; Fax: (360) 267–4152; Email: *wlay@quinault.org*

S

Samish Indian Nation, Michelle Johnson, Family Services Specialist, P.O. Box 217, Anacortes, WA 98221; Telephone: (360) 899–5282; Fax: (360) 299–4357; Email: *mjohnson@samishtribe.nsn.us*

Sauk-Suiattle Indian Tribe, Raju A.T. Dahlstrom, MSW, Program Administrator Indian Child Welfare, 5318 Chief Brown Lane, Darrington, WA 98241; Telephone: (425) 760–0306; Fax: (360) 436–0242; Email: *rdahlstrom@sauk-suiattle.com.*

Shoalwater Bay Tribal Council, Katherine Horne, ICWA Contact, P.O. Box 130, Tokeland, WA 98590; Telephone: (360) 267–6766 Ext. 3100; Fax: (360) 267–0247

Shoshone Bannock Tribe, Brandelle Whitworth, Tribal Attorney, P.O. Box 306, Ft. Hall, ID 83203; Telephone: (208) 478–3923; Fax: (208) 237–9736; Email: *bwitworth@sbtribes.com*

Confederated Tribes of Siletz Indians, Cathern Tufts, Staff Attorney, P.O. Box 549, Siletz, OR 97380; Telephone: (541) 444–8211; Fax: (541) 444–2307; Email: *cathernt@ctsi.nsn.us*

Skokomish Tribal Council, Laura Munn or Ralph Pulsiser, ICWA Contact, N. 80 Tribal Center Road, Shelton, WA 98584–9748; Telephone: (360) 426–7788; Fax: (360) 877–2151

Snoqualmie Tribe, Marie Ramirez, MSW, ICWA Contact, P.O. Box 280, Carnation, WA 98014; Telephone: (425) 333–5425; Fax: (425) 333–5428

Spokane Tribe of Indians, Tawhnee Colvin, Program Manager/Case Manager, P.O. Box 540, Wellpinit, WA 99040; Telephone: (509) 258–7502; Fax: (509) 258–7029; Email: *tawhneec@spokanetribe.com.*

Squaxin Island Tribe, Donald Whitener, Tribal Administrator, 10 SE Squaxin Lane, Shelton, WA 98584–9200; Telephone: (360) 432–3900; Fax: (360) 426–6577; Email: *dwhitener@squaxin.us.*

Stillaguamish Tribe of Indians, Gloria Green, ICW Director, P.O. Box 3782 or 17014 59th Ave NE., Arlington, WA 98223; Telephone: (360) 435–3985 Ext. 21; Fax: (360) 435–2867

Suquamish Indian Tribe of the Port Madison Reservation, Dennis Deaton, ICWA Contact, P.O. Box 498, Suquamish, WA 98392; Telephone: (360) 394–8478; Fax: (360) 697–6774

Swinomish Indian Tribal Community, Tracey Parker, Swinomish Family Services Coordinator, 17337 Reservation Rd, LaConner, WA 98257; Telephone: (360) 466–7222; Email: *tparker@swinomish.nsn.us*

T

Tulalip Tribe, beda?chelh Manager, 2828 Mission Hill Road, Tulalip, WA 98271; Telephone: (360) 716–3284

U

Upper Skagit Indian Tribe, Felice Keegahn, Indian Child Welfare Coordinator, 25959 Community Plaza Way, Sedro Woolley, WA 98284; Telephone: (360) 854–7077; Fax: (360) 854–7125; Email: *felicek@upperskagit.com.*

W

Warm Springs Tribal Court, Confederated Tribes of Warm Springs Reservation, Chief Judge Lola Sohappy, ICWA Contact, P.O. Box 850, Warm Springs, OR 97761; Telephone: (541) 553–3454; Fax: (541) 553–3281

Y

Confederated Tribes and Bands of the Yakama Nation, David Lees, Esq, Chief Prosecutor, P.O. Box 1119, Toppenish, WA 98948; Telephone: (509) 865–5121 Ext: 4558; Fax: (509) 865–7078; Email: *lees@yakama.com.*

8. Pacific Region

Pacific Region Director, BIA, Federal Building, 2800 Cottage Way, Sacramento, CA 95825; Telephone: (916) 978–6000; Fax: (916) 978–6099

A

Agua Caliente Band of Cahuilla Indians, Attn: Tribal Legal Department, 5401 Dinah Shore Drive, Palm Springs, CA 92264; Telephone: (760) 699–6952; Fax: (760) 699–6865

Alturas Rancheria, Chairman, P.O. Box 340, Alturas, CA 96101; Telephone: (530) 233–5571; Fax: 223–4165

Augustine Band of Cahuilla Indians, Mary Ann Green, Chairperson, P.O. Box 846, Coachella, CA 92236; Telephone: (760) 398–4722

B

Barona Band of Mission Indians, Charity White-Voth, Kumeyaay Family Services Director, Southern Indian Health Council, Inc., 4058 Willow Rd., Alpine, CA 91903; Telephone: (619) 445–1188; Fax: (619) 445–0765

Bear River Band of Rohnerville Rancheria, Vevila Hussey, Social Services Director, 27 Bear River Drive, Loleta, CA 95551; Telephone: (707) 773–1900 Ext: 290; Fax: (888) 733–1900; Email: *vevilahussey.brb@nsn.gov*

Berry Creek Rancheria (See Tyme Maidu Tribe) Big Lagoon Rancheria, Chairperson, P.O. Box 3060, Trinidad, CA 95570; Telephone: (707) 826–2079; Fax: (707) 826–0495

Big Pine Paiute Tribe, Rita Mendoza, Tribal Court Clerk/ICWA Representative, P.O. Box 700 or 825 S. Main Street, Big Pine, CA 93513; Telephone: (760) 938–2003; Fax: (760) 938–2942; Email: *r.mendoza@bigpinepaiute.org*

Big Sandy Rancheria Band of Western Mono Indians, Dorothy Barton, MSW, ICWA/Social Services Coordinator, P.O. Box 337, Auberry, CA 93602; Telephone: (559) 374–0049; Fax: (559) 855–4129; Email: *dbarton@bsrnation.com*

Big Valley Rancheria, ICWA, 2726 Mission Rancheria Road, Lakeport, CA 95453; Telephone: (707) 263–3924; Fax: (707) 263–3977; Email: *resparza@big-valley.net*

Bishop Paiute Tribe, Margaret L. Romero, ICWA Specialist; 50 TuSu Lane, Bishop, CA 93514; Telephone: (760) 873–4414; Fax: (760) 873–4143; Email: *margaret.romero@bishoppaiute.org*

Blue Lake Rancheria, Bonnie Mobbs, Exec Assistant, P.O. Box 428, Blue Lake, CA 95525; Telephone: (707) 668–5101; Fax: (707) 668–4272; Email: *bmobbs@bluelakerancheria-nsn.gov*

Bridgeport Indian Colony, Michael Lumsden, Tribal Administrator, P.O. Box 37 or 355 Sage Brush Drive, Bridgeport, CA 93517; Telephone: (760) 932–7083; Fax: (760) 932–7846; Email: *admin@bridgeportindiancolony.com*

Buena Vista Rancheria of Me-Wuk Indians, Penny Arciniaga, Tribal Member Services, 1418 20th Street, Suite 200, Sacramento, CA 95811; Telephone: (916) 491–0011; Fax: (916) 491–0012; Email: *penny@buenavistatribe.com*

C

Cabazon Band of Mission Indians, Chairman, 84–245 Indio Springs Drive, Indio, CA 92201; Telephone: (760) 342–2593; Fax: (760) 347–7880

California Valley Miwok Tribe, Rashel Reznor, ICWA Coordinator, 10601 N. Escondido Pl., Stockton, Calif. 95212; Telephone: (209) 931–4567; Fax: (209) 931–4333; Email: *icwa@californiavalleymiwoktribe-nsn.gov*

Cahuilla Band of Indians, Executive Director, 52701 Hwy 371, Anza, CA 92539; Telephone: (951) 763–5549; Fax: (951) 763–2808; Email: *tribalcouncil@cahuilla.net*

Campo Band of Mission Indians, Charity White-Voth, Kumeyaay, Family

Services Director, Southern Indian Health Council, Inc., 4058 Willow Rd., Alpine, CA 91903; Telephone: (619) 445–1188; Fax: (619) 445–0765

Cedarville Rancheria, Melissa Davis, Administrative Assistant, 300 West First Street, Alturas, CA 96101; Telephone: (530) 233–3969; Fax: (530) 233–4776; Email: *phyrra@rocketmail.com*

Cher-Ae Heights Indian Community of the Trinidad Rancheria, Amy Atkins, Executive Manager, P.O. Box 630, Trinidad, CA 95570; Telephone: (707) 677–0211; Fax: (707) 677–3921; Email: *aatkins@trinidadrancheria.com*

Chicken Ranch Rancheria, Jan Costa, Tribal Administrator, P.O. Box 1159, Jamestown, CA 95327; Telephone: (209) 984–4806; Fax: (209) 984–5606; Email: *chixrnch@mlode.com*

Cloverdale Rancheria of Pomo Indians, Christina Hermosillo, ICWA Advocate, 555 S. Cloverdale Blvd., Cloverdale, CA 95425; Telephone: (707) 894–5775; Fax: (707) 894–5727

Cold Springs Rancheria, Terri Works, ICWA Director, P.O. Box 209, Tollhouse, CA 93667; Telephone: (559) 855–5043/(559) 855–8360; Fax: (559) 855–4445; Email: *csrancheriaterri@netptc.net*

Colusa Indian Community Council, Daniel Gomez Sr., Chairman, 3730 Highway 45, Colusa, CA 95932; Telephone: (530) 458–8231; Fax: (530) 458–4186; Email: *dgomez@colusansn.gov*

Cortina Band of Wintun Indians (Cortina Indian Rancheria), Charlie Wright, Tribal Chairman, P.O. Box 1630, Williams, CA 95987; Telephone: (530) 473–3274, Fax: (530) 473–3301

Coyote Valley Band of Pomo Indians, c/o Lorraine Laiwa, Indian Child And Family Preservation Program, 684 South Orchard Avenue, Ukiah, CA 95482; Telephone: (707) 463–2644; Fax: (707) 463–8956; Email: *lorainnel_1@comcast.net*

Cuyapaipe Ewiiaapaayp Band of Kumeyaay Indians (See Ewiiaapaayp Band of Kumeyaay Indians

D

Dry Creek Rancheria Band of Pomo Indians, Percy Tejada, ICWA Advocate, P.O. Box 607 Geyserville, CA 95441; Telephone: (707) 522–4248; Fax: (707) 522–4291; Email: *percyt@drycreekrancheria.com*

E

Elem Indian Colony Pomo Tribe, Nathan M. Brown II, Chairman, P.O. Box 757 Lower Lake, CA 95457; Telephone: (707) 994–3400; Fax: (707) 994–3408; Email: *nbrown@elemindiancolony.org*

Elk Valley Rancheria, LaWanda Quinnell, Council Secretary, 2332 Howland Hill Rd, Crescent City, CA 95531; Telephone: (707) 464–4680; Fax: (707) 464–4519; Email: *lquinnell@elk-valley.com*

Enterprise Rancheria Estom Yumeka Maidu Tribe, Shari Ghalayini, ICWA Director, 2133 Monte Vista Ave, Oroville, CA 95966; Telephone: (530) 532–9214; Fax: (530) 532–1768; Email: *sharig@enterpriserancheria.org*

Ewiiaapaayp Band of Kumeyaay Indians, Will Micklin, CEO, 4050 Willow Road. Alpine, CA 91901; Telephone: (619) 445–6315; Fax: (619) 445–9126

F

Federated Indians of Graton Rancheria, Lara Walker, Wellness and Justice Director, 6400 Redwood Drive, Suite 300, Rohnert Park, CA 94928; Telephone: (707) 586–6110; Fax: (707) 566–2291; Email: *lwalker@gratonrancheria.com*

Fort Bidwell Reservation, Bernold Pollard, Chairperson, P.O. Box 129, Fort Bidwell, CA 96112; Telephone: (530) 279–6310; Fax: (530) 279–2233

Fort Independence Indian Reservation, Israel Naylor, Tribal Chairman, P.O. Box 67 or 131 North Hwy 395, Independence, CA 93526; Telephone: (760) 878–5160: Fax: (760) 878–2311; Email: *Israel@fortindependence.com*

G

Greenville Rancheria, Dr. Gonzalo Gonzalez, ICWA Representative, P.O. Box 279, Greenville, CA 95947; Telephone: (530) 284–7990; Fax: (530) 284–6612 ; Email: *ggonzalez@greenvillerancheria.com*

Grindstone Indian Rancheria, Aaston Bill, ICWA, P.O. Box 63, Elk Creek, CA 95939; Telephone: (530) 968–5365; Fax: (530) 968–5366

Guidiville Band of Pomo Indians, Merlene Sanchez, Tribal Chairperson, P.O. Box 339, Talmage, CA 95481; Telephone: (707) 462–3682; Fax: (707) 462–9183; Email: *admin@guidiville.net*

H

Habematolel Pomo of Upper Lake, Angelina Arroyo, ICWA Advocate, 375 E. Hwy 20, Suite ''I'', Upper Lake, CA 95485–0516; Telephone: (707) 275–0737; Cell: (707) 275–2947; Fax: (707) 275–0757; Email: *tribaladmin@upperlepomo.com* or *executive.secretary@upperlakepomo.com*

Hoopa Valley Tribe, Director, Human Services, P.O. Box 1348, Hoopa, CA 95546; Telephone: (530) 625–4211; Fax: (530) 625–4594

Hopland Band of Pomo Indians, Tania Mota, ICWA Social Case Management Worker, 3000 Shanel Rd., Hopland, CA 95449; Telephone: (707) 472–2100 Ext: 1114; Fax: (707) 472–2109; Email: *tmota@hoplandtribe.com*

I

Inaja & Cosmit Band of Mission Indians, Tribal Family Services, Manager Indian Health Council, Inc., P.O. Box 406, Pauma Valley, CA 92061; Telephone: (760) 749–1410; Fax: (760) 749–5518

Ione Band of Miwok Indians, Pamela Baumgartner, Tribal Administrator, P.O. Box 699, Plymouth, CA 95669; Telephone: (209) 245–5800 Ext: 5801; Email: *pam@ionemiwok.org*

J

Jackson Rancheria Band of Miwuk Indians, Marshawn Morla, Tribal Secretary, P.O. Box 1090, Jackson, CA 95642; Telephone: (209) 223–1935; Fax: (209) 223–5366; Email: *mmorla@jacksoncasino.com*

Jamul Indian Village, Charity White-Voth, Kumeyaay Family Services Director, Southern Indian Health Council, Inc., 4058 Willow Rd., Alpine, CA 91903; Telephone: (619) 445–1188; Fax: (619) 445–0765

K

Karuk Tribe of California, April Attebury, Administrator, Child Welfare Services Program/ICWA Unit, 1519 S. Oregon Street, Yreka, CA 96097; Telephone: (530) 841–3141; Fax: (530) 842–6283

L

La Jolla Band of Luiseno Indians, Tribal Family Services, Manager, Indian Health Council, Inc., P.O. Box 406, Pauma Valley, CA 92061; Telephone: (760) 749–1410; Fax: (760) 749–5518

La Posta Band of Mission Indians, Charity White-Voth, Kumeyaay Family Services Director, Southern Indian Health Council, Inc., 4058 Willow Rd., Alpine, CA 91903; Telephone: (619) 445–1188; Fax: (619) 445–0765

Laytonville Rancheria, Cherie Smith-Gibson, Tribal Administrator, P.O. Box 1239, Laytonville, CA 95454; Telephone: (707) 984–6197 Ext: 104; Fax: (707) 984–6201; Email: *ta@cahto.org*

Lone Pine Reservation, Kathy Brancroft, Enrollment Committee Chairperson, P.O. Box 747, Lone Pine, CA 93545; Telephone: (760) 876–1034; Fax: (760) 876–8302

Los Coyotes Band of Cahuilla & Cupeno Indians, Tribal Family Services

Manager, Indian Health Council, Inc., P.O. Box 406, Pauma Valley, California 92061; Telephone: (760) 749–1410; Fax: (760) 749–5518

Koi Nation of Northern California, Chairperson, P.O. Box 3162, Santa Rosa, CA 95402; Telephone: (707) 575–5586; Fax: (707) 575–5506

Lytton Rancheria c/o Indian Child and Family Preservation Program, Liz DeRouen, 2525 Cleveland Ave, Suite H, Santa Rosa, CA 95403; Telephone: (707) 544–8509; Fax: (707) 544–8729; email: *lizderouen@sbcglobal.net*

M

Manchester-Point Arena Band of Pomo Indians, Lorraine Laiwa, Executive Director, Indian Child and Family Preservation Program, 684 South Orchard Avenue, Ukiah, CA 95482; Telephone: (707) 463–2644; Fax: (707) 463–8956; Email: *lorrainel_1@comcast.net*

Manzanita Band of Mission Indians, Chairperson, P.O. Box 1302, Boulevard, CA 91905; Telephone: (619) 766–4930; Fax: (619) 766–4957

Mechoopda Indian Tribe of Chico Rancheria, Arlene Ward, Office Manager, 125 Mission Ranch Boulevard, Chico, CA 95926; Telephone: (530) 899–8922; Fax: (530) 899–8517; Email: *baward@mechoopda-nsn.gov*

Mesa Grande Band of Mission Indians, Tribal Family Services, Manager, Indian Health Council, Inc., P.O. Box 406, Pauma Valley, CA 92061; Telephone: (760) 749–1410; Fax: (760) 749–5518

Middletown Rancheria, ICWA Director, Mary Comito, P.O. Box 1829; Middletown, CA 95461; Telephone: (707) 987–8288; Fax: (707) 987–8205; Cell: (707) 326–6876; Email: *mcomito@middletownrancheria.com*

Mooretown Rancheria, Francine McKinley, ICWA Director, 1 Alverda Drive, Oroville, CA 95966; Telephone: (530) 533–3625; Fax: (530) 533–0664; Email: *icwa@mooretown.org;*

Morongo Band of Cahuilla Mission Indians, Paula Tobler, Social Worker, 11581 Potrero Road, Banning, CA 92220; Telephone: (951) 849–4697; Fax: (951) 922–0338

N

North Fork Rancheria of Mono Indians, Elaine Fink, Tribal Chairwoman, P.O. Box 929, North Fork, CA 93643; Telephone: (559) 877–2484; Fax: (559) 877–2467; Email: *efink@northforkrancheria-nsn.gov*

P

Pala Band of Mission Indians, Season Lattin, ICWA Manager, Department of Social Services, 35008 Pala-Temecula Road, PMB 50, Pala, CA 92059. Telephone: (760) 891–3542; Fax: (760) 742–1293

Paskenta Band of Nomlaki Indians, Ines Crosby, Tribal Administrator, 1012 South Street, Orland, CA 95963; Telephone: (530) 865–2010; Fax: (530) 865–1870; Email: *office@paskenta.org*

Pauma & Yuima Band of Mission Indians, Tribal Family Services, Manager, Indian Health Council, Inc., P.O. Box 406, Pauma Valley, CA 92061; Telephone: (760) 749–1410; Fax: (760) 749–5518

Pechanga Band of Mission Indians, Mark Macarro, Spokesman, P.O. Box 1477, Temecula, CA 92593; Telephone: (951) 676–2768; Fax: (951) 695–1778

Picayune Rancheria of the Chukchansi Indians, Orianna C. Walker, ICWA Coordinator, 46575 Road 417, Coarsegold, CA 93614; Telephone: (559) 683–6633 Ext: 212; Fax: (559) 692–8792; Email: *owalker@picayunerancheria-nsn.gov*

Pinoleville Pomo Nation, Lenora Steele, Self-Governance Director, 500 B Pinoleville Drive, Ukiah, CA 95482; Telephone: (707) 463–1454; Fax: (707) 463–6601; Email: *lenora@pinolevillensn.us*

Pit River Tribe, Veronon Ward, Jr., Coordinator, Social Services, 36970 Park Avenue, Burney, CA 96013; Telephone: (530) 335–5530; Fax: (530) 335–3140

Potter Valley Tribe, Salvador Rosales, Tribal Chairman, 2251 South State Street, Ukiah, CA 95482; Telephone: (707) 462–1213; Fax: (707) 462–1240; Email: *pottervalleytribe@pottervalleytribe.com*

Q

Quartz Valley Indian Reservation, Frieda Bennett, Education Director/Social Services, 13601 Quartz Valley Rd., Fort Jones, CA 96032; Telephone: (530) 468–5907; Fax: (530) 468–5908

R

Ramona Band or Village of Cahuilla, Susan Reckker, Tribal Administrator, P.O. Box 391670 Anza, CA 92539; Phone: (951)763–4105; Fax: (951) 763–4325; Email: *sreckker@ramonatribe.com*

Redding Rancheria, Director, Social Services, 2000 Rancheria Road, Redding, CA 96001–5528; Telephone: (530) 225–8979

Redwood Valley Rancheria-Band of Pomo, Janie Navarez, ICWA Coordinator, 3250 Road I, ''A'' Building, Redwood Valley, CA 95470; Telephone: (707) 485–0361; Fax: (707) 485–5726

Resighini Rancheria, Keshan Dowd, Social Services Director, P.O. Box 529, Klamath, CA 95548; Telephone: (707) 482–2431; Fax: (707) 482–3425

Rincon Band of Mission Indians, Tribal Family Services, Manager, Indian Health Council, P.O. Box 406, Pauma Valley, CA 92061; Telephone: (760) 749–1410; Fax: (760) 749–8901

Robinson Rancheria, ICWA Coordinator, P.O. Box 4015, Nice, CA 95464; Telephone: (707) 275–0527; Fax: (707) 275–0235; Email: *mvasquez@robinsonrancheria.com*

Round Valley Indian Tribes, Lois Whipple, Tribal President, 77826 Covelo Road, Covelo, CA 95428; Telephone: (707) 983–6126; Fax: (707) 983–6128; Email: *administrator@rvit.org*

Yocha Dehe Wintun Nation, James Kinter, Tribal Council Secretary, P.O. Box 18, Brooks, CA 95606; Telephone: (530) 796–3400; Fax: (530) 796–2143; Email: *djones@yochadehe-nsn.gov*

S

San Manuel Band of Mission Indians, Tribal Secretary, 26569 Community Center Drive, Highland, CA 92346; Telephone: (909) 864–8933; Fax: (909) 864–3370

San Pasqual Band of Diegueno Indians, Tribal Family Services, Manager, Indian Health Council, Inc., P.O. Box 406, Pauma Valley, CA 92061; Telephone: (760) 749–1410; Fax: (760) 749–5518

Santa Rosa Band of Cahuilla Indians, John Marcus, Chairman, P.O. Box 391820, Anza, CA 92539; Telephone: (951) 659–2700; Fax: (951) 689–2228.

Santa Rosa Rancheria Tachi-Yokut Tribe, Janice Cuara, Tribal Administrator, 16835 Alkali Drive; P.O. Box 8, Lemoore, CA 93245; Telephone: (559) 924–1278 Ext: 4051; Cell: (559) 381–4928; Fax: (559) 925–2931; Email: *jcuara@tachi-yokut.com*

Santa Ynez Band of Chumash Indians, Caren Romero, ICWA Representative, P.O. Box 539, Santa Ynez, CA 93460; Telephone: (805) 694–2671; Fax: (805) 686–2060; Email: *cromero@sythc.com*

Santa Ysabel Band of Mission Indians-Iipay Nation, Linda Ruis, Director, Santa Ysabel Social Services Dept., P.O. Box 701, Santa Ysabel, CA 92070; Telephone: (760) 765–1106; Fax: (760) 765–0312

Scotts Valley Band of Pomo Indians, Tribal ICWA Worker, 1005 Parallel Drive, Lakeport, CA 95453; Telephone: (707) 263–4220; Fax: (707) 263–4345; Email: *cmiller@svpomo.org*

Sherwood Valley Band of Pomo Indians, Stefan Hood, ICWA Advocate, 190 Sherwood Hill Drive, Willits, CA 95490; Telephone: (707) 459–9690;

Fax: (707) 459–6936; Email: *svrchair@gmail.com*

Shingle Springs Band of Miwok Indians (Shingle Springs Rancheria), Malissa Tayaba, Social Services Director, P.O. Box 1340; Shingle Springs, CA 95682; Telephone: (530) 698–1436 or (530) 698–1400; Fax: (530) 387–8041; Email: *mtayaba@ssband.org*

Smith River Rancheria, Dorothy Perry, Director, 140 Rowdy Creek Road, Smith River, CA 95567–9446; Telephone: (707) 487–9255; Fax: (707) 487–0930

Soboba Band of Luiseno Indians, Nancy Currie, Tribal Social Worker, Soboba Tribal Family Services Department; P.O. Box 487, San Jacinto, CA 92581; Telephone: (951) 487–0283; Fax: (951) 487–1738

Kashia Band of Pomo Indians of the Stewarts Point Rancheria, Reno K. Franklin, Tribal Chairman, 1420 Guerneville Rd, Suite 1, Santa Rosa, CA 95403; Telephone: (707) 591–0580; Fax: (707) 591–0583; Email: *Reno@stewartspoint.org*

Susanville Indian Rancheria, Deborah A. Olstad, Tribal Office Manager, 745 Joaquin St., Susanville, CA 96130; Telephone: (530)251–5153; Fax: (530) 257–7986; Email: *dolstad@citilink.net*

Sycuan Band of Mission Indians, Charity White-Voth, Kumeyaay Family Services Director, Southern Indian Health Council, Inc., 4058 Willow Rd., Alpine, CA 91903; Telephone: (619) 445–1188; Fax: (619) 445–0765

T

Table Mountain Rancheria, Frank Marquez Jr., Tribal Chief of Police, 23736 Sky Harbour Rd., Friant, CA 93626; Telephone: (559) 822–6336; Fax: (559) 822–6340; Email: *fmarquezjr@tmr.org*

Tejon Indian Tribe, Kathryn Montes Morgan, Tribal Chair, 1731 Hasti-Acres Drive #108, Bakersfield, CA 93309; Telephone: (661) 834–8566; Email: *kmorgan@tejontribe.net*

Timbi-sha Shoshone Tribe, Attention: Wally Eddy, 621 West Line Street, Suite 109, Bishop, CA 93514; Telephone: (760) 872–3614; Fax: (760) 872–3670; Email: *icwa@timbisha.com*

Torres Martinez Desert Cahuilla Indians, Annette Chihuahua, ICWA Case Assistant/Tribal Delegate TMDCI, 66–725 Martinez Rd., Thermal, CA 92274; Telephone: (760) 578–8334 or (760) 397–0455 Ext: 1101; Fax: (760) 397–3925; Email: *achihuahua@tmdci.org*

Tule River Reservation, Lolita Garfield, MSW, Director Family Social Services, 340 North Reservation Road, Porterville, CA 93258; Telephone: (559) 781–4271 ext: 1013; Fax: (559) 791–2122; Email: *icwadir@tulerivertribe-nsn.gov*

Tuolumne Band of Me-Wuk Indians, Kevin Day, Tribal Chair, P.O. Box 699, Tuolumne, CA 95379; Telephone: (209) 928–5300; Fax: (209) 928–1677; Email: *kday@mewuk.com*

Twenty-Nine Palms Band of Mission Indians, Executive Director, Indian Child & Family Services, P.O. Box 2269, Temecula, CA 92590; Telephone: (951) 676–8832; Fax: (951) 676–3950

Tyme Maidu Tribe (Berry Creek Rancheria), Terilynn Steel, ICWA Supervisor, 5 Tyme Way, Oroville, CA 95966; Telephone: (530) 534–3859, Fax: (530) 534–1151; Email: *jessebrown@berrycreekrancheria.com*

U

United Auburn Indian Community, Melanie Connors, MSW, ICWA Case Manager, 945 Indian Rancheria Rd., Auburn, CA 95603; Telephone: (530) 251–1510; Fax: (530) 878–5470, Email: *MConnors@auburnrancheria.com*

Utu Utu Gwaitu Paiute Tribe, Billie Saulque, Chairman, 25669 Hwy 6, PMB I, Benton, CA 93512; Telephone: (760) 933–2321; Fax: (760) 933–2412; Email: *bentonpaiutetribe@hughes.net*

V

Viejas (Baron Long) Band of Mission Indians, Charity White-Voth, Kumeyaay Family Services Director, Southern Indian Health Council, Inc., 4058 Willow Rd., Alpine, CA 91903; Telephone: (619) 445–1188; Fax: (619) 445–0765

W

Wilton Rancheria, Anastasia Tran, ICWA Advocate, 9300 West Stockton Blvd., Ste. 200 Elk Grove, CA 95758; Telephone: (916) 683–6000; Fax: (916) 683–6015

Wiyot Tribe, Sarah Vevoda, Director of Social Services, 1000 Wiyot Drive, Loleta, CA 95551; Telephone: (707) 733–5055; Fax: (707) 482–1377

Y

Yurok Tribe, Stephanie Weldon, Director Social Services, P.O. Box 1027, Klamath, CA 95548; Telephone: (707) 482–1350; Fax: (707) 482–1377; Email: *sweldon@yuroktribe.nsn.us*

9. Rocky Mountain Region

Rocky Mountain Regional Director, 2021 4th Avenue North, Billings, MT 59101; Telephone: (406) 247–7943; Fax: (406) 247–7976

B

Blackfeet Tribe of Montana, Kathy Calf Boss Ribs, ICWA Coordinator; Darlene H. Peterson, ICWA Inquiry Technician, P.O. Box 588 Browning, MT 59417; Telephone: (406) 338–7806; Fax: (406) 338–7726; Email: *kathybossribs@yahoo.com*

C

Chippewa-Cree Tribe, Rocky Boy's Agency, Montana, Christina Trottier, ICWA Case Manager, 31 Agency Square, Box Elder, MT 59521; Telephone: (406) 395–4735; Fax: (406) 395–5184; Email: *christina.trottier@yahoo.com*

Crow Tribe of the Crow Reservation of Montana, Melveen Paula Fisher, ICWA Coordinator, P.O. Box 340, Crow Agency, MT 59022; Telephone: (406) 638–7429; Fax: (406) 638–7413; Email: *MelveenPaula.Fisher@crow-nsn-gov*

E

Eastern Shoshone Tribe of the Wind River Reservation, Arnella Oldman, ICWA Coordinator, P.O. Box 1796, Fort Washakie, WY 82514; Telephone: (307) 332–2669; Fax: (307) 332–6593

F

Fort Belknap Indian Community, Myron L. Trottier, ICWA Case Manager, Fort Belknap Social Services, 656 Agency Main Street, Harlem, MT 59526; Telephone: (406) 353–8328; Fax: (406) 353–4634; Email: *mtrottier@ftbelknap.org*

Fort Peck Assiniboine and Sioux Tribes, Ms. Lois Weeks, ICWA Case Manager, P.O. Box 1027, Poplar, MT 59255; Telephone: (406) 768–2402; Fax: (406) 768–3710; Email: *lweeks@fptc.org*

N

Northern Arapaho Tribe of the Wind River Reservation, ICWA Coordinator, P.O. Box 396, Fort Washakie, WY 82514; Telephone: (307) 332–6120 ext. 130; Fax: (307) 332–7543

Northern Cheyenne, Michelle Little Wolf Sandcrane, ICWA Coordinator, P.O. Box 128, Lame Deer, Montana 59043; Telephone: (406) 477–4830; Fax: (406) 477–8333; Email: *michelle.littlewolf@cheyennenation.com*

10. Southern Plains Region

Southern Region Director, 1 Mile North, Hwy 281, Anadarko, OK 73005; Telephone: (405) 247–6673; Fax: (405) 247–5611

A

Absentee-Shawnee Tribe of Oklahoma Indians, Ronelle Baker, ICWA Director, 2025 S. Gordon Cooper Drive, Shawnee, OK 74801; Telephone: (405) 874–4702 Ext. 133;

Fax: (405) 878–4540; Email: *rbaker@astribe.com*

Alabama-Coushatta Tribe of Texas, Samantha Battiest (936) 563–1252; Fax: (936) 563–1254; Email: *battiest.samantha@actribe.org*

Apache Tribe of Oklahoma, Anadarko Agency, Community Services, P.O. Box 309, Anadarko Oklahoma, 73005, Sallie Allen, Supervisory Social Worker, (405) 247–8515, Fax (405) 247–2252; Email: *sallie.allen@bia.gov*

Caddo Nation of Oklahoma, Mary Prentiss, ICW Caseworker, P.O. Box 309, Binger, OK 73009; Telephone: (405) 656–9231; Fax: (405) 656–9237; Email: *mprentiss@caddonation.org*

Cheyenne and Arapaho Tribes of Oklahoma, Yolanda Woods, ICW Coordinator, P.O. Box 27, Concho, OK 73022; Telephone: (405) 422–7471; Fax: (405) 422–8249; Email: *ywoods@c-a-tribes.org*

Citizen Potawatomi Nation, Janet Draper, ICW Director, 1601 S. Gordon Cooper Drive, Shawnee, OK 74801; Telephone: (405) 878–4831; Fax: (405) 878–4659; Email: *jdraper@potawatomi.org*

Comanche Nation-Oklahoma, Carol Gooday-Mithlo, ICW Director, P.O. Box 908, Lawton, OK 73502; Telephone: (580) 492–3352; Fax: (580) 354–0808; Email: *carolm@comanchenation.com*

D

The Delaware Nation, Carlos Juan Feliciano, ICW Director, P.O. Box 825, Anadarko, OK 73005; Telephone: (405) 247–2448 Ext: 1152; Fax (405) 247–5942; Email: *jfeliciano@delawarenation.com*

F

Fort Sill Apache Tribe of Oklahoma, Ramona Austin, ICWA Director, 43187 US Highway 281, Apache, OK 73006; Telephone: (580) 588–2298; Fax: (580) 588–2106; Email: *fsaicw08@yahoo.com*

I

Iowa Tribe of Kansas, Chairperson, 3345 B. Thrasher Rd., White Cloud, KS 66094; Telephone: (785) 595–3258

Iowa Tribe of Oklahoma, Mary Davenport, ICW Director, 335588 E. 750 Road, Perkins, OK 74059; Telephone: (405) 547–4234; Fax: (405) 547–1060; Email: *mdavenport@iowanation.org*

K

Kaw Nation, Roger Sober, ICW Director, P.O. Box 5, Kaw City, Oklahoma 74641;Telephone: (580) 269–2003; Email: *rsober@kawnation.com*

Kickapoo Traditional Tribe of Texas, Director Indian Child Welfare, 286 Falcon Blvd., Eagle Pass, TX 78852; Telephone: (830) 766–5601; Work Cell: (830) 513–2937; Fax: (830) 776–5605

Kickapoo Tribe of Indians of The Kickapoo Reservation in Kansas, Chairperson, P.O. Box 271, Horton, KS 66439; Telephone: (785) 486–2131

Kickapoo Tribe of Oklahoma, Jodi Owings, ICW and Family Violence Director, P.O. Box 46, McLoud, OK 74851; Telephone: (405) 964–5426; Fax: (405) 964–5431; Email: *jwarrior@kickapootribeofoklahoma.com*

Kiowa Tribe of Oklahoma, Shannon Ahtone, ICWA Director, P.O. Box 9, Carnegie, Oklahoma 73015; Telephone: (580) 654–2300; Fax: (580) 654–2363

O

Otoe-Missouria Indian Tribe of Oklahoma, Ada Mehojah, Social Services Director, 8151 Highway 177 Red Rock, OK 74651; Telephone: (580) 723–4466 Ext: 256; Cell Phone: (580) 307–7303; Fax: (580) 723–1016; Email: *amehojah@omtribe.org*

P

Pawnee Nation of Oklahoma, Joanna (Jodi) Flanders, BSW, MSW, ICW Coordinator, P.O. Box 470, Pawnee, OK 74058; Telephone: (918) 762–4045; Fax: (918) 762–6449; Email: *jflanders@pawneenation.org*

Ponca Tribe of Oklahoma, Amy Oldfield, ICW Director, 20 White Eagle Drive, Ponca City, OK 74601; Telephone: (580) 763–0133; Fax: (580) 763–0134; Email: *amyo.ponka@gmail.com*

Prairie Band of Potawatomi Nation, Chairperson, 16281 Q. Road, Mayetta, KS 66509; Telephone: (785) 966–2255

S

Sac and Fox Nation in Kansas and Nebraska, Michael Dougherty, Tribal Chairperson, 305 N. Main Street, Reserve, KS 66434; Telephone: (785) 742–0053 Ext: 23; Fax: (785) 742–7146

Sac and Fox Nation, Principal Chief, Route 2, Box 246, Stroud, OK 74079; Telephone: (918) 968–3526

T

Tonkawa Tribe of Oklahoma, Christi Gonzalez, ICWA Director, P.O. Box 70, 1 Rush Buffalo Road, Tonkawa, OK 74653; Telephone: (580) 628–7025; Fax: (580) 628–3336; Email: *cgonzalez@tonkawatribe.com*

W

Wichita & Affiliated Tribes, Joan Williams, Family & Children Services Director, P.O. Box 729, Anadarko, OK 73005; Telephone: (405) 247–8627; Fax: (405) 247–8873; Email: *joan.williams@wichitatribe.com*

11. Southwest Region

Southwest Region Director, 1001 Indian School Road, NW., Albuquerque, NM 87104; Phone: (505) 563–3103; Fax: (505) 563–3101

A

Pueblo of Acoma, Marsha Vallo, Child Welfare Coordinator, P.O. Box 354, Acoma, NM 87034; Phone: (505) 552–5162; Fax: (505) 552–0903; Email: *Mlvallo@puebloofacoma.org*

C

Pueblo de Cochiti, Richard Pecos, Tribal Administrator, 255 Cochiti Street, P.O. Box 70, Cochiti Pueblo, NM 87072; Phone: (505) 465–3104; Fax: (505) 465–1135; Email: *richard_pecos@pueblodeconchiti.org*

I

Pueblo of Isleta, New Mexico, Jacqueline Yalch, ICWA Coordinator, P.O. Box 1270, Isleta, NM 87022; Phone: (505) 869–2772; Fax (505) 869–7575; Email: *Poi05009@isletapueblo.com*

J

Pueblo of Jemez, Annette Chinana, Jemez Social Service Program-Child Advocate, P.O. Box 340, Jemez Pueblo, NM 87024; Phone: (575) 834–7117; Fax: (575) 834–7103; Email: *Annette.chinana@jemezpueblo.us*

Jicarilla Apache Nation, Olivia Nelson-Lucero, Acting Program Manager, Jicarilla Behavioral Health, P.O. Box 546, Dulce, NM 87528; Phone: (575) 759–1712; Fax: (575) 759–3757; Email: *onelson@jbhd.org*

L

Pueblo of Laguna, Marie A. Alarid, Program Manager and Rebecca Quam, Social Services Specialist II (back-up), P.O. Box 194, Laguna, NM 87026; Phone: (505) 552–9712 Fax: (505) 552–6484; Email: *malarid@lagunapueblo-nsn.gov;* or *rquam@lagunapueblo-nsn.gov*

M

Mescalero Apache Tribe, Crystal Lester, Tribal Census Clerk, P.O. Box 227, Mescalero, NM 88340; Phone (575) 464–4494; Fax: (575) 464–9191; Email: *clester@matisp.net*

N

Pueblo of Nambe, Venus Montoya-Felter, Coordinator, 15A NP102 West, Santa Fe, NM 87506; Phone (505) 455–4412; Fax (505) 455–4455; Email: *vmontoya-felter@nambepueblo.org*

O

Ohkay Owingeh, Rochelle Thompson, ICWA Director, P.O. Box 1187, Ohkay Owingeh, NM 87566; Phone (575) 770–0033; Fax: (505) 852–1372; Email: *Rochelle.thompson@ohkayowingehnsn.gov*

P

Pueblo of Picuris, Jose Albert Valdez, P.O. Box 127, Penasco, NM 87553; Phone (575) 587–1003; Cell: (575) 779–2146; Fax (575) 587–1003; Email: *javicwa@aol.com*

Pueblo of Pojoaque, Elizabeth Duran MSW, MPH, Social Services Director, 58 Cities of Gold Road, Suite 4, Santa Fe, NM 87506; Phone: (505) 455–0238; Fax: (505) 455–2363; Email: *eduran@puebloofpojoaque.org*

R

Ramah Navajo School Board, Inc., Marlene Martinez, Administrative Services Director, P.O. Box 10, Pine Hill, NM 87357; Phone (505) 775–3256; Fax: (505) 775–3240; Email: *marlene@rnsb.k12.nm.us*

S

Pueblo of San Felipe, Darlene Valencia, MSW, Family Services Department Director, P.O. Box 4339, San Felipe Pueblo, NM 87004; Phone (505) 771–9900; Fax: (505) 867–6166; Email: *dvalencia@sfpueblo.com*

Pueblo of San Ildelfonso, Julie Sanchez, ICWA Manager/Family Advocate, 02 Tunyo Po, Santa Fe, NM 87506; Phone (505) 455–4164; Fax: (505) 455–7942; Email: *jjsanchez@sanipueblo.org*

Pueblo of Sandia, Randall Berner, Behavioral Health Manager, 481 Sandia Loop, Bernalillo, NM 87004; Phone: (505) 867–5131; Fax: (505) 867–7099; Email: *rberner@sandiapueblo.nsn.us*

Pueblo of Santa Ana, George M. Montoya, Governor, Santa Ana Pueblo, 02 Dove Road, Santa Ana Pueblo, NM 87004; Phone: (505) 771–6702; Fax:(505) 771–6575; Email: *governor@santaana-nsn.gov*

Pueblo of Santa Clara, Cheryl Tafoya, ICWA Worker, P.O. Box 580, Espanola, NM 87532; Phone: (505) 753–0419 or (505) 692–6250; Fax: (505) 753–0420; Email: *ectafoya@santaclarapueblo.org*

Santo Domingo, Doris Bailon, Program Director, P.O. Box 129, Santo Domingo, NM 87052; Phone: (505) 465–0630; Fax: (505) 465–2554; Email: *dbailon@kewa-nsn.us*

Southern Ute Indian Tribe, Jerri Sindelar, ICWA Caseworker, MS 40, P.O. Box 737, Ignacio, CO 81137; Phone (970) 769–2920; Fax (970) 563–0334; Email: *jsindelar@southernute.nsn.us*

T

Pueblo of Taos, Ezra Bayles, Taos Pueblo Health and Community Services, P.O. Box 1846, Taos, NM 87571; Phone: (575) 758–7824; Fax: (575) 758–3346; Email: *EBayles@taospueblo.com*

Pueblo of Tesuque, Jeanette Jagles, Director Social Services, Route 42, Box 360–T, Santa Fe, NM 87506; Phone: (505) 955–7713; Fax: (505) 982–2331; Email: *jjagles@puebloftesuque.org*

U

Ute Mountain Ute Tribe, Constance Lehi, Director, P.O. Box 300, Towaoc, CO 81334; Phone: (970) 564–5302; Fax: (970) 564–5300; Email: *Clehi@utemoutain.org*

Y

Ysleta del Sur Pueblo, Jesus Donacio, ICW Specialist, 9314 Juanchido Ln., El Paso, TX 79907; Phone: (915) 860–6119, Ext. 6174; Fax: (915) 858–2367; Email: *JDonacio@ydsp-nsn.gov*

Z

Pueblo of Zia, Victoria Herrera, ICWA Coordinator, 135 Capital Square Drive, Zia Pueblo, NM 87053; Phone: (505) 867–3304; Fax: (505) 867–3308; Email: *vherrera@ziapueblo.org*

Pueblo of Zuni, Betty Nez, Program Manager, P.O. Box 339, Zuni, NM 87327; Phone: (505) 782–7166; Fax: (505) 782–7221; Email: *betnez@ashiwi.org*

12. Western Region

Western Region Director, 2600 North Central Avenue, Phoenix, AZ 85004; Telephone: (602) 379–6600; Fax: (602) 379–4413; Marjorie Eagleman, MSW, Regional Social Worker, 2600 North Central Avenue, Phoenix, AZ 85004; Telephone: (602) 379–6785; Fax: (602) 379–3010; Email: *Marjorie.eagleman@bia.gov*

A

Ak-Chin Indian Community, Carole Lopez, Enrollment Specialist, 42507 West Peters & Nall Road, Maricopa, AZ 85138; Telephone: (520) 568–1006; Fax: (520) 568–1001; Email: *clopez@AK-chin.nsn.us*

B

Battle Mountain Band Council, Monica Price, Social Worker III/ICWA Coordinator, 37 Mountain View Drive, Battle Mountain, NV 89820; Telephone: (775) 635–2004; Fax: (775) 635–8528

C

Chemehuevi Indian Tribe, Ronald Escobar, Secretary/Treasurer, P.O. Box 1976, Havasu Lake, CA 92363; Telephone: (760) 858–4219; Fax: (760) 858–5400

Cocopah Indian Tribe, Tomas Romero, CTS–ICWA Specialist, 14515 South Veterans Drive, Somerton, AZ 85350; Telephone: (928) 627–3729; Fax: (928) 627–3316; Email: *cocopahicwa@cocopah.com*

Colorado River Indian Tribes, Ray Barnett Social Services Manager, 12302 Kennedy Drive, Parker, AZ 85344; Telephone: (928) 669–8187; Fax: (928) 669–8881; Email: *ray.barnett@CRIT–DHS.org*

Confederated Tribes of the Goshute Reservation, Stefany Sellick, ICWA, P.O. Box HC61 Box 6104,, Ibapah, UT 84034; Telephone: (435) 234–1178; Fax: (435) 234–1219; Email: *stefanysellick@goshutetribe.com*

D

Duckwater Shoshone Tribe, Iskandar Alexandar, MSW, Social Worker ; P.O. Box 140087, Duckwater, NV 89314; Telephone: (775) 863–0222; Fax: (775) 863–0142

E

Elko Band Council of Te- Moak Tribe, Chesarae Christean, Social Worker 1745 Silver Eagle Drive, Elko, NV 89801; Telephone: (775) 738–8889; Fax: (775) 778–3397; Email: *elkobandsocial@frontiernet.net*

Ely Shoshone Tribe, RaeJean Morrill, Social Worker II, 16 Shoshone Circle, Ely, NV 89301; Telephone: (775) 289–4133; Fax: (775) 289–3237

F

Fallon Paiute-Shoshone Tribe, ICWA Representative, 1007 Rio Vista, Fallon, NV 89406; Telephone: (775) 423–1215; Fax: (775) 423–8960; Email: *ssdirector@fpst.org*

Fort McDermitt Paiute-Shoshone Tribe, Dee Crutcher, ICWA Advocate, P.O. Box 68, McDermitt, NV 89421; Telephone: (775) 532–8263, Ext. 111; Fax: (775) 532–8060; Email: *dee.crutcher@fmpst.org*

Fort McDowell Yavapai Nation, James Esquirell, ICWA Coordinator/CPS Worker, P.O. Box 17779, Fountain Hills, AZ 85269; Telephone: (480) 789–7990; Fax: (480) 837–4809; Email: *jesquirell@ftmcdowell.org*

Fort Mojave Indian Tribe, Melvin Lewis Sr., Director, Social Services, 500 Merriman Avenue, Needles, CA 92363; Telephone: (928) 346–1550 or Toll Free Number: (866) 346–6010; Fax: (928) 346–1552; Email: *ssdir@ftmojave.com*

G

Gila River Indian Community, Antoinette Enos, MSW, ICWA Case Manager, Tribal Social Services, P.O. Box 427, Sacaton, AZ 85147; Telephone: (520) 562–3396; Fax: (520) 562–3633; Email: *Antoinette.Enos@gric.nsn.us*

H

Havasupai Tribe, Tanya Watahomigie, ICWA Coordinator, P.O. Box 10, Supai, AZ 86435; Telephone: (928) 448–2661; Fax: (928) 448–2662; *hticwa0@havasupai-nsn.gov*

The Hopi Tribe, Hopi Guidance Center, ICWA Coordinator, P.O. Box 68, Second Mesa, AZ 86043; Telephone: (928) 737–1800; Fax: (928) 737–2697

Hualapai Tribe, Vonda R. Beecher, ICWA Worker, P.O. Box 480, Peach Springs, AZ 86434; Telephone: (928) 769–2269/2383/2384/2397; Fax: (928) 769–2659

K

Kaibab Band of Paiute Indians, Ronica L. Spute, Tribal Administrator; HC 65 Box 2, Fredonia, AZ 86022; Telephone: (928) 643–7245; Fax: (888) 822–3734; Email: *rspute@kaibabpaiute-nsn.gov*

L

Las Vegas Paiute Tribe, Ruth Fitz-Patrick, Social Services Caseworker, 1257 Paiute Circle, Las Vegas, NV 89106; Telephone: (702) 382–0784, #410; Fax: (702) 384–5272; Email: *rfitzpatrick@lvpaiute.com*

Lovelock Paiute Tribe, Fran Machado, Director Social Services Director, 201 Bowean Street, Lovelock, NV 89419; Telephone: (775) 273–5081; Fax: (775) 273–5151; *fmachado@lovelockpaiutetribe.com*

M

Moapa Band of Paiutes, Dawn M. Bruce, Social Services Director, P.O. Box 308, Moapa, NV 89025; Telephone: (702) 865–2708; Fax: (702) 864–0408; Email: *mbopsocialservices@mvdsl.com*

P

Paiute Indian Tribe of Utah, Tyler Goddard, Behavioral Health Director, 440 North Paiute Drive, Cedar City, UT 84721; Telephone: (435) 586–1112; Fax: (435) 867–2659; Email: *tyler.goddard@ihs.gov*

Pascua Yaqui Tribe, Office of the Attorney General, Attn: Tamara Walters, Assistant Attorney General, 7777 S. Camino Huivisim, Bldg. C, Tucson, AZ 85757; Telephone: (520) 883–5108; Fax: (520) 883–5084; Email: *tamara.walters@pascuayaqui-nsn.gov*

Pyramid Lake Paiute Tribe, Rose Mary Joe-Kinale, Social Services Director, P.O. Box 256, Nixon, NV 89424; Telephone: (775) 574–1047; Fax: (775) 574–1052; Email: *rkinale@plpt.nsn.us*

Q

Quechan Tribe, Ft. Yuma, Rod Nelson, Quechan Social Services, Director, P.O. Box 1890, Yuma, AZ 85366–1899; Telephone: (760) 572–0201; Fax: (760) 572–2099; Email: *socialservicedirector@quechantribe.com*

R

Reno-Sparks Indian Colony, Cheryl Douglas, Human Services Manager, 405 Golden Lane, Reno, NV 89502; Telephone: (775) 329–5071; Fax: (775) 785–8758; Email: *cdouglas@rsic.org*

S

Salt River Pima-Maricopa Indian Community, Allison Miller, ICWA Coordinator, SRPMIC Social Services Division, 10005 East Osborn Road, Scottsdale, AZ 85256; Telephone: (480) 362–5645, Direct: (480) 362–7533; Fax: (480) 362–5574; Email: *Allison.Miller@srpmic-nsn.gov*

San Carlos Apache Tribe, Aaron Begay, ICWA Coordinator, P.O. Box 0, San Carlos, AZ 85550; Telephone: (928) 475–2313; Fax: (928) 475–2342; Email: *abegay09@tss.scat-nsn.gov*

San Juan Southern Paiute Tribe, Savania Tsosie, Social Worker, 180 North 200 East, Suite 111, St. George, UT 84770; Telephone: (435) 674–9720; Fax: (435) 674–9714; Email: *savania.tsosie@bia.gov*

Shoshone-Paiute Tribes, Zannetta Hanks, LSW, Social Worker, P.O. Box 219, Owyhee, NV 89832; Telephone: (775) 757–2921, Ext. 26; Fax: (775) 757–2253; Email: *hanks.zannetta@shopai.org*

Skull Valley Band of Goshute Indians, Lori Bear, Chairwoman, P.O. Box 448, Grantsville, UT 84029; Telephone: (435) 882–4532; Fax: (435) 882–4889; Email: *ibear@svgoshutes.com*

South Fork Band Council, Debbie Honeyestewa, Social Services Director, 21 Lee, B–13, Spring Creek, NV 89815; Telephone: (775) 744–4273; Fax: (775) 744–4523

Summit Lake Paiute Tribe, Elizabeth Delaluz, Council Member ICWA Liaison, 1708 H Street, Sparks, NV 89431; Telephone: (775) 827–9670; Fax: (775) 827–9678; Email: *elizabeth.delaluz@summitlaketribe.org*

T

Te-Moak Tribe of Western Shoshone Indians (See Elko Band Council)

Tohono O'odham Nation, Jonathan L. Jantzen, Attorney General, P.O. Box 830, Sells, AZ 85634; Telephone: (520) 383–3410; Fax: (520) 383–2689; Email: *jonathan.jantzen@tonation-nsn.gov*

Tonto Apache Tribe, Brian Echols, Social Services Director, T.A.R. #30, Payson, AZ 85541; Telephone: (928) 474–5000, Ext. 8120, Fax: (928) 474–4159; Email: *bechols@TontoApache.org*

U

Ute Indian Tribe, Floyd M. Wyasket, Social Services Director, Box 190, Fort Duchesne, UT 84026; Telephone: (435) 725–4026 or (435) 823–0141; Fax: (435) 722–5030; Email: *floydw@utetribe.com*

W

Walker River Paiute Tribe, Elliott Aguilar, ICWA Specialist, P.O. Box 146 or 1029 Hospital Road, Schurz, NV 89427; Telephone: (775) 773–2058 Ext: 11; Fax: (775) 773–2096;Email: *eaguilar@wrpt.us*

Washoe Tribe of Nevada and California, Office of the Chairperson, 919 U.S. Highway. 395 South, Gardnerville, NV 89410; Telephone: (775) 265–8600; Fax: (775) 265–6240

Wells Band Te-Moak Shoshone, Sarai Harney, Social Services/ICWA, P.O. Box 809, Wells, NV 89835; Telephone: (775) 345–3079; Fax: (775) 752–2474

White Mountain Apache Tribe, Cora Hinton, ICWA Representative/CPS Supervisor, P.O. Box 1870, Whiteriver, AZ 85941; Telephone: (928) 338–4164, Fax: (928) 338–1469; Email: *chinton@wmat.us*

Winnemucca Tribe, Chairman, P.O. Box 1370, Winnemucca, NV 89446

Y

Yavapai Apache Nation, Linda Fry, Director, Department of Social Services, 2400 West Datsi Street, Camp Verde, AZ 86322; Telephone: (928) 649–7106; Fax: (928) 567–6832; Email: *lfry@yan-tribe.org*

Yavapai-Prescott Indian Tribe, Elsie Watchman, Family Support Supervisor, 530 East Merritt, Prescott, AZ 86301; Telephone: (928) 515–7351; Fax: (928) 541–7945; Email: *ewatchman@ypit.com*

Yerington Paiute Tribe, Vonnie Snooks, Human Services Assistant, 171 Campbell Lane, Yerington, NV 89447; Telephone: (775) 463–7705; Fax: (775) 463–5929; Email: *vsnooks@ypt-nsn.gov*

Yomba Shoshone Tribe, Raylon M. Dyer, Eligibility Worker, HC 61 Box 6275, Austin, NV 89310; Telephone: (775) 964–2463, Ext. 107; Fax: (775) 964–1352; Email: *Socialservices@yombatribe.org*

Dated: November 24, 2014.

Kevin K. Washburn,

Assistant Secretary—Indian Affairs.

[FR Doc. 2014–28510 Filed 12–3–14; 8:45 am]

BILLING CODE 4310–4J–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2011–0060]

Methylene Chloride Standard; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning its proposal to extend the Office of Management and Budget's (OMB) approval of the information collection requirements specified in the Methylene Chloride Standard (29 CFR 1910.1052).

DATES: Comments must be submitted (postmarked, sent, or received) by February 2, 2015.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages you may fax them to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit your comments and attachments to the OSHA Docket Office, Docket No. OSHA–2011–0060, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–2625, 200 Constitution Avenue NW., Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m. to 4:45 p.m., e.t.

Instructions: All submissions must include the Agency name and OSHA docket number (OSHA–2011–0060) for the Information Collection Request (ICR). All comments, including any personal information you provide, are placed in the public docket without change, and may be made available online at *http://www.regulations.gov.* For further information on submitting comments see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION.**

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov* or the OSHA Docket Office at the address above. All documents in the docket (including this **Federal Register** notice) are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download from the Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. You also may contact Theda Kenney at the address below to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT: Theda Kenney or Todd Owen, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, Room N–3609, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent (*i.e.,* employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accord with the Paperwork Reduction Act of 1995 (PRA–95) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (the OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of efforts in obtaining information (29 U.S.C. 657).

The Standard protects workers from the adverse health effects that may result from their exposure to methylene chloride (MC). The requirements in the Standard include worker exposure monitoring, notifying workers of their MC exposures, administering medical examinations to workers, providing examining physicians with specific program and worker information, ensuring that workers receive a copy of their medical examination results, maintaining workers' exposure monitoring and medical examination records for specific periods, and providing access to these records by OSHA, the National Institute for Occupational Safety and Health, the affected workers, and their authorized representatives.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

The Agency is requesting an adjustment decrease in the number of burden hours from 63,560 to 54,481 hours (a total decrease of 9,079 hours). The reduction is a result the Agency's estimate, based on updated data, that the number of establishments and workers affected by the Standard has decreased. Also, part of the decrease in burden hours is related to the determination that the training provision of the Standard, although still in effect, is not considered to be a collection of information. The estimated operation and maintenance cost increased from $19,214,570 to $19,381,635 due to the increase in the cost of medical exams and exposure monitoring associated with the Standard.

Type of Review: Extension of a currently approved collection.

Title: Methylene Chloride Standard (29 CFR 1910.1052).

OMB Control Number: 1218–0179.

Affected Public: Business or other for-profits.

Number of Respondents: 78,770.

Frequency of Response: Annually; semi-annually; quarterly; on occasion.

Total Responses: 214,575.

Average Time per Response: Varies from 1 hour for administering a medical examination to 5 minutes (.08 hour) to maintain a worker's medical or exposure record.

Estimated Total Burden Hours: 54,481.

Estimated Cost (Operation and Maintenance): $19,381,635.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) Electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal; (2) by facsimile; or (3) by hard copy. All comments, attachments, and other material must identify the Agency name and the OSHA docket number (Docket No. OSHA–2011–0060) for this ICR. You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled **ADDRESSES**). The additional materials must clearly identify your electronic comments by your name, date, and docket number so the Agency can attach them to your comments.

Because of security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627).

Comments and submissions are posted without change at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and date of birth. Although all submissions are listed in the *http://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publicly available to read or download from this Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *http://www.regulations.gov* Web site to submit comments and access the docket is available at the Web site's ''User Tips'' link. Contact the OSHA Docket Office for information about materials not available from the Web site, and for assistance in using the Internet to locate docket submissions.

V. Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 1–2012 (77 FR 3912).

Signed at Washington, DC, on December 1, 2014.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2014–28499 Filed 12–3–14; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2011–0196]

The Vinyl Chloride Standard; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning its proposal to extend OMB approval of the information collection requirements specified in the Vinyl Chloride Standard (29 CFR 1910.1017).

DATES: Comments must be submitted (postmarked, sent, or received) by February 2, 2015.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages you may fax them to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, Docket No. OSHA–2011–0196, U.S. Department of Labor, Occupational Safety and Health Administration, Room N–2625, 200 Constitution Avenue NW., Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m. to 4:45 p.m., e.t.

Instructions: All submissions must include the Agency name and the OSHA docket number (OSHA–2011–0196) for the Information Collection Request (ICR). All comments, including any personal information you provide, are placed in the public docket without change, and may be made available online at *http://www.regulations.gov.* For further information on submitting comments see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION.**

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov* or the OSHA Docket Office at the address above. All documents in the docket (including this **Federal Register** notice) are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download from the Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. You may also contact Theda Kenney at the address below to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT: Theda Kenney or Todd Owen, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, Room N–3609, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent (*i.e.,* employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accord with the Paperwork Reduction Act of 1995 (PRA–95) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The

Occupational Safety and Health Act of 1970 (the OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of efforts in obtaining information (29 U.S.C. 657).

The Standard specifies a number of paperwork requirements. The following is a brief description of the collection of information requirements contained in the Vinyl Chloride (VC) Standard.

(A) Exposure Monitoring (§ 1910.1017(d) and (§ 1910.1017(n))

Paragraph 1910.1017(d)(2) requires employers to conduct exposure monitoring at least quarterly if the results show that worker exposures are above the permissible exposure limit (PEL), while those exposed at or above the Action Level (AL) must be monitored no less than semiannually. Paragraph (d)(3) requires that employers perform additional monitoring whenever there has been a change in VC production, process or control that may result in an increase in the release of VC.

Paragraph 1910.1017(n) requires employers to inform each worker of their exposure monitoring results within 15 working days after receiving these results. Employers may notify workers either individually in writing or by posting the monitoring results in an appropriate location that is accessible to the workers. In addition, if the exposure monitoring results show that a worker's exposure exceeds the PEL, the employer must inform the exposed worker of the corrective action the employer is taking to prevent such overexposure.

(B) Written Compliance Plan (§§ 1910.1017(f)(2) and (f)(3))

Paragraph (f)(2) requires employers whose engineering and work practice controls cannot sufficiently reduce worker VC exposures to a level at or below the PEL to develop and implement a plan for doing so. Paragraph (f)(3) requires employers to develop this written plan and provide it upon request to OSHA for examination and copying. These plans must be updated annually.

(C) Respirator Program (§ 1910.1017(g)(2))

When respirators are required, the employer must establish a respiratory protection program in accord with 1910.134, paragraphs (b) through (d) (except (d)(1)(iii) and (d)(3)(iii)(B)(1) and (2)) and (f) through (m). Paragraph 1910.134(c) requires the employer to develop and implement a written respiratory protection program with worksite-specific procedures and elements for required respirator use. The purpose of these requirements is to ensure that employers establish a standardized procedure for selecting, using, and maintaining respirators for each workplace where respirators will be used. Developing written procedures ensures that employers develop a respirator program that meets the needs of their workers.

(D) Emergency Plan (§ 1910.1017(i))

Employers must develop a written operational plan for dealing with emergencies; the plan must address the storage, handling, and use of VC as a liquid or compressed gas. In the event of an emergency, appropriate elements of the plan must be implemented. Emergency plans must maximize workers' personal protection and minimize the hazards of an emergency.

(E) Medical Surveillance (§ 1910.1017(k))

Paragraph (k) requires employers to develop a medical surveillance program for workers exposed to VC in excess of the action level. Examinations must be provided in accord with this paragraph at least annually. Employers must also obtain, and provide to each worker, a copy of a physician's statement regarding the worker's suitability for continued exposure to VC, including use of protective equipment and respirators, if appropriate.

(F) Communication of VC Hazards (§ 1910.1017(l))

Under paragraph 1910.1017(l)(2), the employer shall include vinyl chloride and polyvinyl chloride (PVC) in the program established to comply with the Hazard Communication Standard (HCS) (§ 1910.1200). The employer shall ensure that each employee has access to labels on containers of chemicals and substances associated with vinyl and polyvinyl chloride and to safety data sheets, and is trained in accord with the provisions of HCS and paragraph (l) of this section. The employer shall ensure that at least the following hazard is addressed: Cancer.

(G) Recordkeeping (§ 1910.1017(m))

Employers must maintain worker exposure and medical records. Medical and monitoring records are maintained principally for worker access, but are designed to provide valuable information to both workers and employers. The medical and monitoring records required by this standard will aid workers and their physicians in determining whether or not treatment or other interventions are needed for VC exposure. The information also will enable employers to ensure that workers are not being overexposed; such information may alert the employer that steps must be taken to reduce VC exposures.

Exposure records must be maintained for at least 30 years, and medical records must be kept for the duration of employment plus 20 years, or for a total of 30 years, whichever is longer. Records must be kept for extended periods because of the long latency period associated with VC-related carcinogenesis (*i.e.,* cancer). Cancer often cannot be detected until 20 or more years after the first exposure to VC.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

OSHA is requesting that OMB extend its approval of the information collection requirements contained in the Vinyl Chloride Standard. The Agency is requesting an adjustment decrease in burden hours from 549 to 535 hours, a total decrease of 14 burden hours. The reduction is a result of few VC and PVC establishments identified for this ICR. The currently approved ICR estimates a total of 26 establishments, and this proposed ICR estimates a total of 24 establishments. The adjustment of the burden hours are shown in detail by provision in the supporting statement.

Type of Review: Extension of a currently approved collection.

Title: Vinyl Chloride Standard (29 CFR 1910.1017).

OMB Control Number: 1218–0010.

Affected Public: Business or other for-profits.

Number of Respondents: 24.

Frequency of Responses: On occasion; annually.

Total Responses: 835.

Average Time per Response: Varies from five minutes (.08 hour) for employers to maintain records to 12 hours for employers to update their compliance plans.

Estimated Total Burden Hours: 535.

Estimated Cost (Operation and Maintenance): $43,320.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) Electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal; (2) by facsimile (fax); or (3) by hard copy. All comments, attachments, and other material must identify the Agency name and the OSHA docket number (Docket No. OSHA–2011–0196) for the ICR. You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled **ADDRESSES**). The additional materials must clearly identify your electronic comments by your name, date, and the docket number so the Agency can attach them to your comments.

Because of security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627).

Comments and submissions are posted without change at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and date of birth. Although all submissions are listed in the *http://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publicly available to read or download from this Web site.

All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *http://www.regulations.gov* Web site to submit comments and access the docket is available at the Web site's ''User Tips'' link. Contact the OSHA Docket Office for information about materials not available from the Web site, and for assistance in using the Internet to locate docket submissions.

V. Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 1–2012 (77 FR 3912).

Signed at Washington, DC, on December 1, 2014.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2014–28500 Filed 12–3–14; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2015–014]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice.

SUMMARY: NARA is giving public notice that the agency proposes to reinstate the information collection described in this notice, which is used in the National Historical Publications and Records Commission (NHPRC) grant program. The public is invited to comment on the proposed information collections pursuant to the Paperwork Reduction Act of 1995.

DATES: Written comments must be received on or before February 2, 2015 to be assured of consideration.

ADDRESSES: Comments should be sent to: Paperwork Reduction Act Comments (ISSD), Room 4400, National Archives and Records Administration, 8601 Adelphi Rd, College Park, MD 20740–6001; or faxed to 301–713–7409; or electronically mailed to *tamee.fechhelm@nara.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the proposed information collections and supporting statements should be directed to Tamee Fechhelm at telephone number 301–837–1694, or fax number 301–713–7409.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13), NARA invites the general public and other Federal agencies to comment on proposed information collections. The comments and suggestions should address one or more of the following points: (a) Whether the proposed information collection is necessary for the proper performance of the functions of NARA; (b) the accuracy of NARA's estimate of the burden of the proposed information collection; (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 the use of information technology; and (e) whether small businesses are affected by this collection. The comments that are submitted will be summarized and included in the NARA request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this notice, NARA is soliciting comments concerning the following information collections:

Title: National Historical Publications and Records Commission (NHPRC) Grant Program, Budget Form and Instructions.

OMB number: 3095–0013.

Agency form number: NA Form 17001.

Type of review: Reinstatement of a previously cleared information collection.

Affected public: Nonprofit organizations and institutions, state and local government agencies, Federally acknowledged or state-recognized Native American tribes or groups, and individuals who apply for NHPRC grants for support of historical documentary editions, archival preservation and planning projects, and other records projects.

Estimated number of respondents: 144 per year submit applications; approximately 100 grantees among the applicant respondents also submit semiannual narrative performance reports.

Estimated time per response: 10 hours per application; 2 hours per narrative report.

Frequency of response: On occasion for the application; semiannually for the narrative report. Currently, the NHPRC considers grant applications 2 times per year; respondents usually submit no more than one application per year.

Estimated total annual burden hours: 1,440 hours.

Abstract: The NHPRC posts grant announcements to their Web site and to Grants.gov (*www.grants.gov*), where the information will be specific to the grant opportunity named. The basic information collection remains the same. The NA Form 17001 is used by the NHPRC staff, reviewers, and the Commission to determine if the applicant and proposed project are eligible for an NHPRC grant, and whether the proposed project is methodologically sound and suitable for support.

Dated: November 25, 2014.

Swarnali Haldar,

Executive for Information Services/CIO.

[FR Doc. 2014–28489 Filed 12–3–14; 8:45 am]

BILLING CODE 7515–01–P

OVERSEAS PRIVATE INVESTMENT CORPORATION

Sunshine Act Meeting; Board of Directors Meeting Notice

TIME AND DATE: Thursday, December 11, 2014, 2 p.m. (OPEN Portion), 2:15 p.m. (CLOSED Portion)

PLACE: Offices of the Corporation, Twelfth Floor Board Room, 1100 New York Avenue NW., Washington, DC

STATUS: Meeting OPEN to the Public from 2 p.m. to 2:15 p.m. Closed portion will commence at 2:15 p.m. (approx.)

MATTERS TO BE CONSIDERED:

1. President's Report
2. Minutes of the Open Session of the September 18, 2014 Board of Directors Meeting

FURTHER MATTERS TO BE CONSIDERED

(Closed to the Public 2:15 p.m.):

1. Finance Project—Kenya
2. Finance Project—India
3. Minutes of the Closed Session of the September 18, 2014 Board of Directors Meeting
4. Reports
5. Pending Projects

CONTACT PERSON FOR INFORMATION:

Information on the meeting may be obtained from Connie M. Downs at (202) 336–8438.

Dated: December 1, 2014.

Connie M. Downs,

Corporate Secretary, Overseas Private Investment Corporation.

[FR Doc. 2014–28561 Filed 12–2–14; 11:15 am]

BILLING CODE 3210–01–P

RAILROAD RETIREMENT BOARD

Agency Forms Submitted for OMB Review, Request for Comments

Summary: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Railroad Retirement Board (RRB) is an forwarding Information Collection Request (ICR) to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget (OMB). Our ICR describes the information we seek to collect from the public. Review and approval by OIRA ensures that we impose appropriate paperwork burdens.

The RRB invites comments on the proposed collections of information to determine (1) the practical utility of the collections; (2) the accuracy of the estimated burden of the collections; (3) ways to enhance the quality, utility, and clarity of the information that is the subject of collection; and (4) ways to minimize the burden of collections on respondents, including the use of automated collection techniques or other forms of information technology. Comments to the RRB or OIRA must contain the OMB control number of the ICR. For proper consideration of your comments, it is best if the RRB and OIRA receive them within 30 days of the publication date.

1. Title and purpose of information collection: Student Beneficiary Monitoring; OMB 3220–0123.

Under provisions of the Railroad Retirement Act (RRA), there are two types of benefit payments that are based on the status of a child being in full-time elementary or secondary school attendance at age 18–19: a survivor child's annuity benefit under Section 2(d)(1)(iii) and an increase in the employee retirement annuity under the Special Guaranty computation as prescribed in section 3(f)(2) and 20 CFR 229.

The survivor student annuity is usually paid by direct deposit to a financial institution either into the student's checking or savings account or into a joint bank account with a parent. The requirements for eligibility as a student are prescribed in 20 CFR 216.74, and include students in independent study and home schooling.

To help determine if a child is entitled to student benefits, the RRB requires evidence of full-time school attendance. This evidence is acquired through the RRB's student monitoring program, which utilizes the following forms. Form G–315, Student Questionnaire, obtains certification of a student's full-time school attendance as well as information on the student's marital status, social security benefits, and employment, which are needed to determine entitlement or continued entitlement to benefits under the RRA. Form G–315A, Statement of School Official, is used to obtain, from a school, verification of a student's full-time attendance when the student fails to return a monitoring Form G–315. Form G–315A.1, School Official's Notice of Cessation of Full-Time School Attendance, is used by a school to notify the RRB that a student has ceased full-time school attendance.

Previous Requests for Comments: The RRB has already published the initial 60-day notice (79 FR 57988 on September 26, 2014) required by 44 U.S.C. 3506(c)(2). That request elicited no comments.

Information Collection Request (ICR)

Title: Student Beneficiary Monitoring.

OMB Control Number: 3220–0123.

Form(s) submitted: G–315, G–315A, G–315A.1.

Type of request: Revision of a currently approved collection of information.

Affected public: Individuals or Households.

Abstract: Under the Railroad Retirement Act (RRA), a student benefit is not payable if the student ceases full-time school attendance, marries, works in the railroad industry, has excessive earnings or attains the upper age limit under the RRA. The report obtains information to be used to determine if benefits should cease or be reduced.

Changes proposed: The RRB proposes minor editorial and formatting changes to Forms G–315, G–315A, and G–315A.1.

The burden estimate for the ICR is as follows:

Form No.	Annual responses	Time (minutes)	Burden (hours)
G–315	860	15	215
G–315a	20	3	1
G–315a.1	20	2	1

Form No.	Annual responses	Time (minutes)	Burden (hours)
Total	900		217

2. Title and purpose of information collection: RUIA Claims Notification and Verification System; OMB 3220–0171.

Section 5(b) of the Railroad Unemployment Insurance Act (RUIA), requires that effective January 1, 1990, when a claim for benefits is filed with the Railroad Retirement Board (RRB), the RRB shall provide notice of the claim to the claimant's base year employer(s) to provide them an opportunity to submit information relevant to the claim before making an initial determination. If the RRB determines to pay benefits to the claimant under the RUIA, the RRB shall notify the base-year employer(s).

The purpose of the RUIA Claims Notification and Verification System is to provide two notices, pre-payment Form ID–4K, Prepayment Notice of Employees' Applications and Claims for Benefits Under the Railroad Unemployment Insurance Act, and post-payment Form ID–4E, Notice of RUIA Claim Determination. Prepayment Form ID–4K provides notice to a claimant's base-year employer(s), of each unemployment application and unemployment and sickness claim filed for benefits under the RUIA and provides the employer an opportunity to convey information relevant to the proper adjudication of the claim.

The railroad employer can elect to receive Form ID–4K by one of three options: A computer-generated paper notice, by Electronic Data Interchange (EDI), or online via the RRB's Employer Reporting System (ERS). The railroad employer can respond to the ID–4K notice by telephone, manually by mailing a completed ID–4K back to the RRB, or electronically via EDI or ERS. Completion is voluntary. The RRB proposes no changes to any of the ID–4K options.

Once the RRB determines to pay a claim post-payment Form Letter ID–4E, Notice of RUIA Claim Determination, is used to notify the base-year employer(s). This gives the employer a second opportunity to challenge the claim for benefits.

The ID–4E mainframe-generated paper notice, EDI, and Internet versions are transmitted on a daily basis, generally on the same day that the claims are approved for payment. Railroad employers who are mailed Form ID–4E are instructed to write if they want a reconsideration of the RRB's determination to pay. Employers who receive the ID–4E electronically, may file a reconsideration request by completing the ID–4E by either EDI or ERS. Completion is voluntary.

Previous Requests for Comments: The RRB has already published the initial 60-day notice (79 FR 57988 on September 26, 2014) required by 44 U.S.C. 3506(c)(2). That request elicited no comments.

Information Collection Request (ICR)

Title: RUIA Claims Notification and Verification System.

OMB Control Number: 3220–0171.

Form(s) submitted: ID–4K, ID–4K (INTERNET), ID–4E, ID–4E (INTERNET).

Type of request: Extension without change of a currently approved collection.

Affected public: Private Sector; Businesses or other for-profits.

Abstract: Section 5(b) of the RUIA requires that effective January 1, 1990, when a claim for benefits is filed with the Railroad Retirement Board (RRB), the RRB shall provide notice of such claim to the claimant's base-year employer(s) and afford such employer(s) an opportunity to submit information relevant to the claim before making an initial determination on the claim. When the RRB determines to pay benefits to a claimant under the RUIA, the RRB shall provide notice of such determination to the claimant's base year employer.

Changes proposed: The RRB proposes no changes to the forms in the collection.

The burden estimate for the ICR is as follows:

Form No.	Annual responses	Time (minutes)	Burden (hours)
ID–4K (Manual)	1,250	2	42
ID–4K (EDI)	17,500	(*)	210
ID–4K (Internet)	57,000	2	1,900
ID–4E (Manual)	50	2	2
ID–4E (Internet)	120	2	4
Total	75,920		2,158

*The burden for the 5 participating employers who transmit EDI responses is calculated at 10 minutes each per day, 251 workdays a year or 210 total hours of burden.

Additional Information or Comments: Copies of the forms and supporting documents can be obtained from Dana Hickman at (312) 751–4981 or *Dana.Hickman@RRB.GOV.*

Comments regarding the information collection should be addressed to Charles Mierzwa, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois, 60611–2092 or *Charles.Mierzwa@RRB.GOV* and to the OMB Desk Officer for the RRB, Fax: 202–395–6974, Email address: *OIRA_Submission@omb.eop.gov.*

Charles Mierzwa,

Chief of Information Resources Management.

[FR Doc. 2014–28467 Filed 12–3–14; 8:45 am]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73701; File No. SR–NYSEArca–2014–135]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Reflect a Change to the Process for Determining the Benchmark Values Used by the ETFS Platinum Trust, ETFS Palladium Trust, ETFS Precious Metals Trust and ETFS White Metals Basket Trust

November 28, 2014.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on November 25, 2014, NYSE Arca, Inc. (the ''Exchange'' or ''NYSE Arca'') 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 self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to change rule [sic] to reflect a change to the process for determining the benchmark values used by the ETFS Platinum Trust, the ETFS Palladium Trust, the ETFS Precious Metals Trust and the ETFS White Metals Basket Trust, each of which is currently listed on the Exchange under NYSE Arca Equities Rule 8.201, with respect to calculation of the net asset value of shares of each such trust. The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.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 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 the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to reflect a change in the administrative process for determining the benchmark values used by the ETFS Platinum Trust, the ETFS Palladium Trust, the ETFS Precious Metals Trust and the ETFS White Metals Basket Trust (each a ''Trust'' and, collectively, the ''Trusts'') with respect to calculation of the net asset value (''NAV'') of shares (''Shares'') of each such Trust. The Trusts are listed and traded pursuant to NYSE Arca Equities Rules 8.201 for Commodity-Based Trust Shares. The sponsor for the Trusts is ETFS Services USA LLC (''Sponsor'').

The proposed administrative change would replace as of the close of business November 30, 2014 references to the ''London AM Fix'' and ''London PM Fix,'' (collectively, the ''London Fix''), the current platinum and palladium price mechanism that the London Platinum and Palladium Fixing Company Limited (the ''LPPFCL'') manually administers, with an electronic platinum and palladium bullion price fixing system (known as LMEbullion) administered by the London Metal Exchange (''LME''),[4] as described below.

Revised London Fix Procedures for Platinum and Palladium

On November 18, 2014, the Sponsor issued a press release (''Press Release'') stating that the LPPFCL has announced its intention to revise the London Fix pricing benchmark processes for platinum and palladium after November 30, 2014. The afternoon session of the London Fix has been the ''Benchmark Price'' for valuation of platinum and palladium bullion held respectively by each of the Trusts. The LPPFCL has accepted a proposal by the LME to administer revised platinum and palladium price benchmark mechanisms on its behalf. Commencing December 1, 2014, the LME will operate platinum and palladium bullion price fixing systems (LMEbullion) that will replicate electronically the current manual London Fix processes employed by the LPPFCL as well as provide electronic market clearing processes for platinum and palladium bullion transactions at the fixed prices established by the LME pricing mechanism.[5] The new electronic price fixing processes to be used by the LME will continue to establish and publish fixed prices for troy ounces of platinum and palladium twice each London trading day during fixing sessions beginning at 9:45 a.m. London time (the ''LME AM Fix'') and 2:00 p.m. London time (the ''LME PM Fix''). In addition to utilizing the same London Fix standards and methods, the LME will also supervise the platinum and palladium electronic price fixing processes through its market operations, compliance, internal audit and third-party complaint handling capabilities in order to support the integrity of the LME AM and PM Fixes.

The Sponsor anticipates that, commencing December 1, 2014, the Sponsor will determine that the LME PM Fix will continue to be an appropriate basis for valuing platinum and palladium, as applicable, received upon purchase of a Trust's Shares, delivered upon redemption of a Trust's Shares and for determining the value of a Trust's platinum and palladium bullion, as applicable each trading day. The Sponsor also expects to determine that the LME PM Fix will fairly represent the commercial value of platinum and palladium bullion, as applicable, held by each Trust.

Exchange-Listed Platinum and Palladium-based Products

The Exchange lists and trades shares of exchange traded products that reference the London Fix for one or more purposes. Specifically, the Exchange lists and trades shares of the ETFS Platinum Trust[6], the ETFS

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The LME is regulated by the Financial Conduct Authority (FCA), an independent non-governmental body which exercises statutory regulatory power under the Financial Services and Markets Act of 2000 of the United Kingdom and which also regulates the major participating members of the London Bullion Market Association and the London Platinum and Palladium Market (the ''LPPM'').

[5] In a press release dated October 16, 2014, LME stated that LME's electronic solution relating to the fix for platinum and palladium, LMEbullion, will provide a pricing methodology that fully meets the administrative and regulatory needs of market participants including the International Organization of Securities Commissions (''IOSCO'') Principles for Financial Benchmarks.

[6] *See* Securities Exchange Act Release Nos. 60970 (November 9, 2009), 74 FR 59319 (November 17, 2009) (SR–NYSEArca–2009–95) (notice of filing of proposed rule change to list and trade shares of the ETFS Platinum Trust) (''ETFS Platinum Notice''); 61220 (December 22, 2009), 74 FR 68886 (December 29, 2009) (SR–NYSEArca–2009–95) (order approving proposed rule change to list and trade shares of the ETFS Platinum Trust).

Palladium Trust[7], the ETFS White Metals Basket Trust[8] and the ETFS Precious Metals Basket Trust,[9] each of which is currently listed on the Exchange under NYSE Arca Equities Rule 8.201.

With respect to the Trusts, the NAV of Shares of the respective Trusts is based on the London PM Fix, as described in the applicable rule filings relating to listing and trading of Shares of each of the Trusts[10] and in the registration statement under the Securities Act of 1933 Act (''1933 Act'') relating to each such Trust.[11] After November 30, 2014, the Trusts will utilize the benchmark price ascertained through the LME administered electronic fixing process for purposes of calculating the NAV of such Trust's Shares. The Sponsor of the Trusts has represented that, on December 1, 2014, the Sponsor intends to use the LME PM Fix for purposes of determining the net asset value of Shares of the Trusts. Accordingly, the Exchange proposes to change the benchmark price used by the Trusts for calculation of the NAV of Shares of each of such Trust to the LME PM Fix.

Each LME AM and PM Fix is widely expected to be viewed as a full and fair representation of all market interest. The LME's electronic price fixing processes are similar to the non-electronic processes previously used to establish the applicable London Fix where the London Fix process adjusted the platinum or palladium price up or down until all the buy and sell orders entered by LPPM fixing members are matched, at which time the price was declared fixed. Nevertheless, the LME AM and PM Fixes have several advantages over the previous London Fix. The LME's electronic price fixing processes will be fully transparent in real time to the platinum and palladium market participants and, at the close of each electronic fixing, to the general public. The LME AM and PM Fixes are also to be established by more LBBM [sic] members (initially approximately ten) than was the London Fix (four LPPM fixing members). The LME's electronic price fixing processes also will be fully auditable by third parties since an audit trail exists from the beginning of each fixing session. Moreover, the market operation, compliance, internal audit and third-party complaint handling capabilities of the LME will support the integrity of the LME AM and PM Fix.[12]

The Exchange believes the new LME electronic price fixing processes will serve as an appropriate replacement to the London Fix for purposes of determining the NAV of Shares of the Trusts because of the transparency of the fixing process, the anticipated participation of an increased number of market participants compared to the London Fix, and the auditability of the palladium and platinum pricing mechanism.

In connection with this proposed rule change, (1) the Sponsor of the Trusts will issue a press release informing the public of the date a Trust will first use the LME PM Fix to value the palladium or platinum, as applicable, held by a Trust; (2) the Sponsor will file the applicable press release with the Commission by means of Form 8–K, which will be available on the applicable Trust's Web site; and (3) the Sponsor will file an amendment to the applicable Registration Statement relating to the proposed change.[13]

The Sponsor for the Trusts represents that there is no change to the investment objective of the applicable Trust from that described in the applicable proposed rule change.[14] The Trusts will be subject to all initial and continued listing requirements under NYSE Arca Equities Rule 8.201.

Except for the changes noted above, all other facts presented and representations made in the proposed rule changes referenced above remain unchanged.

[7] *See* Securities Exchange Act Release Nos. 60971 (November 9, 2009), 74 FR 59283 (November 17, 2009) (SR–NYSEArca–2009–94) (notice of filing of proposed rule change to list and trade shares of the ETFS Palladium Trust) (''ETFS Palladium Notice''); 61220 (December 22, 2009), 74 FR 68895 (December 29, 2009) (SR–NYSEArca–2009–94) (order approving proposed rule change to list and trade shares of the ETFS Palladium Trust).

[8] *See* Securities Exchange Act Release No. 62620 (July 30, 2010), 75 FR 47655 (August 6, 2010) (SR–NYSEArca–2010–71) (notice of filing of proposed rule change to list and trade shares of the ETFS White Metals Basket Trust); 62875 (September 9, 2010), 75 FR 56156 (September 15, 2010) (SR–NYSEArca–2010–71) (order approving proposed rule change to list and trade shares of the ETFS White Metals Basket Trust).

[9] *See* Securities Exchange Act Release No. 62402 (June 29, 2010), 75 FR 39292 (July 8, 2010) (SR–NYSEArca–2010–56) (notice of filing of proposed rule change to list and trade shares of the ETFS Precious Metals Basket Trust); 62692 (August 11, 2010), 75 FR 50789 (August 17, 2010) (order approving proposed rule change to list and trade shares of the ETFS Precious Metals Basket Trust).

[10] As described in the ETFS Platinum Notice and the ETFS Palladium Notice, twice daily during London trading hours there is a fix which provides reference platinum and palladium prices for that day's trading. Many long-term contracts will be priced on the basis of either the morning (AM) or afternoon (PM) London Fix, and market participants will usually refer to one or the other of these prices when looking for a basis for valuations. The London Fix is the most widely used benchmark for daily platinum and palladium prices and is quoted by various financial information sources. The LPPM designated the LPPFCL to administer the London Fix. Formal participation in the London Fix is traditionally limited to four firms, each of which is a bullion dealer and a member of the LPPM. The chairmanship now rotates annually among the four LPPM fixing member firms. The morning session of the fix starts at 9:45 a.m. London time and the afternoon session starts at 2:00 p.m. London time. The four LPPM fixing members are currently: BASF SE., Goldman Sachs Group Inc., HSBC Holdings and Standard Bank PLC. Any other market participant wishing to participate in platinum and palladium trading on the fix is required to do so through one of the four LPPM fixing members. Orders are placed either with one of the four LPPM fixing members or with another precious metals dealer who will then be in contact with a LPPM fixing member during the fixing. The fixing members net-off all orders when communicating their net interest at the fixing. The fix begins with the fixing chairman suggesting a ''trying price,'' reflecting the market price prevailing at the opening of the fix. This is relayed by the fixing members to their dealing rooms which have direct communication with all interested parties. Any market participant may enter the fixing process at any time, or adjust or withdraw his order. The platinum or palladium price is adjusted up or down until all the buy and sell orders are matched, at which time the price is declared fixed. All fixing orders are transacted on the basis of this fixed price, which is instantly relayed to the market through various media. The London Fix is widely viewed as a full and fair representation of all market interest at the time of the fix.

[11] *See* the registration statement for the ETFS Palladium Trust on Form S–3, filed with the Commission on April 17, 2014 (No. 333–195335); the registration statement for the ETFS Platinum Trust on Form S–3ASR, filed with the Commission on June 3, 2013, and Post-Effective Amendment No. 1 thereto, filed with the Commission on June 5, 2013 (File No. 333–189061); Post-Effective Amendment No. 1 to the registration statement for the ETFS Precious Metals Trust on Form S–3, filed with the Commission on August 13, 2014 (No. 333–195675); and Post-Effective Amendment No. 1 to the registration statement for the ETFS White Metals Basket Trust on Form S–1, filed with the Commission on August 13, 2014 (No. 333–195441) (each a ''Registration Statement'' and, collectively, the ''Registration Statements'').

[12] The Prudential Regulation Authority (PRA) at the Bank of England has overall responsibility for the prudential regulation of banks, building societies, credit unions, insurers and major investment firms, many of whom are active in the bullion market. The conduct of financial institutions is overseen by the Financial Conduct Authority (FCA), which was formed from the former Financial Services Authority and is separate from the Bank of England.

[13] The Sponsor for the Trusts represents that it manages the Trusts in the manner described in the applicable proposed rule change (*see supra,* notes 6–9), and will not implement the changes described herein until the instant proposed rule change is operative.

[14] *See supra,* notes 6–9.

All terms referenced but not defined herein are defined in the applicable proposed rule changes referenced above.[15]

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(5)[16] 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, according to the LME press release, the new LMEbullion fixing processes will provide a pricing methodology that fully meets the administrative and regulatory needs of market participants, including the IOSCO Principles for Financial Benchmarks (the ''IOSCO Principles'').[17] In order to meet the IOSCO Principles, the LMEbullion electronic process will be auditable and transparent. Moreover, the LME AM and PM Fix will be the clearing prices for platinum and palladium bullion transactions that will clear through an electronic clearing process that the LME is establishing simultaneously with the establishment of the LMEbullion process. The Exchange believes the new LME fixing processes will serve as an appropriate replacement to the London Fix for platinum and palladium for purposes of determining the NAV of Shares of the Trusts because of the transparency of the fixing process, the participation of an increased number of market participants (initially, approximately ten LPPM members) compared to the London Fix (four LPPM members), and the auditability of the pricing mechanism. For each LME AM and PM Fix session, buying and selling order placements will be displayed electronically in real time for all platinum and palladium fixing participants. The LME will observe all fixing session buying and selling order placements, including the identity of those submitting orders. In addition, each LME AM and PM Fix and all order placement information will become publicly available electronically through the LME via financial news media services (such as, Bloomberg, Thomson Reuters, FactSet, Metal Radar and other services) instantly after the conclusion of the fixing process, as described above.

The proposed change will permit the Trusts to continue to function as platinum- and palladium-based exchange-traded products by utilizing a new price mechanism to replace the London Fix, which is not expected to be available after November 30, 2014, and that will provide a sound and reasonable basis for calculation of NAV. Such prices will be widely disseminated by one or more major market data vendors and/or exchanges. Prior to or following the effectiveness of this proposed rule change, (1) the Sponsor of the Trusts will issue a press release informing the public of the date a Trust will first use the LME Fix to value the platinum and palladium held by a Trust; (2) the Sponsor of the Trusts will file the applicable press release with the Commission by means of Form 8–K, which will be available on the applicable Trust's Web site; and (3) the Sponsor will file an amendment to the applicable Registration Statements under the 1933 Act relating to the proposed change. Such press releases and Registration Statement amendments will protect investors and the public interest by providing notification to investors of the new LME price mechanism prior to the use of the LME PM Fix by the Trusts. The Sponsor represents that there is no change to the investment objective of the applicable Trust from that described in the applicable proposed rule change. The Trusts will comply with all initial and continued listing requirements under NYSE Arca Equities Rule 8.201. Except for the changes noted above, all other facts presented and representations made in proposed rule changes referenced above remain unchanged.

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 the LME's electronic price fixing processes will be fully transparent in real time to the platinum and palladium market participants and, at the close of each electronic fixing, to the general public. The LME's electronic price fixing processes also will be fully auditable by third parties since an audit trail exists from the beginning of each fixing session. Moreover, the market operation, compliance, internal audit and third-party complaint handling capabilities of the LME will support the integrity of the LME AM and PM Fix. The Trusts will continue to be listed and traded on the Exchange pursuant to the initial and continued listing criteria in NYSE Arca Equities Rule 8.201. Except for the changes noted above, all other facts presented and representations made in proposed rule changes referenced above remain unchanged.[18]

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. The proposed change will permit the Trusts to continue to function as platinum- or palladium-based exchange-traded products by utilizing an electronic mechanism to replace the manual London Fix, which is not expected to be available after November 30, 2014, and that will provide a sound and reasonable basis for calculation of NAV.

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

Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, the

[15] *See supra,* notes 6–9.

[16] 15 U.S.C. 78f(b)(5).

[17] The IOSCO Principles are designed to enhance the integrity, the reliability and the oversight of benchmarks by establishing guidelines for benchmark administrators and other relevant bodies in the following areas: Governance: To protect the integrity of the benchmark determination process and to address conflicts of interest; Benchmark quality: To promote the quality and integrity of benchmark determinations through the application of design factors; Quality of the methodology: To promote the quality and integrity of methodologies by setting out minimum information that should be addressed within a methodology. These principles also call for credible transition policies in case a benchmark may cease to exist due to market structure change. Accountability mechanisms: To establish complaints processes, documentation requirements and audit reviews. The IOSCO Principles provide a framework of standards that might be met in different ways, depending on the specificities of each benchmark. In addition to a set of high level principles, the framework offers a subset of more detailed principles for benchmarks having specific risks arising from their reliance on submissions and/or their ownership structure. For further information concerning the IOSCO Principles, *see http://www.iosco.org/library/pubdocs/pdf/IOSCOPD415.pdf.*

[18] *See supra,* notes 6–9.

proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [19] and Rule 19b–4(f)(6) thereunder.[20]

The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that the proposed change will provide additional transparency to platinum and palladium pricing compared to the previous London Fix for several reasons. The Exchange represents that LME's electronic price fixing processes will be fully transparent in real time to the platinum and palladium market participants and, at the close of each electronic fixing, to the general public. The Exchange represents that LME's electronic price fixing processes also will be fully auditable by third parties because an audit trail exists from the beginning of each fixing session. Moreover, the Exchange states that the market operation, compliance, internal audit and third-party complaint handling capabilities of the LME will support the integrity of the LME AM and PM Fix. The Exchange represents that the number of platinum and palladium participants that initially are expected to participate in the LMEbullion fixing process (approximately ten LPPM members) exceeds the number of market participants determining the London Fix prior to December 1, 2014 (currently four LPPM fixing members), and will contribute to the integrity and reliability of the pricing process.

The Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest. Waiver of the operative delay will allow the Trusts, whose Shares are actively traded, to use the LME Fix as the basis for calculating the NAV by December 1, 2014, thereby facilitating the transition to the new price mechanism without disruption in trading. Therefore, the Commission designates the proposed rule change to be operative upon filing.[21]

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 under Section 19(b)(2)(B) [22] of the Act to determine whether the proposed rule change 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 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–2014–135 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2014–135. 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 10:00 a.m. and 3:00 p.m. Copies of such 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 Number SR–NYSEArca–2014–135 and should be submitted on or before December 26, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

Brent J. Fields,

Secretary.

[FR Doc. 2014–28473 Filed 12–3–14; 8:45 am]

BILLING CODE 8011–01–P

[19] 15 U.S.C. 78s(b)(3)(A).

[20] 17 CFR 240.19b–4(f)(6). As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

[21] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[22] 15 U.S.C. 78s(b)(2)(B).

[23] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73703; File No. SR–NYSE–2014–59]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing of Proposed Rule Change Amending Rule 13 and Related Rules Governing Order Types and Modifiers To Clarify the Nature of Order Types

November 28, 2014.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on November 14, 2014, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') 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 self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 13 and related rules governing order types and modifiers. The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

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 the Statutory Basis for, the Proposed Rule Change

1. Purpose

On June 5, 2014, in a speech entitled ''Enhancing Our Market Equity Structure,'' Mary Jo White, Chair of the Securities and Exchange Commission (''SEC'' or the ''Commission'') requested the equity exchanges to conduct a comprehensive review of their order types and how they operate in practice, and as part of this review, consider appropriate rule changes to help clarify the nature of their order types.[4] Subsequent to the Chair's speech, the SEC's Division of Trading and Markets requested that the equity exchanges complete their reviews and submit any proposed rule changes by November 1, 2014.[5]

The Exchange notes that it continually assesses its rules governing order types and undertook on its own initiative a review of its rules related to order functionality to assure that its various order types, which have been adopted and amended over the years, accurately describe the functionality associated with those order types, and more specifically, how different order types may interact. As a result of that review, the Exchange submitted a proposed rule change to delete rules relating to functionality that was not available.[6] In addition, over the years, when filing rule changes to adopt new functionality, the Exchange has used those filings as an opportunity to streamline related existing rule text for which functionality has not changed.[7]

The Exchange is filing this proposed rule change to continue with its efforts to review and clarify its rules governing order types, as appropriate. Specifically, the Exchange notes that Rule 13 is currently structured alphabetically, and does not include subsection numbering. The Exchange proposes to provide additional clarity to Rule 13 by re-grouping and re-numbering current rule text and making other non-substantive, clarifying changes. The proposed rule changes are not intended to reflect changes to functionality but rather to clarify Rule 13 to make it easier to navigate.[8] In addition, the Exchange proposes to amend certain rules to remove references to functionality that is no longer operative.

Proposed Rule 13 Restructure

The Exchange proposes to re-structure Rule 13 to re-group existing order types and modifiers together along functional lines.

Proposed new subsection (a) of Rule 13 would set forth the Exchange's order types that are the foundation for all other order type instructions, *i.e.,* the primary order types. The proposed primary order types would be:

• Market Orders. Rule text governing Market Orders would be moved to new Rule 13(a)(1). The Exchange proposes a non-substantive change to replace the reference to ''Display Book'' with a reference to ''Exchange systems.'' [9] The Exchange notes that it proposes to capitalize the term ''Market Order'' throughout new Rule 13.

• Limit Orders. Rule text governing Limit Orders would be moved to new Rule 13(a)(2). The Exchange proposes a non-substantive change to capitalize the term ''Limit Order,'' and to shorten the definition in a manner that streamlines the rule text without changing the meaning of the rule. The Exchange notes that it proposes to capitalize the term ''Limit Order'' throughout new Rule 13.

The Exchange notes that it proposes to delete the definition of ''Auto Ex Order'' because all orders entered electronically at the Exchange are eligible for automatic execution in accordance with Rules 1000–1004 and therefore the Exchange does not believe that it needs to separately define an Auto Ex Order. Rather than maintain a separate definition, the Exchange proposes to specify in proposed Rule 13(a) that all orders entered electronically at the Exchange are eligible for automatic execution consistent with the terms of the order and Rules 1000–1004. The Exchange notes that Rule 13 currently provides for specified instructions for orders that may not execute on arrival, even if marketable, *e.g.,* a Limit Order designated ALO, or may only be eligible to participate in an auction, accordingly, the terms of the order also control whether a marketable order would automatically execute upon arrival. The Exchange further proposes to specify that interest represented manually by Floor brokers, *i.e.,* orally bid or offered at the point of sale on the Trading Floor, is not eligible for automatic execution. The Exchange notes that the order types currently specified in the definition for auto ex order are already separately defined in Rule 13 or Rule 70(a)(ii) (definition of G order).

Proposed new subsection (b) of Rule 13 would set forth the existing Time in Force Modifiers that the Exchange makes available for orders entered at the Exchange. The Exchange proposes to: (i) Move rule text governing Day Orders to new Rule 13(b)(1), without any substantive changes to the rule text; (ii) move rule text governing Good til Cancelled Orders to new Rule 13(b)(2), without any substantive changes to the rule text; and (iii) move rule text governing Immediate or Cancel Orders to new Rule 13(b)(3) without any changes to rule text. The Exchange notes that these time-in-force conditions are not separate order types, but rather are modifiers to orders. Accordingly, the Exchange proposes to re-classify them as modifiers and remove the references to the term ''Order.'' In addition, as noted above, the Exchange proposes to capitalize the term ''Limit Order'' in Rule 13(b).

[4] *See* Mary Jo White, Chair, Securities and Exchange Commission, Speech at the Sandler, O'Neill & Partners, L.P. Global Exchange and Brokerage Conference (June 5, 2014) (available at *www.sec.gov/News/Speech/Detail/Speech/1370542004312#.U5HI-fmwJiw).*

[5] *See* Letter from James Burns, Deputy Director, Division of Trading and Markets, Securities and Exchange Commission, to Jeffrey C. Sprecher, Chief Executive Officer, Intercontinental Exchange, Inc., dated June 20, 2014.

[6] *See* Securities Exchange Act Release No. 71897 (April 8, 2014), 79 FR 20953 (April 14, 2014) (SR–NYSE–2014–16) (amending rules governing pegging interest to conform to functionality that is available at the Exchange).

[7] *See, e.g.,* Securities Exchange Act Release Nos. 68302 (Nov. 27, 2012), 77 FR 71658 (Dec. 3, 2012) (SR–NYSE–2012–65) (amending rules governing pegging interest to, among other things, make non-substantive changes, including moving the rule text from Rule 70.26 to Rule 13, to make the rule text more focused and streamlined) (''2012 Pegging Filing''), and 71175 (Dec. 23, 2013), 78 FR 79534 (Dec. 30, 2013) (SR–NYSE–2013–21) (approval order for rule proposal that, among other things, amended Rule 70 governing Floor broker reserve e-quotes that streamlined the rule text without making substantive changes) (''2013 Reserve e-Quote Filing'').

[8] The Exchange notes that its affiliated exchange, NYSE MKT LLC has filed a proposed rule change with a similar restructuring of its respective order type rules to group order types and modifiers. *See* SR–NYSEMKT–2014–95.

[9] The Exchange proposes to replace the term ''Display book'' with the term ''Exchange systems'' when use of the term refers to the Exchange systems that receive and execute orders. The Exchange proposes to replace the term ''Display Book'' with the term ''Exchange's book'' when use of the term refers to the interest that has been entered and ranked in Exchange systems.

Proposed new subsection (c) of Rule 13 would specify the Exchange's existing Auction-Only Orders. In moving the rule text, the Exchange proposes the following non-substantive changes: (i) Capitalize the terms ''Limit Order,'' ''CO Order,'' and ''Market Order''; (ii) move the rule text for CO Orders to new Rule 13(c)(1); (iii) rename a ''Limit 'At the Close' Order'' as a ''Limit-on-Close (LOC) Order'' and move the rule text to new Rule 13(c)(2); (iv) rename a ''Limit 'On-the-Open' Order'' as a ''Limit-on-Open (LOO) Order'' and move the rule text to new Rule 13(c)(3); (v) rename a ''Market 'At-the-Close' Order'' as a ''Market-on-Close (MOC) Order'' and move the rule text to new Rule 13(c)(4); and (vi) rename a ''Market 'On-the-Open' Order'' as a ''Market-on-Open (MOO) Order'' and move the rule text to new Rule 13(c)(5).

Proposed new subsection (d) of Rule 13 would specify the Exchange's existing orders that include instructions not to display all or a portion of the order. The order types proposed to be included in this new subsection are:

• Mid-point Passive Liquidity (''MPL'') Orders. Existing rule text governing MPL Orders would be moved to new Rule 13(d)(1) with non-substantive changes to capitalize the term Limit Order, update cross references, and refer to ''Add Liquidity Only'' as ALO, since ALO is now a separately defined term in new Rule 13(e)(1). The Exchange also proposes to clarify the rule text by deleting the term ''including'' from the phrase ''[a]n MPL Order is not eligible for manual executions, including openings, re-openings, and closings,'' because MPL Orders would not participate in an opening, re-opening, or closing that is effectuated electronically.[10] The Exchange further proposes to make a substantive amendment to the rule text set forth in new Rule 13(d)(1)(C) to specify that Exchange systems would reject an MPL Order on entry if the Minimum Triggering Volume (''MTV'') is larger than the size of the order and would reject a request to partially cancel a resting MPL Order if it would result in the MTV being larger than the size of the order and make conforming changes to the existing rule text. The Exchange would continue to enforce an MTV restriction if the unexecuted portion of an MPL Order with an MTV is less than the MTV. The Exchange believes that this proposed rule change would prevent an entering firm from causing an MPL Order to have an MTV that is larger than the order, thereby bypassing contra-side interest that is larger than the size of the MPL Order.[11] Finally, the Exchange proposes to make a non-substantive change to new Rule 13(d)(1)(E) to replace the term ''discretionary trade'' with ''d-Quote,'' because d-Quotes are the only type of Exchange interest that is eligible to include discretionary pricing instructions.[12]

• Reserve Orders. Existing rule text governing Reserve Orders would be moved to new Rule 13(d)(2) with non-substantive changes to capitalize the term ''Limit Order'' and hyphenate the term ''Non-Displayed.'' The Exchange proposes further non-substantive changes to the rule text governing Minimum Display Reserve Orders, which would be in new Rule 13(d)(2)(C), to clarify that a Minimum Display Reserve Order would participate in both automatic and manual executions. This is existing functionality relating to Minimum Display Reserve Orders [13] and the proposed rule text aligns with Rule 70(f)(i) governing Floor broker Minimum Display Reserve e-Quotes.[14] Similarly, the Exchange proposes non-substantive changes to the rule text governing Non-Displayed Reserve Orders, which would be in new Rule 13(d)(2)(D), to clarify that a Non-Displayed Reserve Order would not participate in manual executions. This is existing functionality relating to Non-Displayed Reserve Orders [15] and the proposed rule text aligns with Rule 70(f)(ii) governing Non-Display Reserve eQuotes excluded from the DMM.[16] Finally, in proposed new Rule 13(d)(2)(E), the Exchange proposes to clarify that the treatment of reserve interest, which is available for execution only after all displayable interest at that price point has been executed, is applicable to all Reserve Orders, and is not limited to Non-Displayed Reserve Orders.[17]

Proposed new subsection (e) of Rule 13 would specify the Exchange's existing order types that, by definition, do not route. The order types proposed to be included in this new subsection are:

• Add Liquidity Only (''ALO'') Modifiers. Existing rule text governing ALO modifiers would be moved to new Rule 13(e)(1) with non-substantive changes to capitalize the term ''Limit Order'' and update cross-references. Existing rule text that is being moved to new Rule 13(e)(1)(A) currently provides that Limit Orders designated ALO may participate in opens and closes, but that the ALO instructions would be ignored. Because Limit Orders designated ALO could also participate in re-openings, and the ALO instructions would similarly be ignored, the Exchange proposes to clarify new Rule 13(e)(1)(A) to provide that Limit Orders designated ALO could participate in openings, re-openings, and closings, but that the ALO instructions would be ignored.

• Do Not Ship (''DNS'') Orders. Existing rule text governing DNS Orders would be moved to new Rule 13(e)(2) with non-substantive changes to capitalize the term ''Limit Order'' and replace the reference to ''Display Book'' with a reference to ''Exchange systems.''

• Intermarket Sweep Order. Existing rule text governing ISOs would be moved to new Rule 13(e)(3) with non-substantive changes to capitalize the term ''Limit Order'', update cross-references, and replace the reference to ''Display Book'' with a reference to ''Exchange's book.''

Proposed new subsection (f) of Rule 13 would specify the Exchange's other existing order instructions and modifiers, including:

• Do Not Reduce (''DNR'') Modifier. Existing rule text governing DNR Orders would be moved to new Rule 13(f)(1) with non-substantive changes to capitalize the terms ''Limit Order'' and ''Stop Order.'' In addition, the Exchange believes that because DNR instructions would be added to an order, DNR is more appropriately referred to as a modifier rather than as an order type.

• Do Not Increase (''DNI'') Modifiers. Existing rule text governing DNI Orders would be moved to new Rule 13(f)(2) with non-substantive changes to capitalize the terms ''Limit Order'' and

[10] *See* Rule 123C.10 (''Closings may be effectuated manually or electronically'') and Rule 123D(1) (''Openings may be effectuated manually or electronically'').

[11] The Exchange notes that because of technology changes associated with rejecting MPL Orders that have an MTV larger than the size of the order, the Exchange will announce by Trader Update when this element of the proposed rule change will be implemented.

[12] *See* Rule 70.25 (Discretionary Instructions for Bids and Offers Represented via Floor Broker Agency Interest Files (e-Quotes[SM])).

[13] *See* Securities Exchange Act Release No. 57688 (April 18, 2008), 73 FR 22194 at 22197 (April 24, 2008) (SR–NYSE–2008–30) (order approving rule change that, among other things, adopted new Reserve Order for which the non-displayed portion of the order is eligible to participate in manual executions) (''2008 Reserve Order Filing'').

[14] *See* 2013 Reserve e-Quote Filing, *supra* n. 7.

[15] *See* Securities Exchange Act Release No. 58845 (Oct. 24, 2008), 73 FR 64379 at 64384 (Oct. 29, 2008) (SR–NYSE–2008–46) (order approving the Exchange's New Market Model, including adopting a Non-Displayed Reserve Order that would not be eligible to participate in manual executions).

[16] *See* 2013 Reserve e-Quote Filing, *supra* n. 7.

[17] *See* 2008 Reserve Order Filing *supra* n. 13 at 22196 (displayable portion of Reserve Order executed together with other displayable interest at a price point before executing with reserve portion of the order).

''Stop Order.'' In addition, the Exchange believes that because DNI instructions would be added to an order, DNI is more appropriately referred to as a modifier rather than as an order type.

• Pegging Interest. Existing rule text governing Pegging Interest and related subsections would be moved to new Rule 13(f)(3) with one clarifying change to the existing rule text and one proposed clarifying addition to the rule text. Because Pegging Interest is currently available for e-Quotes and d-Quotes only, the Exchange proposes to replace the term ''can'' with the term ''must'' in new Rule 13(f)(3)(a)(i) to provide that Pegging Interest ''must be an e-Quote or d-Quote.'' In addition, the Exchange proposes to add rule text to new Rule 13(f)(3)(A)(iv)(a) to clarify the definition of ''next best-priced available interest''[sic] in that Rule. Specifically, the Exchange has recently adopted non-displayed order types that are priced based on the PBBO, including MPL Orders, discussed above, and Retail Price Improvement Orders (''RPI''), defined in Rule 107C(a)(4).[18] Because Pegging Interest would not peg to either MPL Orders or RPIs, the Exchange proposes to clarify that for purposes of new Rule 13(f)(3)(A)(iv)(a), the term next available best-priced interest refers to the highest-(lowest-) priced buy (sell) interest within the specified price range of pegging interest to buy (sell), including displayable bids (offers), Non-Display Reserve Orders, Non-Display Reserve e-Quotes, odd-lot sized interest, and protected bids (offers) on away markets, but does not include non-displayed interest that is priced based on the PBBO. The Exchange notes that this would be applicable regardless of whether an MPL Order or RPI is marketable.[19]

• Retail Modifiers. Existing rule text governing Retail Modifiers and related subsections would be moved to new Rule 13(f)(4) with non-substantive changes to update cross-references.

• Self-Trade Prevention (''STP'') Modifier. Existing rule text governing STP Modifiers and related subsections would be moved to new Rule 13(f)(5) with non-substantive changes to capitalize the terms ''Limit Orders,'' ''Market Orders,'' and ''Stop Orders'' and hyphenate the term ''Self-Trade Prevention.''

• Sell ''Plus''—Buy ''Minus'' Instructions. Existing rule text governing Sell ''Plus''—Buy ''Minus'' Orders would be moved to new Rule 13(f)(6) with non-substantive changes to break the rule into subsections, capitalize the terms ''Market Order,'' ''Limit Order,'' and ''Stop Order,'' and replace the references to Display Book with references to Exchange systems. In addition, the Exchange proposes to re-classify this as an order instruction rather than as a separate order.

• Stop Orders. Existing rule text governing Stop Orders would be moved to new Rule 13(f)(7) with non-substantive changes to break the rule into subsections, capitalize the term ''Market Order,'' and replace references to ''Exchange's automated order routing system'' with references to ''Exchange systems.''

As part of the proposed restructure of Rule 13, the Exchange proposes to move existing rule text in Rule 13 governing the definition of ''Routing Broker'' to Rule 17(c), without any change to the rule text. The Exchange believes that Rule 17 is a more logical location for the definition of Routing Broker because Rule 17(c) governs the operations of Routing Brokers.

In addition, the Exchange proposes to delete existing rule text in Rule 13 governing Not Held Orders and add rule text relating to not held instructions to supplementary material .20 to Rule 13. Supplementary material .20 to Rule 13 reflects obligations that members have in handling customer orders. Because not held instructions are instructions from a customer to a member or member organization regarding the handling of an order, and do not relate to instructions accepted by Exchange systems for execution, the Exchange believes that references to not held instructions are better suited for this existing supplementary material.

Accordingly, the Exchange proposes to amend supplementary material .20 to Rule 13 to add that generally, an instruction that an order is ''not held'' refers to an unpriced, discretionary order voluntarily categorized as such by the customer and with respect to which the customer has granted the member or member organization price and time discretion. The Exchange believes that this proposed amendment aligns the definition of ''not held'' with guidance from the Financial Industry Regulatory Authority, Inc. (''FINRA'') and other markets regarding not held instructions.[20] The Exchange notes that the existing Rule 13 text regarding how to mark a Not Held Order, *e.g.,* ''not held,'' ''disregard tape,'' ''take time,'' etc., are outdated references regarding order marking between a customer and a member or member organization. All Exchange members and member organizations that receive customer orders are subject to Order Audit Trail System (''OATS'') obligations, consistent with Rule 7400 Series and FINRA Rule 7400 Series, which require that order-handling instructions be documented in OATS. Among the order-handling instructions that can be captured in OATS is whether an order is not held.[21] The Exchange believes that these OATS-related obligations now govern how a member or member organization records order-handling instructions from a customer and therefore the terms currently set forth in Rule 13 relating to Not Held Orders are no longer necessary.

Finally, the Exchange proposes to amend Rule 70.25 governing d-Quotes to clarify that certain functionality set forth in the Rule is no longer available. Specifically, Rule 70.25(c)(ii) currently provides that a Floor broker may designate a maximum size of contra-side volume with which it is willing to trade using discretionary pricing instructions. Because this functionality is not available, the Exchange proposes to delete references to the maximum discretionary size parameter from Rules 70.25(c)(ii) and (c)(v). In addition, the Exchange proposes to amend Rule 70.25(c)(iv) to clarify that the circumstances of when the Exchange would consider interest displayed by other market centers at the price at which a d-Quote may trade are not limited to determining when a d-Quote's minimum or maximum size range is met. Accordingly, the Exchange proposes to delete the clause ''when determining if the d-Quote's minimum

[18] *See* Securities Exchange Act Release Nos. 71330 (Jan. 16, 2014), 79 FR 3895 (Jan. 16, 2014)[sic] (SR–NYSE–2013–71) (approval order for the Exchange's adoption of the MPL Order); and 67347 (July 3, 2012), 77 FR 40673 (July 10, 2012) (SR–NYSE–2011–55) (approval order for the Exchange's Retail Liquidity Program, which adopted the new RPI).

[19] For example, assume the best protected bid (''PBB'') is $10.00, the Exchange has pegging interest to buy at $9.99, an MPL Order priced at $9.98 and a Non-Displayed Reserve Order to buy priced at $9.97. Because the PBB is outside the specified price range of the pegging interest to buy, it would peg to the next available best-priced interest, which in this scenario would be the Non-Displayed Reserve Order to buy priced at $9.97. The pegging interest to buy would not peg to the MPL Order to buy priced at $9.98.

[20] *See* FINRA Regulatory Notice 11–29, Answer 3 (June 2011) (''Generally, a 'not held' order is an unpriced, discretionary order voluntarily categorized as such by the customer and with respect to which the customer has granted the firm price and time discretion.''). *See also* Definition of Market Not Held Order on Nasdaq.com Glossary of Stock Market Terms, available at *http://www.nasdaq.com/investing/glossary/m/market-not-held-order.*

[21] *See* FINRA OATS Frequently Asked Questions—Technical, at T21 (''An order submitted by a customer who gives the broker discretion as to the price and time of execution is denoted as a ''Not Held'' order.''), available at *http://www.finra.org/Industry/Compliance/MarketTransparency/OATS/FAQ/P085542.*

and/or maximum size range is met.'' The Exchange believes that the proposed changes to Rule 70.25(c) will provide clarity and transparency regarding the existing functionality relating to d-Quotes at the Exchange.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[22] in general, and furthers the objectives of Section 6(b)(5),[23] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. Specifically, the Exchange believes that the proposed restructuring of Rule 13, to group existing order types to align by functionality, would remove impediments to and perfect the mechanism of a free and open market by ensuring that members, regulators, and the public can more easily navigate the Exchange's rulebook and better understand the order types available for trading on the Exchange. In addition, the Exchange believes that the proposed revisions to Rule 13 promote clarity regarding existing functionality that has been approved in prior rule filings, but which may not have been codified in rule text.[24] Moreover, the Exchange believes that moving rule text defining a Routing Broker to Rule 17 represents a more logical location for such definition, thereby making it easier for market participants to navigate Exchange rules. Likewise, the Exchange believes the proposed changes to ''Not Held Order,'' to move it to supplementary material .20 to Rule 13 and revise the rule text to conform with guidance from FINRA and OATS requirements, would remove impediments to and perfect the mechanism of a free and open market and a national market system by applying a uniform definition of not held instructions across multiple markets, thereby reducing the potential for confusion regarding the meaning of not held instructions.

The Exchange further believes that the proposed amendment regarding MPL Orders to reject both MPL Orders with an MTV larger than the size of the order and instructions to partially cancel an MPL Order that would result in an MTV larger than the size of the order would remove impediments to and perfect the mechanism of a free and open market and national market system in general because it could potentially reduce the ability of a member organization from using MPL Orders to bypass contra-side interest that may be larger than the size of the MPL Order.

Finally, the Exchange believes that the proposed changes to Rule 70.25(c) would remove impediments to and perfect the mechanism of a free and open market and national market system in general because it assures that the Exchange's rules align with the existing functionality available at the Exchange for d-Quotes.

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. The proposed change is not designed to address any competitive issue but rather would re-structure Rule 13 and remove rule text that relates to functionality that is no longer operative, thereby reducing confusion and making the Exchange's rules easier to navigate.

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 up to 90 days of such date (i) as the Commission may designate 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–NYSE–2014–59 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2014–59. 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 such 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–NYSE–2014–59 and should be submitted on or before December 26, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

Brent J. Fields,

Secretary.

[FR Doc. 2014–28476 Filed 12–3–14; 8:45 am]

BILLING CODE 8011–01–P

[22] 15 U.S.C. 78f(b).

[23] 15 U.S.C. 78f(b)(5).

[24] *See supra* nn. 13–18.

[25] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73704; File No. SR–CBOE–2014–062]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing of Amendment Nos. 1 and 2 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2, To Adopt Extended Trading Hours for SPX and VIX

November 28, 2014.

I. Introduction

On August 26, 2014, Chicago Board Options Exchange, Incorporated (the ''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (the ''Commission'') a proposed rule change pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] to establish a separate early morning trading session specifically for options on the S&P 500 Index (''SPX'') and CBOE Volatility Index (''VIX''). The proposed rule change was published for comment in the **Federal Register** on September 12, 2014.[3] On October 24, 2014, CBOE filed Amendment No. 1 to the proposed rule change and also granted the Commission an extension of time to consider its proposal to November 3, 2014.[4] On October 31, 2014, CBOE granted the Commission an additional extension of time until November 24, 2014. On November 21, 2014, CBOE filed Amendment No. 2 to the proposed rule change and also granted the Commission a further extension of time to consider its proposal to December 3, 2014.[5] The Commission received no substantive comments on the proposal.[6] The Commission is publishing this notice to solicit comments on Amendment Nos. 1 and 2 from interested persons and is approving the proposed rule change, as modified by Amendment Nos. 1 and 2, on an accelerated basis.

II. Description of the Proposed Rule Change, as Modified by Amendment Nos. 1 and 2[7]

Currently, transactions in index options may be effected on the Exchange generally between 8:30 a.m. and 3:15 p.m.,[8] Monday through Friday (''Regular Trading Hours''). CBOE has proposed to adopt rules that will allow it to conduct a separate, fully-electronic trading session from 2:00 a.m. to 8:15 a.m. Monday through Friday (''Extended Trading Hours'') for SPX and VIX, two index options that are exclusively-listed on CBOE. According to the Exchange, it is proposing Extended Trading Hours to meet demand from investors who want to trade these two products outside of Regular Trading Hours.[9]

Under the proposal, Extended Trading Hours will be a separate trading session from Regular Trading Hours and there will be no carryover from one trading session to the other and no interaction between Extended Trading Hours and Regular Trading Hours.[10] Extended Trading Hours will operate using separate Exchange servers[11] and hardware from those used during Regular Trading Hours.[12] Accordingly, the electronic order book used during Regular Trading Hours will not be connected to the electronic order book used during Extended Trading Hours, and orders and quotes will not interact between the two sessions.[13] Rather, all orders will be cancelled at the end of each Extended Trading Hours session.[14]

During Extended Trading Hours, all Exchange rules will apply, except as set forth in proposed CBOE Rule 6.1A (Extended Trading Hours), and except for CBOE rules that by their terms are inapplicable during Extended Trading Hours.[15] For example, since all trading during Extended Trading Hours will be electronic on the Hybrid Trading System,[16] all CBOE rules relating to open outcry trading and the Hybrid 3.0 System will be inapplicable to Extended Trading Hours.[17] However, CBOE rules relating to business conduct, doing business with the public, due diligence, and best execution will apply during Extended Trading Hours.[18]

Access. As is true during Regular Trading Hours, only authorized Trading Permit Holders, their nominees, and their associated persons will be able to access CBOE's electronic trading system.[19] However, trading privileges will be separate and distinct for

---

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 73017 (September 8, 2014), 79 FR 54758 (September 12, 2014) (''Notice'').

[4] CBOE filed Amendment No. 1 to the proposed rule change to (i) amend the requirements for foreign Trading Permit Holders to ensure, in part, that foreign Trading Permit Holders will be able to provide the Exchange with information, including their books and records; (ii) clarify why VIX index values will not be calculated and disseminated during Extended Trading Hours; (iii) clarify that CBOE will make available the number of Trading Permits during Extended Trading Hours to comply with Section 6(c)(4) of the Act; (iv) represent that the Exchange will establish procedures to ensure that Trading Permit Holders only utilize clearing brokers that are authorized by OCC for clearing during Extended Trading Hours; (v) represent that CBOE's systems are designed to prohibit unauthorized access; and (vi) correct an internal cross-reference in proposed CBOE Rule 6.1A(e)(iii)(B). *See* Amendment No. 1 to File No. SR–CBOE–2014–062, dated October 24, 2014 (''Amendment No. 1''). To promote transparency of its proposed amendment, when CBOE filed Amendment No. 1 with the Commission, it also submitted Amendment No. 1 as a comment letter to the file, which the Commission posted on its Web site and placed in the public comment file for SR–CBOE–2014–062. The Exchange also posted a copy of its Amendment No. 1 on its Web site at *http://www.cboe.com/publish/RuleFilingsSEC/SR-CBOE-2014-062.a1.pdf* when it filed the amendment with the Commission.

[5] CBOE filed Amendment No. 2 to the proposed rule change to delete proposed rule text in Exhibit 5 and delete related parts in the purpose and statutory basis sections of its Form 19b–4 submission, as well as Exhibit 1 and Item 8 in the Form 19b–4 (each as amended by Amendment No. 1), all of which related to the removal of proposed requirements that would have applied to foreign Trading Permit Holders. *See* Amendment No. 2 to File No. SR–CBOE–2014–062, dated November 21, 2014 (''Amendment No. 2''). To promote transparency of its proposed amendment, when CBOE filed Amendment No. 2 with the Commission, it also submitted Amendment No. 2 as a comment letter to the file, which the Commission posted on its Web site and placed in the public comment file for SR–CBOE–2014–062. The Exchange also posted a copy of its Amendment No. 2 on its Web site at *http://www.cboe.com/publish/RuleFilingsSEC/SR-CBOE-2014-062.a2.pdf* when it filed the amendment with the Commission.

[6] *See infra* notes 4 and 5 (noting that when CBOE submitted each Amendment to its proposal, it also submitted them as a comment letter to the file to promote the broad dissemination of its Amendments).

[7] A full description of the proposed rule change can be found in the Notice. *See* Notice, *supra* note 3.

[8] *See* CBOE Rule 24.6. All times in this order refer to Chicago time.

[9] *See* Notice, *supra* note 3 at 54758.

[10] *See id.*

[11] Bandwidth packets will be sold separately for Regular Trading Hours and Extended Trading Hours. *See id.* at 54766. Also, while the same telecommunications lines may be used for both Regular and Extended Trading Hours, those lines will be connected to a separate application server at the Exchange to trade during Extended Trading Hours. *See id.* at note 45.

[12] *See id.* at 54758.

[13] *See id.* at 54759.

[14] *See id.* at 54763.

[15] *See* proposed CBOE Rule 6.1A(a).

[16] According to the Exchange, SPX currently trades on the Hybrid 3.0 trading platform during Regular Trading Hours (except that the weekly SPX series trade on the Hybrid trading platform during Regular Trading Hours). Pursuant to proposed Rule 6.1A(b), SPX will trade on the Hybrid trading platform (and not the Hybrid 3.0 trading platform) during Extended Trading Hours and thus will trade pursuant to rules applicable to the Hybrid trading platform (rather than the Hybrid 3.0 trading platform) during Extended Trading Hours. *See* Notice, *supra* note 3 at note 18.

[17] *See id.* at 54759.

[18] *See id.* at note 13.

[19] *See id.* at 54760. This requirement will apply to any non-U.S. based person seeking access to the Extended Trading Hours session. Persons that are not Trading Permit Holders, such as employees of affiliates of Trading Permit Holders located outside of the United States, will not have direct access to the Exchange, and thus their orders and quotes must be submitted to the Exchange through a Trading Permit Holder, subject to applicable laws, rules, and regulations. *See id.* at note 59.

Extended Trading Hours. In other words, a broker-dealer that is not currently a CBOE member, as well as a current CBOE Trading Permit Holder (for Regular Trading Hours) will both need to obtain a *separate* Extended Trading Hours Trading Permit if they want to trade during CBOE's new Extended Trading Hours session.[20] The separate nature of access for the two trading sessions means that Trading Permit Holders will need to use separate log-ins for Extended versus Regular Trading Hours.[21] In this respect, CBOE's systems will be designed to prevent unauthorized access by persons not eligible to trade on CBOE during the Extended Trading Hours session.[22]

Market Makers. CBOE's proposal contemplates participation from Market Makers in the Extended Trading Hours session. To be eligible, Market Makers will need to obtain a separate Extended Trading Hours Trading Permit and also will need to request a separate appointment during Extended Trading Hours.[23] During Extended Trading Hours, Market Makers will be required to maintain continuous electronic quotes in 60% of the non-adjusted options series of the Market Maker's appointed classes that expire in less than nine months for 90% of the time when the Market Maker is quoting in a class.[24] In addition, the Exchange's proposal gives it the authority to determine to have no bid/ask differential requirement in the Extended Trading Hours session.[25] Further, Market Makers generally will be able to use the same Exchange functionality during Extended Trading Hours that is available to them during Regular Trading Hours. For example, Market Makers may elect to use a quote risk monitor (''QRM'') mechanism during Extended Trading Hours. Although, a Market Maker that elects to use QRM for both Regular Trading Hours *and* Extended Trading Hours will need to establish parameters separately for each trading session (even though a Market Maker may elect to use the same parameters for both trading sessions or use QRM for one trading session and not the other).[26]

LMMs. The Exchange also may approve one or more Market Makers to act as Lead Market Makers (''LMMs'') in each class during Extended Trading Hours.[27] Unlike Regular Trading Hours, however, LMMs will only be required to comply with the continuous quoting obligations and other obligations applicable to regular Market Makers in their assigned classes.[28] Consequently, LMMs will *not* be entitled to receive a participation entitlement in the Extended Hours Session.[29] However, if an LMM meets specific performance criteria during a month, it will be eligible to receive a specified monetary incentive from CBOE. Specifically, if an LMM: (1) Provides continuous electronic quotes in at least the lesser of 99% of the non-adjusted series or 100% of the non-adjusted series minus one call-put pair in an Extended Trading Hours allocated class (excluding intra-day add-on series on the day during which such series are added for trading) during Extended Trading Hours in a given month and (2) ensures an opening of the same percentage of series by 2:05 a.m. for at least 90% of the trading days during Extended Trading Hours in a given month, the LMM will be eligible to receive a rebate for that month in an amount set forth in the Exchange Fees Schedule.[30] For purposes of this heightened continuous quoting standard, an LMM will be deemed to have provided continuous electronic quotes during Extended Trading Hours if the LMM provides electronic two-sided quotes for 90% of the time in Extended Trading Hours in a given month.[31]

Trading. During Extended Trading Hours, the Exchange proposes to limit the available order types that may be entered into the system. Specifically, in recognition of the expected reduced liquidity, higher volatility, and wider spreads during Extended Trading Hours, the Exchange will not allow market orders, market-on-close orders, stop orders, and good-til-cancelled orders.[32] Otherwise, order processing during Extended Trading Hours will operate in the same manner as it does for Regular Trading Hours and there will be no change to ranking, display, or allocation algorithms rules.[33] Moreover, there will be no change between Regular and Extended Trading Hours in regards to the processes for clearing, settlement, exercise, and expiration.[34] In addition, the Exchange will report the best bid and offer and executed trades to the Options Price Reporting Authority (''OPRA'') during Extended Trading Hours in the same manner that it reports that information to OPRA during Regular Trading Hours.[35]

The Exchange also may halt trading during Extended Trading Hours in the interests of a fair and orderly market largely in the same manner that it can during Regular Trading Hours.[36] For

[20] *See* proposed CBOE Rule 6.1A(d). The Exchange represents that it will make available a sufficient number of Trading Permits during Extended Trading Hours to comply with Section 6(c)(4) of the Act. *See* Amendment No. 1, *supra* note 4. The Exchange intends to set the initial limit of Extended Trading Hours Trading Permits at 900 Market Maker Trading Permits and 150 Electronic Access Trading Permits (the same total number as available during Regular Trading Hours). *See id.*

[21] *See* Notice, *supra* note 3 at 54765.

[22] *See* Amendment No. 1, *supra* note 4.

[23] *See* proposed CBOE Rule 6.1A(e). For Extended Trading Hours, the appointment cost for VIX will be 0.5 and for SPX it also will be 0.5. Each Extended Trading Hours Trading Permit will have an appointment credit of 1.0 (the same as a Regular Trading Hours Trading Permit), so at the launch of Extended Trading Hours, a Market Maker will only need to hold one Extended Trading Hours Trading Permit if it wants to quote in both SPX and VIX during Extended Trading Hours. *See* Notice, *supra* note 3 at 54760. *See also* proposed CBOE Rule 6.1A(e)(i).

[24] *See* proposed CBOE Rule 6.1A(e)(ii).

[25] *See id.*

[26] *See* proposed CBOE Rule 8.18.

[27] *See* proposed CBOE Rule 6.1A(e)(iii)(A).

[28] *See* proposed CBOE Rule 6.1A(e)(iii)(B).

[29] *See, e.g.,* CBOE Rules 6.45B and 8.15B (concerning participation entitlements).

[30] CBOE's adoption of any such rebate will be subject to the rule filing process of Section 19 of the Act. CBOE is not proposing any rebate in this current proposal.

[31] *See* proposed CBOE Rule 6.1A(e)(iii)(C). Because the heightened quoting standard for LMMs in the Extended Hours Trading session is applicable only to a fee rebate and not a participation entitlement, the monthly measuring period is separate and distinct from the heightened quoting standard in the Regular Trading Hours session, which is measured on a daily basis. *See* Notice, *supra* note 3 at 54762.

[32] *See* Notice, *supra* note 3 at 54763. *See also* proposed CBOE Rule 6.1A(f).

[33] *See* Notice, *supra* note 3 at 54765. The Exchange also intends to activate the complex order auction and the automated improvement mechanism (''AIM'') auction during Extended Trading Hours. These auctions will operate in the same manner as they do during Regular Trading Hours, except with respect to AIM, the requirement that three Market Makers must be quoting to initiate an AIM auction will not apply during Extended Trading Hours. *See id.* at note 43.

[34] *See* Notice, *supra* note 3 at 54765. According to the Exchange, the Options Clearing Corporation has stated that it will be able to clear and settle all transactions and handle exercises of options during Extended Trading Hours. *See id.* at note 48. In addition, the Exchange has represented that it will work with OCC to establish procedures in connection with on-boarding Trading Permit Holders to ensure that Extended Trading Hours Trading Permit Holders only utilize clearing brokers that are properly authorized by OCC for operating during Extended Trading Hours. *See* Amendment No. 1, *supra* note 4.

[35] *See* Notice, *supra* note 3 at 54765. The operator of OPRA has informed CBOE that it intends to add a modifier to the disseminated information during Extended Trading Hours. *See id.* at note 57. The Exchange also will disseminate Extended Trading Hours data through its proprietary data feed in the same format and manner that it distributes data during Regular Trading Hours. *See id.* at 54765. Any fees to be charged by CBOE for the Extended Trading Hours proprietary data feed will be subject to a separate fee change filing. *See id.* at note 49.

[36] *See* proposed CBOE Rule 24.7(d). Further, clearly erroneous trade breaks during Extended Trading Hours will be processed in the same manner as Regular Trading Hours, except that during Extended Trading Hours, only two Exchange Officials that are members of the Exchange's staff

Continued

example, if there was a marketwide trading halt at the end of the prior trading day, CBOE could consider that as an ''unusual condition'' in determining whether to halt trading during the following day's Extended Trading Hours session.[37] Separately, CBOE proposed to amend its trade halt rule to provide that it also may consider whether trading in related futures has been halted as a factor in determining whether to halt trading in an option.[38]

Surveillance and Disclosures. The Exchange has represented that it will perform all necessary surveillance coverage and will have appropriately trained and qualified regulatory and operations staff in place during Extended Trading Hours to satisfy its regulatory obligations and administer the Extended Trading Hours session in real time.[39] In addition, because of the differences in the nature of the market and trading between Regular and Extended Trading Hours, CBOE will require Trading Permit Holders to disclose to customers that trading during Extended Trading Hours may involve material risks, including, in part, the possibility of lower liquidity, higher volatility, and lack of an updated underlying index or portfolio value,[40] prior to accepting an order from a customer for execution during Extended Trading Hours.[41] The Exchange also will distribute a Regulatory Circular detailing, among other things, some of the risks of trading during Extended Trading Hours.[42]

III. Discussion and Commission Findings

After careful consideration, the Commission finds that the proposed rule change, as modified by Amendment Nos. 1 and 2, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[43] In particular, the Commission finds that the proposed rule change, as amended, is consistent with Section 6(b)(5) of the Act,[44] which requires, among other things, that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. While no other options exchange is currently open for trading outside of Regular Trading Hours, the Commission notes that it has previously approved extended trading hours in the cash equities markets.[45]

The proposed rule change, as modified by Amendment Nos. 1 and 2, will allow investors additional trading opportunities to trade in two CBOE exclusively-listed products outside of CBOE's current Regular Trading Hours. The hours of CBOE's proposed Extended Trading Hours roughly coincide with the regular trading hours in Europe, and therefore CBOE's proposal may be of particular interest to traders located in non-U.S. jurisdictions. At the same time, CBOE has proposed certain limitations and protections on access and trading during Extended Trading Hours that are designed to promote just and equitable principles of trade and foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities. For example, as discussed above, only authorized Trading Permit Holders, their nominees, and their associated persons will be able to access the CBOE trading system during Extended Trading Hours, and CBOE's system is designed to allow CBOE to restrict unauthorized access to its systems in Extended Trading Hours.[46] Specifically, CBOE is requiring a new class of trading permits for Extended Trading Hours with their own unique log-in ID, and only persons in possession of those credentials will have access to CBOE's systems to trade during Extended Trading Hours. Moreover, consistent with fostering cooperation and coordination with persons engaged in clearing and settling transactions in securities, CBOE has represented that it will work with OCC to establish procedures in connection with on-boarding Extended Trading Hours permit holders to ensure that Trading Permit Holders only utilize clearing brokers that have been properly authorized by OCC for operating during Extended Trading Hours.[47] This process is designed to help assure the orderly functioning of the clearing process in Extended Trading Hours by avoiding any risk associated with a CBOE permit holder trading through a clearing broker during Extended Trading Hours if such clearing broker does not, in OCC's opinion, meet OCC's standards for clearing outside of regular trading hours.

In addition, as discussed above, all of CBOE's rules, with certain exceptions, will continue to apply during Extended Trading Hours. These rules, among other things, prohibit Trading Permit Holders from engaging in acts or practices inconsistent with just and equitable principles of trade, making any willful or material misrepresentation or omission in any

will be necessary to make such a determination. *See* Notice, *supra* note 3 at 54765.

[37] *See* Notice, *supra* note 3 at 54766; and proposed CBOE Rule 24.7(d). Also, under the proposed rule change, CBOE will not have to consider during Extended Trading Hours existing factors that are not applicable to the Extended session, such as (i) the extent to which trading is not occurring in the stocks or options underlying the index; (ii) the current calculation of the index derived from the current market prices of the stocks is not available; (iii) the ''current index level'' for a volatility index is not available or the cash (spot) value for a volatility index is not available; and (iv) the extent to which the rotation has been completed or other factors regarding the status of the rotation, in determining whether to halt trading during Extended Trading Hours. *See* Notice, *supra* note 3 at note 53; and proposed CBOE Rule 24.7(d).

[38] *See* proposed CBOE Rule 24.7, Interpretation and Policies .01. Currently, CBOE's rule allows it to consider the activation of price limits on futures exchanges when determining whether to halt trading in an index options. The proposed change will allow CBOE to consider *any* halt in futures trading, including halts called in situations other than in response to the activation of a price limit. *See* Notice, *supra* note 3 at 54765.

[39] *See* Notice, *supra* note 3 at 54765 and 54767.

[40] CBOE is the index calculator for the VIX. According to CBOE, the accuracy of the calculation for VIX indicative (or spot) values depends upon the quality of bid and offer quotes for constituent SPX option series. CBOE is unsure whether the SPX option quotes displayed during Extended Trading Hours will be sufficient to calculate accurate and meaningful VIX indicative quote values during Extended Hours. Accordingly, CBOE has determined to not calculate VIX spot values during Extended Trading Hours. *See* Amendment No. 1, *supra* note 4. However, as the Exchange and market participants gain experience with the Extended Trading Hours session and if activity and market maker participation increases, the Commission expects CBOE to reevaluate this decision and consider disseminating a VIX index value if and when quoting activity becomes sufficient to allow CBOE to calculate accurate and meaningful VIX index values during the Extended Trading Hours session.

[41] *See* proposed CBOE Rule 6.1A(j).

[42] *See* Notice, *supra* note 3 at 54764.

[43] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[44] 15 U.S.C. 78f(b)(5).

[45] *See e.g.,* Securities Exchange Act Release Nos. 29237 (May 24, 1991), 56 FR 24853 (May 31, 1991) (SR–NYSE–90–52 and SR–NYSE–90–53) (approving an off-hours trading facility on a pilot basis); 42004 (October 13, 1999), 64 FR 56548 (October 20, 1999) (SR–CHX–99–16) (approving extended trading hours on a pilot basis); and 56985 (December 18, 2007), 72 FR 73388 (December 27, 2007) (SR–NASDAQ–2007–098) (approving the trading of certain securities outside of regular market hours).

[46] The Commission notes that in order to be a Trading Permit Holder, an individual or organization must be, in part, registered as a broker or dealer pursuant to Section 15 of the Act or be associated with a Trading Permit Holder organization that is registered as a broker or dealer pursuant to Section 15 of the Act. *See* CBOE Rules 3.2 and 3.3.

[47] *See* Amendment No. 1, *supra* note 4.

application, report, or other communication to the Exchange or the OCC, and from effecting or inducing the purchase, sale, or exercise of any security for the purpose of manipulating the price or activity of the security,[48] as well as impose best execution requirements and prohibit trading ahead of customer orders.[49] In addition, the Exchange has represented that it will revise its surveillance procedures to incorporate transactions that occur and orders and quotations that are submitted during Extended Trading Hours and perform all necessary surveillance coverage during Extended Trading Hours.[50] Importantly, CBOE has represented that it will have a sufficient number of appropriately qualified staff on-site and otherwise available as necessary during Extended Trading Hours to provide support and handle any operations and regulatory issues that may arise.[51] CBOE's represented commitment to adequately staff its operations during Extended Trading Hours is important to assure the integrity of CBOE's operations during those early morning hours and necessary to assure that CBOE is able to carry out and enforce its rules during this session, including rules relating to trading halts and obvious error trades, as well as thoroughly monitor trading and the operations of its trading systems. Accordingly, the Commission believes that CBOE has designed its Extended Trading Hours session to promote just and equitable principles of trade and prevent fraudulent and manipulative acts and practices to the same extent that its Regular Trading Hours session has been so designed.

The Commission also believes that CBOE's disclosure requirement that obligates members to make certain written disclosures to customers regarding material trading risks that may exist during Extended Trading Hours is consistent with the protection of investors.[52] Specifically, Trading Permit Holders will be required to make certain disclosures to customers regarding the risk of lower liquidity, higher volatility, and wider spreads during Extended Trading Hours as compared to Regular Trading Hours.[53] The Commission believes that such disclosures should help ensure that customers are reasonably informed about the specific risks associated with trading in the non-core market before they decide to submit their first order in the Extended Trading Hours session. Further, these requirements are designed to mitigate, to the extent possible, the likelihood of investor confusion regarding the significant differences between the character of the market typical of Regular and Extended Trading Hours sessions.

The Commission further believes that CBOE's proposal to use a fully electronic trading platform during Extended Trading Hours that shares most of the functionality of its Hybrid System is reasonable. As discussed above, CBOE will use separate servers and hardware for the Extended Trading Hours session and the two sessions will not be linked or otherwise interact with each other. Nevertheless, according to the Exchange, orders will be processed in the same manner during Extended Trading Hours as Regular Trading Hours and there will be no changes to the ranking, display, or allocation algorithm rules.[54] CBOE also explained that there will be no changes to the processes for clearing, settlement, exercise, and expiration.[55] The Commission believes that maintaining separate infrastructure for the two separate trading systems is designed to protect the resiliency of the Regular Trading Hours session. Further, utilizing the existing trading and clearing process for the Extended Trading Hours session that CBOE uses for its electronic trading during Regular Trading Hours should facilitate the ability of CBOE members to trade in the new session on terms and with functionality that is familiar to them.

However, there will be some differences during Extended Trading Hours, such as returning certain kicked-out orders to a Trading Permit Holder in lieu of routing such order to PAR, and limiting the types of orders available for electronic processing to avoid the use of market orders or any order that could convert into a market order. The Commission believes these differences reflect that the character of trading during Extended Trading Hours will likely differ from typical trading during Regular Trading Hours, including the likelihood of reduced liquidity, higher volatility, and wider spreads during Extended Trading Hours.

Furthermore, CBOE has proposed to provide for Market Makers during Extended Trading Hours. Any Market Maker that elects to have an appointment during Extended Trading Hours will be subject to the same general quoting obligations as are applicable during Regular Trading Hours, though CBOE may determine not to impose bid/ask differential requirements during Extended Trading Hours.[56]

CBOE also has provided for Lead Market Makers, though the Commission notes that LMMs will not be entitled to a participation entitlement in Extended Trading Hours. However, LMMs that satisfy a heightened quoting standard during a month will be eligible to receive a rebate from CBOE for that month.[57] The Commission believes that CBOE's proposed LMM incentive program during Extended Trading Hours is designed to encourage two-sided liquidity during Extended Trading Hours and, to the extent it is successful, may contribute to the maintenance of fair and orderly markets during Extended Trading Hours. To the extent that CBOE is successful in encouraging active participation of Market Makers and LMMs during Extended Trading Hours, then CBOE may be able to help address some of the risks inherent in a non-core hours trading session, including the risks of reduced liquidity, higher volatility, and wider markets. Therefore, the proposal's provision for Market Makers and LMMs during the Extended Trading Hours session is consistent with the protection of investors and the public interest as well as the promotion of fair and orderly markets.

The Commission also believes that CBOE's proposed changes to its trading halt rule are consistent with the Act and designed to promote fair and orderly markets. The Commission notes that the Exchange will consider halting trading during Extended Trading Hours in the interests of a fair and orderly market in the same manner that it could halt trading during Regular Trading Hours. CBOE's proposed amendment to the trading halt rule to allow it to consider a halt in trading in related futures contracts is a reasonable additional

[48] *See* Chapter IV (Business Conduct) of CBOE's rules.

[49] *See* CBOE Rules 53.2 (Prohibition Against Trading Ahead of Customer Orders) and 53.8 (Best Execution and Interpositioning). The Commission notes that CBOE Rule 53.2, Interpretations and Policies .07, specifically provides that Trading Permit Holders may limit the life of a customer order to the period of normal market hours. However, if the customer and Trading Permit Holder agree to the processing of the customer's order outside normal market hours, the protections of the rule will apply to that customer's order for the entirety of the agreed upon executable time.

[50] *See* Notice, *supra* note 3 at 54765 and 54767.

[51] *See id.*

[52] *See* proposed CBOE Rule 6.1A(j).

[53] *See id.*

[54] *See* Notice, *supra* note 3 at 54758.

[55] *See id.* at 54765.

[56] As noted above, Market Makers will not have to satisfy the open outcry quoting obligations since all trading during Extended Trading Hours will be electronic. *See* proposed CBOE Rule 6.1A(e)(ii).

[57] The Commission notes that the Exchange will need to submit a proposed rule change pursuant to Section 19(b) of the Act if and when it seeks to add such a rebate for LMMs to the Exchange's fee schedule.

factor and consistent with the existing factors under the rule that allows CBOE to consider the activation of price limits in the futures markets.[58]

In addition, the Commission finds that the proposed rule change, as amended, is consistent with Section 11A(a)(1)(C) of the Act.[59] Congress found in those provisions that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities, and to assure the practicability of brokers executing investors' orders in the best market. The proposed rule change is designed to accomplish these objectives by ensuring that the Exchange will report its best bid and offer and executed trades to OPRA during Extended Trading Hours in the same manner that they are reported during Regular Trading Hours,[60] thereby providing public transparency of activity in the Extended Trading Hours market.

IV. Solicitation of Comments on Amendment Nos. 1 and 2

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether Amendment Nos. 1 and 2 are 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 No. SR–CBOE–2014–062 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–CBOE–2014–062. 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 10:00 a.m. and 3:00 p.m. Copies of such 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–CBOE–2014–062 and should be submitted on or before December 26, 2014.

V. Accelerated Approval of Proposed Rule Change as Modified by Amendment Nos. 1 and 2

The Commission finds good cause to approve the proposed rule change, as modified by Amendment Nos. 1 and 2, prior to the thirtieth day after the date of publication of notice of Amendment Nos. 1 and 2 in the **Federal Register**. The Commission notes that, in addition to filing Amendment Nos. 1 and 2 with the Commission, CBOE also submitted Amendment No. 1 and 2 as comments to the file, which the Commission promptly posted on its Web site on October 27, 2014 and November 21, 2014, respectively, in order to promote public availability and accessibility of the Amendments. The Commission notes that it did not receive any comments on CBOE's initial proposal or on either Amendment Nos. 1 or 2 prior to the date of this order.

In Amendment No. 1, the Exchange made several discrete changes to its proposal to provide additional clarity and further legal support for why its proposal is consistent with the Act. In particular, CBOE represented that it will establish procedures with OCC to ensure that Trading Permit Holders only utilize clearing brokers that have been authorized by OCC to clear during Extended Trading Hours.[61] Further, CBOE clarified that it will be able to prohibit an unauthorized user from accessing the trading system during Extended Trading Hours.[62] CBOE also represented that it will comply with the provisions of Section 6(c)(4) of the Act in making Trading Permits available during Extended Trading Hours by authorizing a total of 1,050 total permits for the Extended Trading Hours session.[63] Finally, CBOE provided additional support to justify its decision to not disseminate VIX values during Extended Trading Hours.[64] As the index calculator for VIX, CBOE explained that it does not currently know whether SPX options quotes (on which the VIX index is calculated) displayed in Extended Trading Hours will be sufficient to calculate an accurate and meaningful VIX indicative value in the same manner as what typically occurs during Regular Trading Hours. CBOE further pledged to reconsider the issue in the future and reassess whether trading in the Extended Trading Hours session rises to a sufficient level that is capable of supporting the calculation of accurate and meaningful VIX indicative values. The Commission believes that these proposed changes in Amendment No. 1 are reasonable and clarify the application and operation of CBOE's original proposal in a manner that is materially consistent with the scope of what CBOE originally proposed and what the Commission noticed for public comment in the **Federal Register**.

In addition, in Amendment No. 1, CBOE revised its proposed rules regarding foreign Trading Permit Holders and access from foreign jurisdictions. However, in Amendment No. 2 CBOE withdrew those proposed rule changes. The Commission believes that those proposed changes were incidental to the Exchange's core proposal to adopt an Extended Trading Hours session for SPX and VIX, and that their deletion from the proposal does not raise any concerns with the remainder of the proposal. If, in the future, CBOE decides to revisit its rules applicable to foreign Trading Permit Holders, it would need to submit a proposed rule change filing pursuant to Section 19(b) of the Act.[65]

Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act, to approve the proposed rule change, as modified by Amendment Nos. 1 and 2, on an accelerated basis.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[66] that the

[58] *See* proposed CBOE Rule 24.7, Interpretations and Policies .01.

[59] 15 U.S.C. 78k–1(a)(1)(C).

[60] *See* Notice, *supra* note 3 at 54765. *See also supra* note 35 (noting that OPRA intends to add a modifier to Extended Trading Hours quotes and trades).

[61] *See* Amendment No. 1, *supra* note 4.

[62] *See id.*

[63] *See id.*

[64] *See id.*

[65] 15 U.S.C. 78s(b).

[66] 15 U.S.C. 78s(b)(2).

proposed rule change, as modified by Amendment Nos. 1 and 2, (SR–CBOE–2014–062), be, and it hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[67]

Brent J. Fields,

Secretary.

[FR Doc. 2014–28475 Filed 12–3–14; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73702; File No. SR–BX–2014–048]

Self-Regulatory Organizations; NASDAQ OMX BX, Inc.; Order Granting Approval to Proposed Rule Change To Establish the Retail Price Improvement Program on a Pilot Basis Expiring Twelve Months From the Date of Implementation

November 28, 2014.

I. Introduction

On October 17, 2014, The NASDAQ OMX BX Stock Market LLC (the ''Exchange'' or ''BX'') filed with the Securities and Exchange Commission (''Commission'') pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to establish a Retail Price Improvement (''RPI'') Program (the ''Program'') on a pilot basis for a period of 12 months from the date of implementation, if approved. The proposed rule change was published for comment in the **Federal Register** on October 29, 2014.[3] The Commission did not receive any comments on the proposed rule change.

In connection with the proposal, the Exchange requested exemptive relief from Rule 612 of Regulation NMS,[4] which, among other things, prohibits a national securities exchange from accepting or ranking orders priced greater than $1.00 per share in an increment smaller than $0.01.[5] On October 10, 2014, the Exchange submitted a letter requesting that the staff of the Division of Trading and Markets not recommend any enforcement action under Rule 602 of Regulation NMS based on the Exchange's and its Members' participation in the Program.[6]

This order approves the proposed rule change and grants the exemption from the Sub-Penny Rule sought by the Exchange in relation to the proposed rule change.

II. Description of the Proposal

The Exchange is proposing a 12-month pilot program to attract additional retail order flow to the Exchange, while also providing the potential for price improvement to retail order flow. The Program would be limited to trades occurring at prices equal to or greater than $1.00 per share.[7] All Regulation NMS securities traded on the Exchange would be eligible for inclusion in the Program.

Under the Program, a new class of market participants called Retail Member Organizations (''RMOs'')[8] would be eligible to submit certain retail order flow (''Retail Orders'') to the Exchange. All Exchange Members would be permitted to provide potential price improvement for Retail Orders in the form of designated non-displayed interest, called a Retail Price Improvement Order (''RPI Order'' or ''RPI interest''), that is priced more aggressively than the Protected National Best Bid or Offer (''Protected NBBO'')[9] by at least $0.001 per share. When RPI interest priced at least $0.001 per share better than the Protected Bid or Protected Offer for a particular security is available in the Exchange's system (the ''System''), the Exchange would disseminate an identifier, known as the Retail Liquidity Identifier, indicating that such interest exists. A Retail Order would interact, to the extent possible, with available contra-side RPI Orders and other price improving liquidity.[10]

Types of Orders and Identifier

A Retail Order would be an agency or riskless principal[11] order that originates from a natural person and is submitted to the Exchange by an RMO, provided that no change is made to the terms of the order with respect to price (except in the case of a market order being changed to a marketable limit order) or side of market and provided that the order does not originate from a trading algorithm or any other computerized methodology. A Retail Order is an Immediate or Cancel Order. As discussed in greater detail below, Retail Orders may be designated as Type 1 or Type 2. Retail Orders, regardless of Type, may be entered in sizes that are odd lots, rounds lots, or mixed lots.

An RPI Order would be non-displayed liquidity on the Exchange that is priced better than the Protected NBBO by at

---

[67] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 73410 (October, 23, 2014), 79 FR 64447 (SR–BX–2014–048) (''Notice'').

[4] 17 CFR 242.612 (''Sub-Penny Rule'').

[5] *See* Letter from Jeffrey Davis, Deputy General Counsel, NASDAQ OMX BX, Inc., to Brent J. Fields, Secretary, Commission, dated October 10, 2014 (''Request for Sub-Penny Rule Exemption''). The Request for Sub-Penny Rule Exemption was submitted contemporaneously with the Exchange's original filing for this proposed rule change, which was filed on October 10, 2014. Because that filing did not comply with the rules of the Commission relating to the required form of a filing on Form 19b-4, it was rejected.

[6] *See* Letter from Jeffrey Davis, Deputy General Counsel, NASDAQ OMX BX, Inc., to Stephen Luparello, Director, Division of Trading and Markets, Commission, dated October 10, 2014. This letter was submitted contemporaneously with the Exchange's original filing for this proposed rule change, which was filed on October 10, 2014. As noted above, that filing was rejected because it did not comply with the rules of the Commission relating to the required form of a filing on Form 19b–4.

[7] The Exchange notes that certain orders submitted to the Program designated as eligible to interact with liquidity outside of the Program—Type 2 Retail Orders, discussed below—could execute at prices below $1.00 if they do in fact execute against liquidity outside of the Program.

[8] An RMO would be a Member (or a division thereof) that has been approved by the Exchange to submit Retail Orders. *See* Proposed BX Rule 4780. A ''Member'' is any registered broker or dealer that has been admitted to membership in the Exchange. *See* BX Rule 0120(i).

[9] The terms Protected Bid and Protected Offer are defined in Rule 600(b)(57) of Regulation NMS. 17 CFR 242.600(b)(57). The Exchange represents that, generally, the Protected Bid and Protected Offer, and the national best bid (''NBB'') and national best offer (''NBO,'' together with the NBB, the ''NBBO''), will be the same. However, it further represents that a market center is not required to route to the NBB or NBO if that market center is subject to an exception under Regulation NMS Rule 611(b)(1) or if such NBB or NBO is otherwise not available for an automatic execution. In such case, the Exchange states that the Protected NBBO would be the best-priced protected bid or offer to which a market center must route interest pursuant to Rule 611 of Regulation NMS.

[10] As explained further below, the Exchange has proposed two types of Retail Orders, one of which could execute against other contra-side interest if it was not completely filled by contra-side RPI Interest or other price-improving liquidity. All Retail Orders would first execute against available contra-side RPI Orders or other price-improving liquidity. Any remaining portion of the Retail Order would then either cancel, be executed as an immediate-or-cancel order, or be routed to another market for execution, depending on the type of Retail Order. The Exchange notes that other price improving liquidity may include, but is not limited to: Booked non-displayed orders with a limit price that is more aggressive than the then-current NBBO; midpoint-pegged orders (which are by definition non-displayed and priced more aggressively than the NBBO); non-displayed orders pegged to the NBBO with an aggressive offset, as defined in Proposed BX Rule 4780(a)(4) as Other Price Improving Contra-Side Interest. Orders that do not constitute other price improving liquidity include, but are not limited to: Orders with a time-in-force instruction of IOC; displayed orders; limit orders priced less aggressively than the NBBO.

[11] In order to qualify as a ''Retail Order,'' a ''riskless principal'' order must satisfy the criteria set forth in FINRA Rule 5320.03. RMOs that submit riskless principal orders as Retail Orders must maintain supervisory systems to reconstruct such orders in a time-sequenced manner, and the RMOs must submit reports contemporaneous with the execution of the facilitated orders that identify such trades as riskless principal.

least $0.001 per share and that is identified as such. RPI interest can be priced either as an explicitly priced limit order or implicitly priced as relative to the NBBO with an offset of at least $0.001. The price of an RPI Order with an offset would be determined by a Member's entry of the following into the Exchange: (1) RPI buy or sell interest; (2) an offset from the Protected NBBO, if any; and (3) a ceiling or floor price. RPI Orders submitted with an offset would be similar to other peg orders available to Members in that the order is tied or ''pegged'' to a certain price, and would have its price automatically set and adjusted upon changes in the Protected NBBO, both upon entry and any time thereafter.

RPI Orders in their entirety (the buy or sell interest, the offset, and the ceiling or floor) will remain non-displayed. The Exchange will also allow Members to enter RPI Orders that establish the exact limit price, which is similar to a non-displayed limit order currently accepted by the Exchange today, except that the Exchange will accept sub-penny limit prices on RPI Orders in increments of $0.001.[12] The Exchange will monitor whether RPI buy or sell interest, adjusted by any offset and subject to the ceiling or floor price, is eligible to interact with incoming Retail Orders.

When RPI interest priced at least $0.001 better than the Exchange's Protected Bid or Protected Offer for a particular security is available in the System, the Exchange would disseminate an identifier, known as the Retail Liquidity Identifier, indicating that such interest exists. The Exchange would implement the Program in a manner that allowed the dissemination of the identifier through consolidated data streams (*i.e.,* pursuant to the Consolidated Tape Association Plan/ Consolidated Quotation Plan (''CTA/CQ Plan'') for Tape A and Tape B securities, and the Nasdaq UTP Plan for Tape C securities as well as through proprietary Exchange data feeds). The Retail Liquidity Identifier would reflect the symbol and the side (buy or sell) of the RPI Order, but it would not include the price or size. In particular, the consolidated quoting outputs would include a field for codes related to the Retail Liquidity Identifier. The codes will indicate RPI interest that is priced better than the Exchange's Protected Bid or Protected Offer by at least the minimum level of price improvement as required by the Program.

Retail Member Organizations

In order to become an RMO, a Member must conduct a retail business or handle retail orders on behalf of another broker-dealer. Any Member that wishes to obtain RMO status would be required to submit: (1) An application form; (2) supporting documentation sufficient to demonstrate the retail nature and characteristics of the applicant's order flow; [13] and (3) an attestation, in a form prescribed by the Exchange, that substantially all orders submitted by the Member as a Retail Order would meet the qualifications for such orders under Proposed BX Rule 4780(b). If the Exchange disapproves the application, it would provide a written notice to the Member. The disapproved applicant could appeal the disapproval as provided below or re-apply 90 days after the disapproval notice is issued by the Exchange. An RMO also could voluntarily withdraw from RMO status at any time by giving written notice to the Exchange.

The Exchange would require an RMO to have written policies and procedures reasonably designed to assure that it will only designate orders as Retail Orders if all the requirements of a Retail Order are met. Such written policies and procedures would have to require the Member to exercise due diligence before entering a Retail Order to assure that entry as a Retail Order is in compliance with the proposed rule and to monitor whether orders entered as Retail Orders meet the applicable requirements. If the RMO represents Retail Orders from another broker-dealer customer, the RMO's supervisory procedures must be reasonably designed to assure that the orders received from the broker-dealer customer that are designated as Retail Orders meet the definition of a Retail Order. The RMO must obtain, from each broker-dealer customer that sends it orders to be designated as Retail Orders, an annual written representation, in a form acceptable to the Exchange, that entry of orders as Retail Orders will be in compliance with the requirements of this proposed rule, and the RMO must monitor whether its broker-dealer customer's Retail Order flow continues to meet the applicable requirements.[14]

Retail Order Designations

Under Proposed BX Rule 4780(f), an RMO submitting a Retail Order could choose one of two designations dictating how the Retail Order would interact with available contra-side interest. First, a Retail Order could interact only with available contra-side RPI interest and other price-improving liquidity. The RMO would label this a Type 1 Retail Order, and such orders would not interact with available non-price-improving, contra-side interest in the System or route to other markets. Portions of a Type 1 Retail Order that were not executed would be cancelled immediately and automatically.

Second, an RMO could label a Retail Order as a Type 2-designated Retail Order. A Type 2-designated Retail Order would interact first with available contra-side RPI Orders and other price-improving liquidity, and any remaining portion would be eligible to interact with other interest in the System and, if designated as eligible for routing, would route to other markets in compliance with Regulation NMS and pursuant to BX Rule 4758. Any portion of the Retail Order that remained unexecuted would then be cancelled.

Priority and Allocation

Under Proposed BX Rule 4780(g), the Exchange would follow price-time priority, ranking RPI interest in the same security according to price and then time of entry into the System.[15] Any remaining unexecuted RPI Orders would remain available to interact with other incoming Retail Orders if such interest is at an eligible price. Any remaining unexecuted portion of a Retail Order would cancel or execute in accordance with Proposed BX Rule 4780(f).[16]

Failure of RMO To Abide by Retail Order Requirements

Proposed BX Rule 4780(c) addresses an RMO's failure to abide by Retail Order requirements. If an RMO were to designate orders submitted to the Exchange as Retail Orders and the

[12] As noted above, *supra* note 5 and accompanying text, in connection with the Program, the Exchange requested exemptive relief from the Sub-Penny Rule of Regulation NMS, which, among other things, prohibits a national securities exchange from accepting or ranking orders priced greater than $1.00 per share in an increment smaller than $0.01.

[13] For example, a prospective RMO could be required to provide sample marketing literature, Web site screenshots, other publicly disclosed materials describing the retail nature of their order flow, and such other documentation and information as the Exchange may require to obtain reasonable assurance that the applicant's order flow would meet the requirements of the Retail Order definition.

[14] The Exchange represents that it or another self-regulatory organization on behalf of the Exchange will review an RMO's compliance with these requirements through an exam-based review of the RMO's internal controls. *See* Notice, *supra* note 3, 79 FR at 6449 n.8.

[15] *See also* BX Rule 4757 (setting forth the Exchange's price-time priority methodology).

[16] The Exchange has provided three examples of how the priority and ranking of RPI Orders would operate. *See* Notice, *supra* note 3, 79 FR at 64449–50.

Exchange determined, in its sole discretion, that those orders failed to meet any of the requirements of Retail Orders, the Exchange could disqualify a Member from its status as an RMO. When disqualification determinations are made, the Exchange would provide a written disqualification notice to the Member. A disqualified RMO could appeal the disqualification as provided below or re-apply 90 days after the disqualification notice is issued by the Exchange.

Appeal of Disapproval or Disqualification

Under Proposed BX Rule 4780(d), the Exchange would establish a Retail Price Improvement Program Panel (''RPI Panel'') to review disapproval or disqualification decisions. If a Member disputes the Exchange's decision to disapprove or disqualify it as an RMO, such Member could request, within five business days after notice of the decision is issued by the Exchange, that the RPI Panel review the decision to determine if it was correct. The RPI Panel would consist of the Exchange's Chief Regulatory Officer (or his or her designee) and two officers of the Exchange designated by the Exchange's Chief Executive Officer, and it would review the facts and render a decision within the timeframe prescribed by the Exchange. The RPI Panel could overturn or modify an action taken by the Exchange under Proposed Rule 4780, and all determinations by the RPI Panel would constitute final action by the Exchange on the matter at issue.

III. Discussion and Commission Findings

After careful review of the proposal, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange. In particular, the Commission finds that the proposed rule change, subject to its term as a pilot, is consistent with Section 6(b)(5) of the Act,[17] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices; to promote just and equitable principles of trade; to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities; to remove impediments to and perfect the mechanism of a free and open market and a national market system; and, in general, to protect investors and the public interest and that the rules of a national securities exchange not be designed to permit unfair discrimination between customers, issuers, brokers or dealers.

The Commission finds that the Program, as it is proposed on a pilot basis, is consistent with the requirements of the Act because the Program is reasonably designed to benefit retail investors by providing price improvement to retail order flow.[18] The Commission also believes that the Program could promote competition for retail order flow among execution venues and that this could benefit retail investors by creating additional price improvement opportunities for their order flow. Currently, most marketable retail order flow is executed in the over-the-counter (''OTC'') markets, pursuant to bilateral agreements, without ever reaching a public exchange. The Commission has noted that ''a very large percentage of marketable (immediately executable) order flow of individual investors'' is executed, or ''internalized,'' by broker-dealers in the OTC markets.[19] A previous review of the order flow of eight retail broker-dealers revealed that nearly 100% of their customer market orders were routed to OTC market makers.[20] The same review found that such routing is often done pursuant to arrangements under which retail brokers route their order flow to certain OTC market makers in exchange for payment for such order flow.[21] To the extent that the Program may provide price improvement to retail orders that equals what would be provided under such OTC internalization arrangements, the Program could benefit retail investors. So that the Exchange and the Commission can better understand the Program's potential impact, the Exchange represents that it ''will produce data throughout the pilot, which will include statistics about participation, the frequency and level of price improvement provided by the Program, and any effects on the broader market structure.'' [22]

The Program proposes to create additional price improvement opportunities for retail investors by segmenting retail order flow on the Exchange and requiring liquidity providers that want to interact with such retail order flow to do so at a price at least $0.001 per share better than the Protected NBBO. The Commission finds that, while the Program would treat retail order flow differently from order flow submitted by other market participants, such segmentation would not be inconsistent with Section 6(b)(5) of the Act, which requires that the rules of an exchange are not designed to permit unfair discrimination. The Commission previously has recognized that the markets generally distinguish between individual retail investors, whose orders are considered desirable by liquidity providers because such retail investors are presumed on average to be less informed about short-term price movements, and professional traders, whose orders are presumed on average to be more informed.[23] The Commission has further recognized that, because of this distinction, liquidity providers are generally more inclined to offer price improvement to less informed retail orders than to more informed professional orders.[24] Absent opportunities for price improvement, retail investors may encounter wider spreads that are a consequence of liquidity providers interacting with informed order flow. By creating

[17] 15 U.S.C. 78f(b)(5).

[18] The Commission has approved similar programs for New York Stock Exchange LLC and NYSE MKT LLC, Securities Exchange Act Release No. 67347 (July 3, 2012), 77 FR 40673 (July 10, 2012) (SR–NYSE–2011–55; SR–NYSEAmex–2011–84) (''NYSE RLP Approval Order''), BATS Y-Exchange, Inc., Securities Exchange Act Release No. 68303 (November 27, 2012), 77 FR 71652 (December 3, 2012) (SR–BYX–2012–019) (''BATS Y RPI Approval Order''), and The NASDAQ Stock Market LLC, Securities Exchange Act Release No. 68937 (February 15, 2013), 78 FR 12397 (February 22, 2013) (SR–NASDAQ–2012–129) (''NASDAQ RPI Approval Order'').

[19] *See* Securities Exchange Act Release No. 61358 (Jan. 14, 2010), 75 FR 3594, 3600 (Jan. 21, 2010) (''Concept Release on Equity Market Structure'').

[20] *See id.*

[21] *See id.*

[22] *See* Notice, *supra* note 3, 79 FR at 64450.

[23] *See* NASDAQ RPI Approval Order, *supra* note 18, BATS Y RPI Approval Order, *supra* note 18 and NYSE RLP Approval Order, *supra* note 18. *See also* Concept Release on Equity Market Structure, *supra* note 19; Securities Exchange Act Release No. 64781 (June 30, 2011), 76 FR 39953 (July 7, 2011) (SR–BATS–2011–009) (approving a program proposed by an options exchange that would provide price improvement opportunities to retail orders based, in part, on questions about execution quality of retail orders under payment for order flow arrangements in the options markets).

[24] *See* NASDAQ RPI Approval Order, *supra* note 18, BATS Y RPI Approval Order, *supra* note 18 and NYSE RLP Approval Order, *supra* note 18. *See also* Securities Exchange Act Release No. 64781 (June 30, 2011), 76 FR 39953, 39957 n.50 (July 7, 2011) (SR–BATS–2011–009) (noting that ''it is well known in academic literature and industry practice that prices tend to move against market makers after trades with informed traders, often resulting in losses for market makers,'' and that such losses are often borne by uninformed retail investors through wider spreads (citing H.R. Stoll, ''The supply of dealer services in securities markets,'' *Journal of Finance* 33 (1978), at 1133–51; L. Glosten & P. Milgrom, ''Bid ask and transaction prices in a specialist market with heterogeneously informed agents,'' *Journal of Financial Economics* 14 (1985), at 71–100; and T. Copeland & D. Galai, ''Information effects on the bid-ask spread,'' *Journal of Finance* 38 (1983), at 1457–69)).

additional competition for retail order flow, the Program is reasonably designed to attract retail order flow to the exchange environment, while helping to ensure that retail investors benefit from the better price that liquidity providers are willing to give their orders.

The Commission notes that the Program might also create a desirable opportunity for institutional investors to interact with retail order flow that they are not able to reach currently. Today, institutional investors often do not have the chance to interact with marketable retail orders that are executed pursuant to internalization arrangements. Thus, by submitting RPI Orders, institutional investors may be able to reduce their possible adverse selection costs by interacting with retail order flow.

When the Commission is engaged in rulemaking or the review of a rule filed by a self-regulatory organization, and is required to consider or determine whether an action is necessary or appropriate in the public interest, the Commission shall also consider, in addition to the protection of investors, whether the action will promote efficiency, competition, and capital formation.[25] As discussed above, the Commission believes this Program will promote competition for retail order flow by allowing Exchange Members to submit RPI Orders to interact with Retail Orders. Such competition may promote efficiency by facilitating the price discovery process. Moreover, the Commission does not believe that the Program will have a significant effect on market structure, or will create any new inefficiencies in current market structure. Finally, to the extent the Program is successful in attracting retail order flow, it may generate additional investor interest in trading securities, thereby promoting capital formation.

The Commission also believes that the Program is sufficiently tailored to provide the benefits of potential price improvement only to bona fide retail order flow originating from natural persons.[26] The Commission finds that the Program provides an objective process by which a Member organization could become an RMO and that the Program provides for appropriate oversight by the Exchange to monitor for continued compliance with the terms of these provisions. The Exchange has limited the definition of Retail Order to an agency or riskless principal order that originates from a natural person and not from a trading algorithm or any other computerized methodology. Furthermore, a Retail Order must be submitted by an RMO that is approved by the Exchange. In addition, RMOs would be required to maintain written policies and procedures to help ensure that they designate as Retail Orders only those orders that qualify under the Program. If a Member's application to become an RMO is denied by the Exchange, that Member may appeal the determination or re-apply. The Commission believes that these standards should help ensure that only retail order flow is submitted into the Program and that these standards thereby promote just and equitable principles of trade and protect investors and the public interest, while also providing an objective process through which Members may become RMOs.

In addition, the Commission finds that the Program's proposed dissemination of a Retail Liquidity Identifier would increase the amount of pricing information available to the marketplace and that is consistent with the requirement of the Act. The identifier would be disseminated through the consolidated public market data stream and proprietary Exchange data feeds to advertise the presence of a RPI Order with which Retail Orders could interact. The identifier would reflect the symbol for a particular security and the side of the RPI Order interest, but it would not include the price or size of such interest. The identifier would alert market participants to the existence of a RPI Order and should provide market participants with more information about the availability of price improvement opportunities for retail orders than is currently available.[27]

The Exchange asserts that the Program will operate in substantially the same manner as NASDAQ Rule 4780[28] and BATS Y-Exchange Rule 11.24,[29] which set forth the NASDAQ and BATS Y-Exchanges' Retail Price Improvement Programs, respectively, and that it would be similar to, but with distinctions from, New York Stock Exchange LLC's (''NYSE'') Rule 107C, which governs NYSE's Retail Liquidity Program.[30] Accordingly, the Exchange believes that the Program should both enhance competition among market participants and encourage competition among exchange venues.[31] Specifically, the Exchange asserts that allowing all Members to enter RPI Orders on equal terms, as opposed to adopting a special category of retail liquidity providers, as NYSE did with its Retail Liquidity Program, could result in a higher level of competition and maximize price improvement to incoming Retail Orders; [32] that the Program should provide the maximum price improvement available to incoming Retail Orders because they will always interact with resting RPI Orders and other resting non-displayed liquidity; [33] and that the Program will provide all of the price improvement available to incoming Retail Orders by allowing executions at multiple price levels, as opposed to a single clearing price level.[34] The Commission finds that the Program is reasonably designed to enhance competition among market participants and encourage competition among exchange venues. The Commission also finds that the distinctions between the Exchange's Program and the approved programs on

[25] *See* 15 U.S.C. 78c(f).

[26] In addition, the Commission believes that the Program's provisions concerning the approval and potential disqualification of RMOs are not inconsistent with the Act. *See, e.g.,* NASDAQ RPI Approval Order, *supra* note 18, 78 FR at 12400 n.32, BATS Y RPI Approval Order, *supra* note 18, 77 FR at 71656 n.41 and NYSE RLP Approval Order, *supra* note 18, 77 FR at 40680 n.77.

[27] As the Commission noted when approving the comparable NASDAQ, BATS Y-Exchange, and NYSE programs, the Commission believes that the Program will not create any best execution challenges for brokers that are not already present in today's markets. A broker's best execution obligations are determined by a number of facts and circumstances, including: (1) The character of the market for the security (*e.g.,* price, volatility, relative liquidity, and pressure on available communications); (2) the size and type of transaction; (3) the number of markets checked; (4) accessibility of the quotation; and (5) the terms and conditions of the order that results in the transaction. *See* NASDAQ RPI Approval Order, *supra* note 18, 78 FR at 12400 n.33, BATS Y RPI Approval Order, *supra* note 18, 77 FR at 71657, and NYSE RLP Approval Order, *supra* note 18, 77 FR at 40680 n.75 (all citing FINRA Rule 5310).

[28] *See* NASDAQ RPI Approval Order, *supra* note 18.

[29] *See* BATS Y RPI Approval Order, *supra* note 18.

[30] *See* NYSE RLP Approval Order, *supra* note 18.

[31] *See* Notice, *supra* note 3, 79 FR at 64451.

[32] *See id.* at 64450. The NYSE's Retail Liquidity Program creates a category of members, Retail Liquidity Providers, who are required to maintain a NYSE Retail Price Improvement Order that betters the protected best bid or offer at least 5% of the trading day in each assigned security and who receive lower execution fees as a result.

[33] *See* Notice, *supra* note 3, 79 FR at 64450. In contrast, pursuant to NYSE Rule 107C(k)(1), a NYSE Type 1-designated Retail Order will interact only with available contra-side NYSE Retail Price Improvement Orders and NYSE Mid-Point Passive Liquidity Orders. Pursuant to NYSE Rule 13, a Mid-Point Passive Liquidity Order ''is an undisplayed limit order that automatically executes at the mid-point of the protected best bid or offer.''

[34] *See* Notice, *supra* note 3, 79 FR at 64450–51. Under the NYSE'S Retail Liquidity Program, Retail Orders execute at the single price at which the order will be fully executed, unless there are separate MPL Orders with better pricing on the other side of the Retail Order. *See* NYSE Rule 107C(l) (providing examples of how orders execute under the NYSE's Retail Liquidity Program).

other exchanges are reasonably designed to enhance the Program's price-improvement benefits to retail investors and are, therefore, consistent with the Act.

The Commission notes that it is approving the Program on a pilot basis. Approving the Program on a pilot basis will allow the Exchange and market participants to gain valuable practical experience with the Program during the pilot period. This experience should allow the Exchange and the Commission to determine whether modifications to the Program are necessary or appropriate prior to any Commission decision to approve the Program on a permanent basis. The Exchange also has agreed to provide the Commission with a significant amount of data that should assist the Commission in its evaluation of the Program. Specifically, the Exchange has represented that it ''will produce data throughout the pilot, which will include statistics about participation, the frequency and level of price improvement provided by the Program, and any effects on the broader market structure.'' [35] The Commission expects that the Exchange will monitor the scope and operation of the Program and study the data produced during that time with respect to such issues and that the Exchange will propose any modifications to the Program that may be necessary or appropriate.

The Commission also welcomes comments, and empirical evidence, on the Program during the pilot period to further assist the Commission in its evaluation of the Program. The Commission notes that any permanent approval of the Program would require a proposed rule change by the Exchange, and any such proposed rule change would provide an opportunity for public comment prior to further Commission action.

IV. Exemption From the Sub-Penny Rule

Pursuant to its authority under Rule 612(c) of Regulation NMS,[36] the Commission hereby grants the Exchange a limited exemption from the Sub-Penny Rule to operate the Program. For the reasons discussed below, the Commission determines that such an exemption is necessary or appropriate in the public interest and is consistent with the protection of investors. The exemption shall operate for a period of 12 months, ending on the same date as the 12-month pilot period of the Program.

When the Commission adopted the Sub-Penny Rule in 2005, it identified a variety of problems caused by sub-pennies that the Sub-Penny Rule was designed to address:

- If investors' limit orders lose execution priority for a nominal amount, investors may over time decline to use them, thus depriving the markets of liquidity.
- When market participants can gain execution priority for a nominal amount, important customer protection rules such as exchange priority rules and the Manning Rule could be undermined.
- Flickering quotations that can result from widespread sub-penny pricing could make it more difficult for broker-dealers to satisfy their best execution obligations and other regulatory responsibilities.
- Widespread sub-penny quoting could decrease market depth and lead to higher transaction costs.
- Decreasing depth at the inside could cause institutions to rely more on execution alternatives away from the exchanges, potentially increasing fragmentation in the securities markets.[37]

At the same time, the Commission ''acknowledge[d] the possibility that the balance of costs and benefits could shift in a limited number of cases or as the markets continue to evolve.'' [38] Therefore, the Commission also adopted Rule 612(c), which provides that the Commission may grant exemptions from the Sub-Penny Rule, either unconditionally or on specified terms and conditions, if it determined that such an exemption is necessary or appropriate in the public interest, and is consistent with the protection of investors.

The Commission believes that the Exchange's proposal raises such a case. As described above, under the current market structure, few marketable retail orders in equity securities are routed to exchanges. The vast majority of marketable retail orders are internalized by OTC market makers, who typically pay retail brokers for their order flow. Retail investors can benefit from such arrangements to the extent that OTC market makers offer them price improvement over the NBBO. Price improvement is typically offered in sub-penny amounts.[39] An internalizing broker-dealer can offer sub-penny executions, provided that such executions do not result from impermissible sub-penny orders or quotations. Accordingly, OTC market makers typically select a sub-penny price for a trade without quoting at that exact amount or accepting orders from retail customers seeking that exact price. Exchanges—and exchange member firms that submit orders and quotations to exchanges—cannot compete for marketable retail order flow on the same basis, because it would be impractical for exchange electronic systems to generate sub-penny executions without exchange liquidity providers or retail brokerage firms having first submitted sub-penny orders or quotations, which the Sub-Penny Rule expressly prohibits.

The limited exemption granted today should promote competition between exchanges and OTC market makers in a manner that is reasonably designed to minimize the problems that the Commission identified when adopting the Sub-Penny Rule. Under the Program, sub-penny prices will not be disseminated through the consolidated quotation data stream, which should avoid quote flickering and reduced depth at the inside quotation. Furthermore, while the Commission remains concerned about providing enough incentives for market participants to display limit orders, the Commission does not believe that granting this exemption (and approving the accompanying proposed rule change) will reduce such incentives. Market participants that display limit orders currently are not able to interact with marketable retail order flow because it is almost entirely routed to internalizing OTC market makers that offer sub-penny executions. Consequently, enabling the Exchanges to compete for this retail order flow through the Program should not materially detract from the current incentives to display limit orders, while potentially resulting in greater order interaction and price improvement for marketable retail orders. To the extent that the Program may raise Manning and best-execution issues for broker-dealers, these issues are already presented by the existing practices of OTC market makers.

The exemption being granted today is limited to a one-year pilot. The Exchange has stated that ''sub-penny trading and pricing could potentially

[35] *See supra* note 22 and accompanying text.

[36] 17 CFR 242.612(c).

[37] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37551–52 (June 29, 2005).

[38] *Id.* at 37553.

[39] When adopting the Sub-Penny Rule, the Commission considered certain comments that asked the Commission to prohibit broker-dealers from offering sub-penny price improvement to their customers, but declined to do so. The Commission stated that ''trading in sub-penny increments does not raise the same concerns as sub-penny quoting'' and that ''sub-penny executions due to price improvement are generally beneficial to retail investors.'' *Id.* at 37556.

result in undesirable market behavior'' and that, therefore, it will ''monitor the Program in an effort to identify and address any such behavior.'' [40] Furthermore, the Exchange has represented that it ''will produce data throughout the pilot, which will include statistics about participation, the frequency and level of price improvement provided by the Program, and any effects on the broader market structure.'' [41] The Commission expects to review the data and observations of the Exchange before determining whether and, if so, how to extend the exemption from the Sub-Penny Rule.[42]

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[43] that the proposed rule change (SR–BX–2014–048) be, and hereby is, approved on a one-year pilot basis.

It is also hereby ordered that, pursuant to Rule 612(c) of Regulation NMS, the Exchange is given a limited exemption from Rule 612 of Regulation NMS allowing it to accept and rank orders priced equal to or greater than $1.00 per share in increments of $0.001, in the manner described in the proposed rule change above, for a period of 12 months, ending on the same date as the 12-month pilot period of the Program.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[44]

Brent J. Fields,

Secretary.

[FR Doc. 2014–28474 Filed 12–3–14; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF STATE

[Public Notice 8963]

Determination by the Secretary of State Relating to Iran Sanctions

SUMMARY: This notice is to inform the public that the Secretary of State determined on November 20, 2014, pursuant to Section 1245(d)(4)(D) of the National Defense Authorization Act for Fiscal Year 2012 (NDAA) (Pub. L. 112–81), as amended, that as of November 20, 2014, each of the following purchasers of oil from Iran has qualified for the 180-day exception outlined in section 1245(d)(4)(D): Malaysia, Singapore, and South Africa. The Secretary of State last made exception determinations under Section 1245(d)(4)(D) of the NDAA regarding these purchasers on May 27, 2014.

Dated: November 28, 2014.

Robert F. Ichord,

Deputy Assistant Secretary, Bureau of Energy Resources, U.S. Department of State.

[FR Doc. 2014–28520 Filed 12–3–14; 8:45 am]

BILLING CODE 4710–09–P

[40] *See* Request for Sub-Penny Rule Exemption, *supra* note 5, at 3, n.6.

[41] *See supra* note 22 and accompanying text.

[42] In particular, the Commission expects the Exchange to observe how maker/taker transaction charges, whether imposed by the Exchange or by other markets, might impact the use of the Program. Market distortions could arise where the size of a transaction rebate, whether for providing or taking liquidity, is greater than the size of the minimum increment permitted by the Program ($0.001 per share).

[43] 15 U.S.C. 78s(b)(2).

[44] 17 CFR 200.30–3(a)(12); 17 CFR 200.30–3(a)(83).

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Report of Inspections Required by Airworthiness Directives

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. Airworthiness Directives (ADs) are regulations issued to require correct corrective action to correct unsafe conditions in aircraft, engines, propellers, and appliances. Reports of inspections are often needed when emergency corrective action is taken to determine if the action was adequate to correct the unsafe condition. The respondents are aircraft owners and operators. Currently, FAA has blanket Paperwork Reduction Act approval from OMB for all ADs with information collection requirements. Per OMB's request, this collection is being converted to a generic information collection request, which will require FAA to submit individual ADs to OMB for approval prior to their release.

DATES: Written comments should be submitted by February 2, 2015.

ADDRESSES: Send comments to the FAA at the following address: Ms. Kathy DePaepe, Room 126B, Federal Aviation Administration, AES–200, 6500 S. MacArthur Blvd., Oklahoma City, OK 73169.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Kathy DePaepe at (405) 954–9362, or by email at: *Kathy.DePaepe@faa.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0056.

Title: Report of Inspections Required by Airworthiness Directives.

Form Numbers: There are no FAA forms associated with this collection.

Type of Review: Renewal of an information collection; conversion to generic information collection request.

Background: Title 14 CFR part 39, Airworthiness Directives (AD), authorized by §§ 40113(a), 44701, and 44702 of Title 49 United States Code, prescribes how the FAA issues ADs. The FAA issues ADs when an unsafe condition is discovered on a specific aircraft type. If the condition is serious enough and more information is needed to develop corrective action, specific information may be required from aircraft owners/operators. If it is necessary for the aircraft manufacturer or airworthiness authority to evaluate the information, owners/operators will be instructed to send the information to them.

Respondents: Approximately 1,120 aircraft owners/operators.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 5 minutes.

Estimated Total Annual Burden: 3,080 hours.

Issued in Washington, DC, on December 1, 2014.

Albert R. Spence,

FAA Assistant Information Collection Clearance Officer, IT Enterprises Business Services Division, ASP–110.

[FR Doc. 2014–28517 Filed 12–3–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Aviation Insurance

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The requested information is included in air carriers applications for insurance when insurance is not available from private sources.

DATES: Written comments should be submitted by February 2, 2015.

ADDRESSES: Send comments to the FAA at the following address: Ms. Kathy DePaepe, Room 126B, Federal Aviation Administration, ASP–110, 6500 S. MacArthur Blvd., Oklahoma City, OK 73169.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Kathy DePaepe at (405) 954–9362, or by email at: *Kathy.DePaepe@faa.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0514.

Title: Aviation Insurance.

Form Numbers: There are no FAA forms associated with this collection.

Type of Review: Renewal of an information collection.

Background: The information submitted by applicants for insurance under Chapter 443 of Title 49 U.S.C. is used by the FAA to identify the eligibility of parties to be insured, the amount of coverage required, and insurance premiums. Without collection of this information, the FAA would not be able to issue required insurance.

Respondents: Approximately 61 applicants.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 4 hours.

Estimated Total Annual Burden: 616 hours.

Issued in Washington, DC, on December 1, 2014.

Albert R. Spence,

FAA Assistant Information Collection Clearance Officer, IT Enterprises Business Services Division, ASP–110.

[FR Doc. 2014–28522 Filed 12–3–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Certification Procedures for Products and Parts

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. 14 CFR part 21 prescribes certification standards for aircraft, aircraft engines, propellers appliances and parts. The information collected is used to determine compliance and applicant eligibility. The respondents are aircraft parts designers, manufacturers, and aircraft owners.

DATES: Written comments should be submitted by February 2, 2015.

ADDRESSES: Send comments to the FAA at the following address: Ms. Kathy DePaepe, Room 126B, Federal Aviation Administration, ASP–110, 6500 S. MacArthur Blvd., Oklahoma City, OK 73169.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Kathy DePaepe at (405) 954–9362, or by email at: *Kathy.DePaepe@faa.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0018.

Title: Certification Procedures for Products and Parts.

Form Numbers: FAA Forms 8110–12, 8130–1, 8130–6, 8130–9, 8130–12.

Type of Review: Renewal of an information collection.

Background: 14 CFR part 21 prescribes certification standards for aircraft, aircraft engines, propellers appliances and parts. The information collected is used to determine compliance and applicant eligibility. FAA Airworthiness inspectors, designated inspectors, engineers, and designated engineers review the required data submittals to determine that aviation products and articles and their manufacturing facilities comply with the applicable requirements, and that the products and articles have no unsafe features.

Respondents: Approximately 13,339 aircraft parts designers, manufacturers, and aircraft owners.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 30 minutes.

Estimated Total Annual Burden: 19,487 hours.

Issued in Washington, DC, on December 1, 2014.

Albert R. Spence,

FAA Assistant Information Collection Clearance Officer, IT Enterprises Business Services Division, ASP–110.

[FR Doc. 2014–28519 Filed 12–3–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Airport Noise Compatibility Planning

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The respondents are those airport operators voluntarily submitting noise exposure maps and noise

compatibility programs to the FAA for review and approval.

DATES: Written comments should be submitted by February 2, 2015.

ADDRESSES: Send comments to the FAA at the following address: Ms. Kathy DePaepe, Room 126B, Federal Aviation Administration, ASP–110, 6500 S. MacArthur Blvd., Oklahoma City, OK 73169.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Kathy DePaepe at (405) 954–9362, or by email at: *Kathy.DePaepe@faa.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0517.

Title: Airport Noise Compatibility Planning.

Form Numbers: There are no FAA forms associated with this collection.

Type of Review: Renewal of an information collection.

Background: The voluntarily submitted information from the current CFR part 150 collection, *e.g.,* airport noise exposure maps and airport noise compatibility programs, or their revisions, is used by the FAA to conduct reviews of the submissions to determine if an airport sponsor's noise compatibility program is eligible for Federal grant funds. If airport operators did not voluntarily submit noise exposure maps and noise compatibility programs for FAA review and approval, the airport operator would not be eligible for the set aside of discretionary grant funds.

Respondents: Approximately 15 airport operators.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 3882.6 hours.

Estimated Total Annual Burden: 56,160 hours.

Issued in Washington, DC, on December 1, 2014.

Albert R. Spence,

FAA Assistant Information Collection Clearance Officer, IT Enterprises Business Services Division, ASP–110.

[FR Doc. 2014–28523 Filed 12–3–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Fractional Aircraft Ownership Programs

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. Fractional Ownership is a program that offers increased flexibility in aircraft ownership. Owners purchase shares of an aircraft and agree to share their aircraft with others having an ownership share in that same aircraft. Owners agree to put their aircraft into a ''pool'' of other shared aircraft and to lease their aircraft to another owner in that pool.

DATES: Written comments should be submitted by February 2, 2015.

ADDRESSES: Send comments to the FAA at the following address: Ms. Kathy DePaepe, Room 126B, Federal Aviation Administration, ASP–110, 6500 S. MacArthur Blvd., Oklahoma City, OK 73169.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Kathy DePaepe at (405) 954–9362, or by email at: *Kathy.DePaepe@faa.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0684.

Title: Fractional Aircraft Ownership Programs.

Form Numbers: There are no FAA forms associated with this collection.

Type of Review: Renewal of an information collection.

Background: Each fractional ownership program manager and each fractional owner must comply with the requirements of 14 CFR part 91, subpart K. Information is used to determine if these entities are operating in accordance with the minimum safety standards of these regulations. The FAA will use the information it reviews and collects to evaluate the effectiveness of the program and make improvements as needed, and ensure compliance and adherence to regulations.

Respondents: 11 fractional aircraft program managers/operators.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 46 minutes.

Estimated Total Annual Burden: 19,609 hours.

Issued in Washington, DC, on December 1, 2014.

Albert R. Spence,

FAA Assistant Information Collection Clearance Officer, IT Enterprises Business Services Division, ASP–110.

[FR Doc. 2014–28524 Filed 12–3–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection(s): Criteria for Internet Communications of Aviation Weather, NOTAM, and Aeronautical Data

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. An Advisory Circular (AC) establishes criteria for Qualified Internet Communications Providers (ICP), who provide access to aviation weather, Notices to Airmen (NOTAM), and aeronautical data via the Public Internet. The information collected is used to determine the provider's eligibility.

DATES: Written comments should be submitted by February 2, 2015.

ADDRESSES: Send comments to the FAA at the following address: Ms. Kathy DePaepe, Room 126B, Federal Aviation Administration, ASP–110, 6500 S. MacArthur Blvd., Oklahoma City, OK 73169.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a)

Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Kathy DePaepe at (405) 954–9362, or by email at: *Kathy.DePaepe@faa.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0672.

Title: Criteria for Internet Communications of Aviation Weather, NOTAM, and Aeronautical Data.

Form Numbers: There are no FAA forms associated with this collection of information.

Type of Review: Renewal of an information collection.

Background: Any interested person or organization desiring to become a QICP shall provide the FAA Aviation Weather Division, ANG–C6 with a written application documenting their capability to meet the QICP criteria. The purpose of the information is to ensure the reliability, accessibility and security of aviation weather data, NOTAM and aeronautical data accessed via the Internet as well as to encourage data providers to identify the approval status (*e.g.,* experimental or operational) of aviation weather products.

Respondents: Approximately 6 applicants.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 240 hours.

Estimated Total Annual Burden: 3,840 hours.

Issued in Washington, DC, on December 1, 2014.

Albert R. Spence,

FAA Assistant Information Collection Clearance Officer, IT Enterprises Business Services Division, ASP–110.

[FR Doc. 2014–28521 Filed 12–3–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Charter Renewal of the Commercial Space Transportation Advisory Committee (COMSTAC)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: The FAA announces the charter renewal of the COMSTAC, a Federal Advisory Committee that provides information, advice, and recommendations to the Department of Transportation and the Administrator of the Federal Aviation Administration (FAA) on the critical matters facing the U.S. commercial space transportation industry.

DATES: *Effective Date:* December 4, 2014. The effective date of the charter renewal is November 17, 2014, and will expire after 2 years.

FOR FURTHER INFORMATION CONTACT: Michael Beavin, COMSTAC Executive Director, telephone (202) 267–9051; email *michael.beavin@faa.gov,* FAA Office of Commercial Space Transportation (AST–3), 800 Independence Avenue SW., Room 331, Washington, DC 20591.

SUPPLEMENTARY INFORMATION: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), FAA is giving notice of the charter renewal for the COMSTAC. This charter renewal took effect on November 17, 2014, and will expire after 2 years.

The primary goals of COMSTAC are to: Evaluate economic, technological, and institutional developments relating to the U.S. commercial space transportation industry; provide a forum for the discussion of problems involving the relationship between industry activities and government requirements; and make recommendations to the FAA Administrator on issues and approaches for Federal policies and programs regarding the industry.

COMSTAC membership consists of senior executives from the commercial space transportation industry; representatives from the satellite industry, both manufacturers and users; state and local government officials; representatives from firms providing insurance, financial investment and legal services for commercial space activities; and representatives from academia, space advocacy organizations, and industry associations.

Complete information regarding COMSTAC is available on the FAA Web site at: *http://www.faa.gov/about/office_org/headquarters_offices/ast/advisory_committee/.*

Issued in Washington, DC, on November 24, 2014.

George C. Nield,

Associate Administrator for Commercial Space Transportation.

[FR Doc. 2014–28525 Filed 12–3–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Passenger Facility Charge (PFC) Approvals and Disapprovals

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Monthly Notice of PFC Approvals and Disapprovals. In October 2014, there were eight applications approved. This notice also includes information on two applications, approved in September 2014, inadvertently left off the September 2014 notice. Additionally, 11 approved amendments to previously approved applications are listed.

SUMMARY: The FAA publishes a monthly notice, as appropriate, of PFC approvals and disapprovals under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Pub. L. 101–508) and Part 158 of the Federal Aviation Regulations (14 CFR part 158). This notice is published pursuant to paragraph d of § 158.29.

PFC Applications Approved

Public Agency: Westmoreland County Airport Authority, Latrobe, Pennsylvania.

Application Number: 14–03–C–00–LBE.

Application Type: Impose and use a PFC.

PFC Level: $4.50.

Total PFC Revenue Approved in This Decision: $382,641.

Earliest Charge Effective Date: March 1, 2016.

Estimated Charge Expiration Date: July 1, 2017.

Class of Air Carriers Not Required To Collect PFC's: None.

Brief Description of Projects Approved for Collection and Use:

Install runway 23 vertical/visual guidance system.
Master plan update.
Expand terminal parking.
Rehabilitate parallel taxiway phase 1 design.
Sustainable master plan.
Terminal improvements.
Terminal expansion design.
Rehabilitate parallel taxiway phase 2 construction.
Rehabilitate main terminal apron.

Brief Description of Withdrawn Project: Acquire snow removal equipment.

Date of Withdrawal: September 18, 2014.

Decision Date: September 29, 2014.

FOR FURTHER INFORMATION CONTACT: Lori Ledebohm, Harrisburg Airports District Office, (717) 730–2835.

Public Agency: Metropolitan Airports Commission, Minneapolis, Minnesota.

Application Number: 13–11–C–00–MSP.

Application Type: Impose and use a PFC.

PFC Level: $4.50.

Total PFC Revenue Approved In This Decision: $52,827,265.

Earliest Charge Effective Date: March 1, 2018.

Estimated Charge Expiration Date: October 1, 2018.

Class of Air Carriers Not Required To Collect PFC's: Air taxi/commercial operators filing FAA Form 1800–31.

Determination: Approved. Based on information contained in the public agency's application, the FAA has determined that the approved class accounts for less than 1 percent of the total annual enplanements at Minneapolis-St. Paul International Airport (MSP).

Brief Description of Projects Approved for Collection and Use at MSP at a $3.00 PFC Level:

Terminal 1—Lindbergh Concourse F pedestrian bridge rehabilitation.
Electronic video information display systems.
Runway 12R/30L service road tunnel improvements.
Aircraft rescue and firefighting station 2/building roof replacements.
Taxiway C extension.
Orange parking ramp skyway link/terminal expansion.

Brief Description of Projects Approved for Collection and Use at MSP at a $4.50 PFC Level:

Terminal 1—Lindbergh passenger boarding bridges replacement.
Perimeter fence/gate security improvements.
Runway 30L engineered materials arresting system replacement.
Terminal 2—Humphrey security checkpoint.
Terminal 2—Humphrey passenger boarding bridges replacement.

Brief Description Of Disapproved Projects:

Runway 30R maximum intensity approach lighting system with sequence flashers.

Determination: Disapproved. The FAA determined that the proposed project did not improve the visibility minimums for runway 30R. Therefore, the project did not meet the requirements of § 158.15(b).

Airport noise and operations monitoring system upgrades.

Determination: Disapproved. The FAA determined that the proposed upgrade was not addressing a deficiency in the existing noise monitoring system. Therefore, the project did not meet the requirements of § 158.15(b).

Decision Date: September 30, 2014.

FOR FURTHER INFORMATION CONTACT: Chris Hugunin, Minneapolis Airports District Office, (612) 253–4630.

Public Agency: Huntsville-Madison County Airport Authority, Huntsville, Alabama.

Application Number: 14–20–C–00–HSV.

Application Type: Impose and use a PFC.

PFC Level: $4.50.

Total PFC Revenue Approved in This Decision: $1,750,085.

Earliest Charge Effective Date: October 1, 2023.

Estimated Charge Expiration Date: August 1, 2024.

Classes of Air Carriers Not Required To Collect PFC'S:

(1) Air taxi/commercial operators filing FAA Form 1800–31, operating at Huntsville International Airport (HSV), and having fewer than 500 annual passenger enplanements; (2) certified air carriers filing Department of Transportation (DOT) Form T–100, operating at HSV, and having fewer than 500 annual enplanements; (3) certified route air carriers filing DOT Form T–100, operating at HSV, and having fewer than 500 annual passenger enplanements; and (4) foreign air carriers filing DOT Form T–100(f), operating at HSV, and having fewer than 500 annual passenger enplanements.

Determination: Approved. Based on information contained in the public agency's application, the FAA has determined that each approved class accounts for less than 1 percent of the total annual enplanements at HSV.

Brief Description of Project Approved for Collection and Use: Group VI airfield improvements 18L/36R.

Decision Date: October 2, 2014.

FOR FURTHER INFORMATION CONTACT: Matthew Felton, Jackson Airports District Office, (601) 664–9894, ext. 194.

Public Agency: Pee Dee Regional Airport Authority, Florence South Carolina.

Application Number: 14–02–C–00–FLO.

Application Type: Impose and Use a PFC.

PFC Level: $4.50.

Total PFC Revenue Approved in This Decision: $827,258.

Earliest Charge Effective Date: December 1, 2014.

Estimated Charge Expiration Date: February 1, 2018.

Class of Air Carriers Not Required To Collect PFC's: Air taxi/commercial operators filing FAA Form 1800–31 and operating at Florence Regional Airport (FLO).

Determination: Approved. Based on information contained in the public agency's application, the FAA has determined that the approved class accounts for less than 1 percent of the total annual enplanements at FLO.

Brief Description of Projects Approved for Collection:

Install an animal control fence.
General aviation terminal facility (design and construction).
Construct a new aircraft rescue and firefighting facility (design and construction).

Brief Description of Projects Approved for Collection and use:

Removal of airspace obstructions.
Terminal renovations reimbursement—design and construction.
Terminal apron reimbursement—design and construction.
Taxiways D, B, and E lighting and generator (phase II construction).
Upgrade airfield signage.
Perform wildlife assessment study.
Refurbish airfield storm water drainage systems (design and construction).
Purchase airfield pavement sweeper.
Master plan update.
Refurbish and upgrade the airport beacon.
Refurbish the airfield electrical vault.
Install a new airport wind cone.
PFC application development.
PFC administration.

Decision Date: October 20, 2014.

FOR FURTHER INFORMATION CONTACT: Robert Rau, Atlanta Airports District Office, (404) 305–7162.

Public Agency: Metropolitan Nashville Airport Authority, Nashville, Tennessee.

Application Number: 14–20–C–00–BNA.

Application Type: Impose and use a PFC.

PFC Level: $4.50.

Total PFC Revenue Approved In This Decision: $4,900,000.

Earliest Charge Effective Date: August 1, 2016.

Estimated Charge Expiration Date: November 1, 2016.

Class of Air Carriers Not Required To Collect PFC's: Air taxi/commercial operators filing FAA Form 1800–31 and operating at Nashville International Airport (BNA).

Determination: Approved. Based on information contained in the public agency's application, the FAA has determined that the approved class

accounts for less than 1 percent of the total annual enplanements at BNA.

Brief Description of Projects Approved for Collection and Use at a $4.50 PFC Level:

Reconstruct taxiway T3.
Reconstruct taxiways L and J-east.

Decision Date: October 22, 2014.

FOR FURTHER INFORMATION CONTACT: Cynthia Wills, Memphis Airports District Office, (901) 322–8190.

Public Agency: City of Long Beach, California.

Application Number: 14–07–C–00–LGB.

Application Type: Impose and use a PFC.

PFC Level: $4.50.

Total PFC Revenue Approved in This Decision: $10,697,988.

Earliest Charge Effective Date: June 1, 2032.

Estimated Charge Expiration Date: April 1, 2034.

Class of Air Carriers Not Required To Collect PFC's: Non-scheduled/on-demand air carriers filing FAA Form 1800–31.

Determination: Approved. Based on information contained in the public agency's application, the FAA has determined that the approved class accounts for less than 1 percent of the total annual enplanements at Long Beach/Daugherty Field Airport.

Brief Description of Projects Approved for Collection and Use:

Reconstruction of air carrier apron—phases II and III.
Pavement management and maintenance program.
Airfield geometry study and strategic planning.
Runway 30 safety area improvements.
Runway 07L/25R rehabilitation.
Perimeter security improvements.
Terminal access road improvements.
PFC application and program administration.

Decision Date: October 24, 2014.

FOR FURTHER INFORMATION CONTACT: Darlene Williams, Los Angeles Airports District Office, (310) 725–3625.

Public Agency: Los Angeles World Airports, Los Angeles, California.

Application Number: 13–09–C–00–LAX.

Application Type: Impose and use a PFC.

PFC Level: $3.00.

Total PFC Revenue Approved in This Decision: $44,378,659.

Earliest Charge Effective Date: June 1, 2019.

Estimated Charge Expiration Date: October 1, 2019.

Class of Air Carriers Not Required To Collect PFC's: Air taxi/Commercial operators filing FAA Form 1800–31.

Determination: Approved. Based on information contained in the public agency's application, the FAA has determined that the approved class accounts for less than 1 percent of the total annual enplanements at Los Angeles International Airport.

Brief Description of Project Partially Approved for Collection and Use: Inglewood Unified School District soundproofing program.

Determination: Partially approved. The FAA determined that two schools (Inglewood High School and Hudnall Elementary School) proposed for inclusion in this project were not eligible for PFC funding. In addition, the FAA determined that two items of work (annual audit reports and ARUP consultants) were not eligible for PFC funding. Therefore, the approved PFC amount was reduced from the amount requested.

Decision Date: October 24, 2014.

FOR FURTHER INFORMATION CONTACT: Darlene Williams, Los Angeles Airports District Office, (310) 725–3625.

Public Agency: Greater Peoria Airport Authority, Peoria, Illinois.

Application Number: 15–06–C–00–PIA.

Application Type: Impose and use a PFC.

PFC Level: $4.50.

Total PFC Revenue Approved in This Decision: $11,708,250.

Earliest Charge Effective Date: February 1, 2015.

Estimated Charge Expiration Date: September 1, 2023.

Class of Air Carriers Not Required To Collect PFC'S: Non-scheduled/on-demand air carriers filing FAA Form 1800–31 that are operating at General Wayne A. Downing Peoria International Airport (PIA).

Determination: Approved. Based on information contained in the public agency's application, the FAA has determined that the approved class accounts for less than 1 percent of the total annual enplanements at PIA.

Brief Description of Projects Approved for Collection and Use:

Drainage improvements and slope stabilization.
Expand terminal parking lot.
Rehabilitate airport entrance road.
Snow removal equipment building.
Master plan and airport layout plan update.
PFC application costs.

Brief Description of Project Partially Approved for Collection and Use: Additional terminal gates/Federal Inspection Services.

Determination: Partially approved. The FAA determined that PFC eligibility is limited to the new gate facilities and general aviation facilities portion of the project.

Decision Date: October 24, 2014.

FOR FURTHER INFORMATION CONTACT: Michael Brown, Chicago Airports District Office, (847) 294–7195.

Public Agency: Border Coast Regional Airport Authority, Crescent City, California.

Application Number: 15–05–C–00–CEC.

Application Type: Impose and use a PFC.

PFC Level: $4.50.

Total PFC Revenue Approved in This Decision: $263,158.

Earliest Charge Effective Date: December 1, 2014.

Estimated Charge Expiration Date: February 1, 2021.

Class of Air Carriers Not Required To Collect PFC's: Non-scheduled/on-demand air carriers filing FAA Form 1800–31.

Determination: Approved. Based on information contained in the public agency's application, the FAA has determined that the approved class accounts for less than 1 percent of the total annual enplanements at Jack McNamara Field Airport.

Brief Description of Projects Approved for Collection and Use:

Runway safety area improvements—design.
Terminal building design—phase I.
Terminal building design—design phase II.

Decision Date: October 28, 2014.

FOR FURTHER INFORMATION CONTACT: Neil Kumar, San Francisco Airports District Office, (650) 827–7627.

Public Agency: Grand Forks Regional Airport Authority, Grand Forks, North Dakota.

Application Number: 15–10–C–00–GFK.

Application Type: Impose and use a PFC.

PFC Level: $4.50.

Total PFC Revenue Approved in This Decision: $1,867,720.

Earliest Charge Effective Date: January 1, 2019.

Estimated Charge Expiration Date: February 1, 2022.

Class of Air Carriers Not Required To Collect PFC's: Air taxi/Commercial operators filing FAA Form 1800–31 that are operating at Grand Forks International Airport (GFK).

Determination: Approved. Based on information contained in the public agency's application, the FAA has determined that the approved class accounts for less than 1 percent of the total annual enplanements at GFK.

Brief Description of Projects Approved for Collection and Use:

Purchase snow removal equipment.
Construct snow removal equipment building.
Construct aircraft rescue and fire fighting building.
Reconstruct taxiways A, B, and D intersection.

Decision Date: October 28, 2014.

FOR FURTHER INFORMATION CONTACT: Chris Hugunin, Minneapolis Airports District Office, (612) 253–4630.

AMENDMENTS TO PFC APPROVALS

Amendment No. city, state	Amendment approved date	Original approved net PFC revenue	Amended approved net PFC revenue	Original estimated charge exp. date	Amended estimated charge exp. date
09–14–C–01–OAK, Oakland, CA	09/26/14	$293,219,000	$396,564,898	04/01/21	01/01/28
08–14–C–03–BNA, Nashville, TN	09/30/14	66,013,179	66,013,179	06/01/16	06/01/16
11–17–C–03–BNA, Nashville, TN	09/30/14	2,797,105	2,722,105	06/01/17	04/01/17
13–19–C–01–BNA, Nashville, TN	09/30/14	4,430,000	4,750,000	11/01/17	11/01/17
10–05–C–01–BIS, Bismarck, ND	10/08/14	7,099,409	4,036,922	02/01/22	02/01/15
01–03–C–02–BFL, Bakersfield, CA	10/10/14	9,086,000	10,526,514	12/01/17	01/01/21
10–05–C–01–CIC, Chico, CA	10/10/14	590,000	7,569	12/01/16	12/01/14
12–10–C–01–LSE, La Crosse, WI	10/14/14	2,665,657	4,175,370	01/01/23	05/01/28
08–14–C–04–BNA, Nashville, TN	10/15/14	66,013,179	56,871,177	06/01/16	05/01/15
09–15–C–02–BNA, Nashville, TN	10/15/14	6,196,434	4,314,382	09/01/16	09/01/16
10–03–C–02–DAL, Dallas, TX	10/16/14	383,636,108	374,336,108	04/01/26	04/01/25

Issued in Washington, DC, on December 1, 2014.

Joe Hebert,

Manager, Financial Analysis and Passenger Facility Charge Branch.

[FR Doc. 2014–28535 Filed 12–3–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Passenger Facility Charge (PFC) Approvals and Disapprovals

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Monthly Notice of PFC Approvals and Disapprovals. In November 2014, there were two applications approved. Additionally, four approved amendments to previously approved applications are listed.

SUMMARY: The FAA publishes a monthly notice, as appropriate, of PFC approvals and disapprovals under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Pub. L. 101–508) and Part 158 of the Federal Aviation Regulations (14 CFR part 158). This notice is published pursuant to paragraph d of § 158.29.

PFC Applications Approved

Public Agency: Capital Region Airport Commission, Richmond, Virginia.

Application Number: 14–07–U–00–RIC.

Application Type: Use PFC revenue.

PFC Level: $4.50.

Total PFC Revenue Approved for Use in This Decision: $9,559,375.

Charge Effective Date: October 1, 2019.

Estimated Charge Expiration Date: March 1, 2025.

Class of Air Carriers Not Required To Collect PFC's: No change from previous decision.

Brief Description of Projects Approved for Use:

Construct cargo apron improvements.
Construct general aviation apron improvements.
Reconstruction of taxiway E and a portion of taxiway L.
Construct snow removal building.

Decision Date: November 6, 2014.

FOR FURTHER INFORMATION CONTACT: Jeffrey Breeden, Washington Airports District Office, (703) 661–1363.

Public Agency: Williamsport Regional Airport, Montoursville, Pennsylvania.

Application Number: 14–04–I–00–IPT.

Application Type: Impose and use a PFC.

PFC Level: $4.50.

Total PFC Revenue Approved in This Decision: $1,500,000.

Earliest Charge Effective Date: June 1, 2015.

Estimated Charge Expiration Date: September 1, 2028.

Class of Air Carriers Not Required To Collect PFC's: None.

Brief Description of Project Approved for Collection: Construct new passenger terminal building.

Decision Date: November 10, 2014.

FOR FURTHER INFORMATION CONTACT: Lori Ledebohm, Harrisburg Airports District Office, (717) 730–2835.

AMENDMENT TO PFC APPROVALS

Amendment No., city, state	Amendment approved date	Original approved net PFC revenue	Amended approved net PFC revenue	Original estimated charge exp. date	Amended estimated charge exp. date
12–08–C–01–SUN, Hailey, ID	11/03/14	$527,500	$526,722	07/01/14	07/01/14
10–09–C–01–BTM, Butte, MT	11/03/14	271,635	222,908	02/01/13	01/01/14
11–05–C–01–SFO, San Francisco, CA	11/07/14	610,451,805	741,744,636	06/01/23	10/01/24
12–05–C–01–CHA, Chattanooga, TN	11/12/14	6,896,122	7,969,956	06/01/17	10/01/15

Issued in Washington, DC, on December 1, 2014.

Joe Hebert,

Manager, Financial Analysis and Passenger Facility Charge Branch.

[FR Doc. 2014–28526 Filed 12–3–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

Release of Waybill Data

The Surface Transportation Board has received a request from BTGPactual (WB980–1—12/1/14) for permission to use certain data from the Board's 2013 Carload Waybill Sample. A copy of this request may be obtained from the Office of Economics.

The waybill sample contains confidential railroad and shipper data; therefore, if any parties object to these requests, they should file their objections with the Director of the Board's Office of Economics within 14 calendar days of the date of this notice. The rules for release of waybill data are codified at 49 CFR 1244.9.

Contact: Alexander Dusenberry, (202) 245–0319.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2014–28483 Filed 12–3–14; 8:45 am]

BILLING CODE 4915–01–P

FEDERAL REGISTER

Vol. 79 Thursday,
No. 233 December 4, 2014

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 201

Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling; Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products—Content and Format; Draft Guidance for Industry; Availability; Final Rule and Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. FDA–2006–N–0515 (formerly Docket No. 2006N–0467)]

RIN 0910–AF11

Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations governing the content and format of the ''Pregnancy,'' ''Labor and delivery,'' and ''Nursing mothers'' subsections of the ''Use in Specific Populations'' section of the labeling for human prescription drug and biological products. The final rule requires the removal of the pregnancy categories A, B, C, D, and X from all human prescription drug and biological product labeling. For human prescription drug and biological products subject to the Agency's 2006 Physician Labeling Rule, the final rule requires that the labeling include a summary of the risks of using a drug during pregnancy and lactation, a discussion of the data supporting that summary, and relevant information to help health care providers make prescribing decisions and counsel women about the use of drugs during pregnancy and lactation. The final rule eliminates the ''Labor and delivery'' subsection because information about labor and delivery is included in the ''Pregnancy'' subsection. The final rule requires that the labeling include relevant information about pregnancy testing, contraception, and infertility for health care providers prescribing for females and males of reproductive potential. The final rule creates a consistent format for providing information about the risks and benefits of prescription drug and/or biological product use during pregnancy and lactation and by females and males of reproductive potential. These revisions will facilitate prescriber counseling for these populations.

DATES: This rule is effective June 30, 2015. See section IV of this document for the implementation dates of this final rule.

FOR FURTHER INFORMATION CONTACT: Kathy Schreier, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6246, Silver Spring, MD 20993–0002, 301–796–3432; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

Table of Contents

Executive Summary
Purpose of the Regulatory Action
Summary of the Major Provisions of the Regulatory Action in Question
Costs and Benefits
I. Background
  A. History of FDA-Approved Pregnancy and Lactation Labeling for Prescription Drugs
  B. Development of the Proposed Rule
  C. The Proposed Rule
  D. Mental Models Research
II. Overview of the Final Rule Including Significant Changes to the Proposed Rule
  A. Overview
  B. Significant Changes to the Proposed Rule
III. Comments on the Proposed Rule
  A. Proposed Rule as a Whole
  B. Specific Provisions of the Proposed Rule
IV. Implementation
V. Legal Authority
  A. Statutory Authority
  B. First Amendment
VI. Environmental Impact
VII. Summary of Final Regulatory Impact Analysis
  A. Introduction
  B. Summary of Costs and Benefits
VIII. Paperwork Reduction Act of 1995
IX. Federalism
X. References

Executive Summary

Purpose of the Regulatory Action

FDA is amending its regulations governing the content and format of the ''Pregnancy,'' ''Labor and delivery,'' and ''Nursing mothers'' subsections of the ''Use in Specific Populations'' section (under § 201.57 (21 CFR 201.57)) and the ''Precautions'' section (under § 201.80 (21 CFR 201.80)) of the labeling for human prescription drug and biological products (both referred to as ''drugs'' or ''drug products'' in this final rule). In this rulemaking, the Agency is finalizing many of the provisions in the proposed rule issued on May 29, 2008 (73 FR 30831).

This rulemaking is part of a broad effort by the Agency to improve the content and format of prescription drug labeling. The final rule creates a consistent format for providing information about the risks and benefits of drug use during pregnancy and lactation and by females and males of reproductive potential. FDA's revisions to the content and format requirements for prescription drug and biological product labeling are authorized by the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and by the Public Health Service Act (PHS Act).

Summary of the Major Provisions of the Regulatory Action in Question

The final rule requires that for the labeling of certain drug products (as described in the ''Implementation'' section of this document), the subsections ''Pregnancy,'' ''Nursing mothers,'' and ''Labor and delivery'' be replaced by three subsections entitled ''Pregnancy,'' ''Lactation,'' and ''Females and Males of Reproductive Potential.'' The final rule also requires the removal of the pregnancy categories A, B, C, D, and X from all drug product labeling.

''Pregnancy''

The final rule merges the current ''Pregnancy'' and ''Labor and delivery'' subsections into a single ''Pregnancy'' subsection of labeling. If there is a scientifically acceptable pregnancy exposure registry for the drug, the ''Pregnancy'' subsection must contain a specified statement about the existence of the registry, followed by contact information needed to enroll or to obtain information about the registry. The Agency has concluded that including information about pregnancy exposure registries in prescription drug labeling will encourage participation in registries, thereby improving data collection in pregnant women. Under ''Pregnancy,'' the final rule also requires that the labeling include a summary of the risks of using a drug during pregnancy. If data demonstrate that a drug is not absorbed systemically, the ''Risk Summary'' must contain only a specified statement regarding this fact. If data demonstrate that the drug is absorbed systemically, the ''Risk Summary'' must include risk statements based on data from all relevant sources (human, animal, and/or pharmacologic), that describe, for the drug, the risk of adverse developmental outcomes.

The labeling must also contain relevant information, if it is available, to help health care providers make prescribing decisions and counsel women about the use of the drug during pregnancy; this could include information on disease-associated maternal and/or embryo/fetal risk, dose adjustments during pregnancy and the postpartum period, maternal adverse reactions, fetal/neonatal adverse reactions, and/or the effect of the drug on labor or delivery. FDA believes that including such information supports

health care providers' understanding of drug product risks and benefits and facilitates informed prescribing decisions and patient counseling. The labeling must also describe the data that are the basis for the risk statements and clinical information included in the ''Pregnancy'' subsection of labeling.

''Lactation''

The final rule requires that the ''Lactation'' subsection of labeling contain a summary of the risks of using a drug during lactation. If data demonstrate that the drug is not absorbed systemically, this summary must contain only a specified statement regarding this fact. If data demonstrate that the drug is absorbed systemically by the mother, this summary must include, to the extent it is available, relevant information on the presence of the drug in human milk, effects of the drug on the breast-fed child, and effects of the drug on milk production. For drugs absorbed systemically, a risk and benefit statement must appear at the end of the summary of risks, unless breastfeeding is contraindicated during drug therapy. FDA has determined that the inclusion of a risk and benefit statement will provide a useful framework for health care providers to use when making prescribing decisions for a lactating patient.

The ''Lactation'' subsection must also include, to the extent information is available, relevant information concerning ways to minimize drug exposure in the breast-fed child in certain situations and concerning available interventions for monitoring or mitigating the adverse reactions presented elsewhere in the labeling. In addition, the labeling must also include pertinent information about the data that are the basis for the risk summary and clinical information included in the ''Lactation'' subsection of labeling.

''Females and Males of Reproductive Potential''

FDA determined that because there was no consistent placement in the labeling of information about pregnancy testing, contraception, and infertility, it was difficult for health care providers to find this important information that can affect decisionmaking before or during pregnancy. Thus, the final rule requires that the ''Females and Males of Reproductive Potential'' subsection include relevant information when pregnancy testing or contraception is required or recommended before, during, or after drug therapy or when there are human or animal data that suggest drug-associated fertility effects.

Removal of Pregnancy Categories

Through experience and stakeholder feedback, FDA learned that the pregnancy categories were confusing and did not accurately and consistently communicate differences in degrees of fetal risk. In addition, FDA learned that the pregnancy categories were heavily relied upon by clinicians but were often misinterpreted and misused in that prescribing decisions were being made based on the pregnancy category, rather than an understanding of the underlying information that informed the assignment of the pregnancy category. FDA believes that a narrative structure for pregnancy labeling, rather than a category system, is best able to capture and convey the potential risks of drug exposure based on animal or human data, or both. FDA has determined that retaining the pregnancy categories is inconsistent with the need to accurately and consistently communicate differences in degrees of fetal risk. Therefore, the final rule requires the removal of the pregnancy categories A, B, C, D, and X from all drug product labeling.

Costs and Benefits

We estimate that over 10 years with a 7 percent discount rate, the present value of one-time costs of the rule equal $52.4 million and the present value of the annual costs equal $14.4 million; with a 3 percent discount rate, the present value of one-time costs equal $60.1 million and the present value of the annual costs equal $18.2 million. The present value of the total costs equal $66.8 million with a 7 percent discount rate and $78.2 million with a 3 percent discount rate. The annualized costs of the rule total $9.5 million with a 7 percent discount rate and $9.2 million with a 3 percent discount rate. The final rule will address issues raised by experts and stakeholders and improve the quality of the affected sections of prescription drug labeling. Better quality prescribing information will enhance the usefulness of the labeling. The public health benefits of the final rule would result from improved health outcomes. However, because we have no information about how improved labeling will affect prescriber behavior and patient outcomes, we are unable to quantify the benefits of the final rule.

SUMMARY OF BENEFITS AND COSTS OF THE FINAL RULE

Total benefits	Present value of total costs with 3 percent discount rate ($ mil)	Present value of total costs with 7 percent discount rate ($ mil)	Total annualized costs over 10 years with 3 percent discount rate ($ mil)	Total annualized costs over 10 years with 7 percent discount rate ($ mil)
Not estimated	78.2	66.8	9.2	9.5

I. Background

In the **Federal Register** of May 29, 2008 (73 FR 30831), FDA issued a proposed rule to amend the content and format of the ''Pregnancy,'' ''Labor and delivery,'' and ''Nursing mothers'' subsections of the ''Use in Specific Populations'' section of labeling for human prescription drug and biological products, which appear in § 201.57. The proposed rulemaking was part of a broad effort by the Agency to improve the content and formatting of prescription drug labeling.

A. History of FDA-Approved Pregnancy and Lactation Labeling for Prescription Drugs

Under sections 502 and 505 of the FD&C Act (21 U.S.C. 352 and 355), FDA has responsibility for ensuring that prescription drug and biological products (both referred to as ''drugs'' or ''drug products'' in this final rule) are accompanied by labeling (including prescribing information) that summarizes scientific information concerning their safe and effective use. FDA regulations on labeling for use during pregnancy, during labor and delivery, and by nursing mothers were originally issued in 1979 as part of a rule prescribing the content and format

for labeling for human prescription drugs (part 201 (21 CFR part 201)) (44 FR 37434, June 26, 1979) (the 1979 regulations).[1] The requirements on content and format of labeling for drug products were revised on January 24, 2006, in the final rule on ''Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products'' (71 FR 3922), commonly referred to as the ''Physician Labeling Rule'' (PLR).[2] As part of the January 2006 revision, the subsections of the labeling on pregnancy, labor and delivery, and nursing mothers were moved from the ''Precautions'' section under § 201.57 to the ''Use in Specific Populations'' section. The content of these sections in part 201 was not revised, but the sections were redesignated as § 201.57(c)(9)(i) through (c)(9)(iii). The previous labeling regulation (adopted in 1979) was redesignated as § 201.80, and applies to products not affected by the January 2006, revisions. In redesignated § 201.80, the subsections on pregnancy, labor and delivery, and nursing mothers are § 201.80(f)(6) through (f)(8).

The 1979 regulations provided, at what was redesignated in 2006 as § 201.57(c)(9)(i) and § 201.80(f)(6)(i), that unless a drug was not absorbed systemically and was not known to have a potential for indirect harm to a fetus, a ''Pregnancy'' subsection must be included within the ''Precautions'' section of the labeling. The 1979 regulations required that the ''Pregnancy'' subsection contain information on the drug's teratogenic effects and other effects on reproduction and pregnancy and, when available, a description of human studies with the drug and data on its effects on later growth, development, and functional maturation of the child. The 1979 regulations also required that each product be classified under one of five pregnancy categories (A, B, C, D, or X) on the basis of risk of reproductive and developmental adverse effects or, for certain categories, on the basis of such risk weighed against potential benefit.[3]

With regard to labor and delivery, the 1979 regulations stated, at what was redesignated in 2006 as § 201.57(c)(9)(ii) and § 201.80(f)(7), that under certain circumstances, the labeling must include information on the effects of the drug on, among other things, the mother and the fetus, the duration of labor and delivery, and the effect of the drug on the later growth, development, and functional maturation of the child.

With regard to labeling on lactation, the 1979 regulations required, at what was redesignated in 2006 as § 201.57(c)(9)(iii) and § 201.80(f)(8), that a ''Nursing mothers'' subsection be included in the ''Precautions'' section of the labeling. The ''Nursing mothers'' subsection provided that if a drug was absorbed systemically, the labeling must contain information about excretion of the drug in human milk and effects on the nursing infant, as well as a description of any pertinent adverse effects observed in animal offspring. The ''Nursing mothers'' subsection required the use of certain standard statements depending on whether the drug was known to be excreted in human milk and whether it was associated with serious adverse reactions.[4]

B. Development of the Proposed Rule

Over a number of years after the 1979 regulations were issued, FDA received feedback on the issues and concerns with the ''Pregnancy,'' ''Labor and delivery,'' and ''Nursing mothers'' subsections of prescription drug labeling as defined by the 1979 regulations. In response to this feedback, FDA held a part 15 public hearing, conducted focus groups, and convened two advisory committees to provide expert input. During this process, many stakeholders stated that these subsections of prescription drug labeling lacked clarity, often failed to provide meaningful clinical information about drug exposure during pregnancy and lactation, and did not address the potential maternal and fetal consequences of discontinuing needed maternal drug therapy during pregnancy. Experts and other stakeholders noted that the pregnancy categories, although highly relied upon by health care providers, were often misinterpreted and misused. FDA also sought input on the development of a model format for these subsections of labeling, and the resulting model served as the basis for the May 29, 2008, proposed rule (73 FR 30831). The preamble to the proposed rule contains a detailed discussion about the background of the development of the proposed rule and additional details regarding the 1979 regulations governing labeling of drug products for use during pregnancy, during labor and delivery, and while nursing (73 FR 30831 at 30832–30838).

C. The Proposed Rule

FDA proposed to amend the content and format of the ''Pregnancy,'' ''Labor and delivery,'' and ''Nursing mothers'' subsections of the ''Use in Specific Populations'' section of physician labeling for prescription drug products subject to § 201.57. The Agency's proposed changes were intended to create a consistent format for providing information about the effects of a drug on pregnancy and lactation that would be useful for decisionmaking by health care providers and their patients. With respect to the ''Pregnancy,'' ''Labor and delivery,'' and ''Nursing mothers'' subsections of the ''Precautions'' section of prescription drug labeling for drug products subject to § 201.80, the Agency proposed only to remove the pregnancy category from the ''Pregnancy'' subsection.

1. Proposed Provisions for New and Recently Approved Drugs

FDA proposed the following format and content changes to the ''Pregnancy,'' ''Labor and delivery,'' and ''Nursing mothers'' subsections of prescription drug labeling for products subject to § 201.57.

- Merge the current ''Pregnancy'' and ''Labor and delivery'' subsections into a single ''Pregnancy'' subsection designated 8.1 under the section ''8 Use in Specific Populations.''
- Rename the ''Nursing mothers'' subsection as ''Lactation'' designated with the identifying number 8.2 under the section ''8 Use in Specific Populations.''
- Reserve the identifying number 8.3 for future use.
- Replace the format and content of the ''Pregnancy'' subsection in its entirety with the following:
  - If there is a pregnancy exposure registry for the drug, the telephone number or other information needed to enroll in the registry or to obtain information about the registry must be included at the beginning of the ''Pregnancy'' subsection of labeling.
  - Require the inclusion of a general statement about background risk, specifically ''All pregnancies have a background risk of birth defect, loss, or other adverse outcome regardless of drug exposure. The fetal risk summary below describes (name of drug)'s potential to increase the risk of developmental abnormalities above the background risk.''

[1] Thus, the labeling for drugs originally approved before 1979 may not contain the information required by those regulations regarding pregnancy, labor and delivery, and nursing mothers.

[2] FDA's regulations governing the content and format of labeling for human prescription drug and biological products are contained in §§ 201.56, 201.57, and 201.80.

[3] For further discussion of the pregnancy categories, see 73 FR 30831 at 30832 through 30833.

[4] For further discussion of the history of both the ''Pregnancy'' and the ''Nursing mothers'' subsections of prescription drug labeling, see 73 FR 30831 at 30833.

○ Under the subheading ''Fetal Risk Summary,'' require the labeling to contain a risk conclusion and a narrative description of the risk(s) (if the risk conclusion is based on human data).

○ Require the fetal risk summary to characterize the likelihood that the drug increases the risk of developmental abnormalities and other risks in humans.

○ Require that if data demonstrate that a drug is not systemically absorbed, the fetal risk summary contain only the following statement: (Name of drug) is not absorbed systemically from (part of body) and cannot be detected in the blood. Maternal use is not expected to result in fetal exposure to the drug.

○ When both human and animal data are available, require that risk conclusions based on human data be presented before risk conclusions based on animal data. Require that a risk conclusion based on human data be followed by a narrative description of the risks.

○ When human data are sufficient to reasonably determine the likelihood that the drug increases the risk of fetal developmental abnormalities or specific developmental abnormalities, require the labeling to contain one of two risk conclusions: Human data do not indicate that (*name of drug*) increases the risk of (*type of developmental abnormality or specific developmental abnormality*) or Human data indicate that (*name of drug*) increases the risk of (*type of developmental abnormality or specific developmental abnormality*).

○ When human data are available but not sufficient to reasonably determine the drug's effects on fetal developmental abnormalities, require the labeling to characterize the likelihood that the drug increases the risk of developmental abnormalities as low, moderate, or high.

○ Require that when the data on which the risk conclusion is based are animal data, the fetal risk summary characterize the likelihood that the drug increases the risk of developmental abnormalities using one of the following risk conclusions: Not predicted to increase the risk, low likelihood of increased risk, moderate likelihood of increased risk, high likelihood of increased risk, or insufficient animal data on which to assess the likelihood of increased risk.

○ When human data are available, require that in addition to the risk conclusion(s), the fetal risk summary be followed by a brief narrative description of the risks of developmental abnormalities as well as on other relevant risks associated with the drug.

○ Require the fetal risk summary to refer to the ''Contraindications'' and/or ''Warnings and Precautions'' sections of the labeling if there is any information in those sections on an increased risk to the fetus from exposure to the drug.

○ Require under the subheading ''Clinical Considerations'' the inclusion of information about the known or predicted risks to the fetus from inadvertent exposure to the drug, including human or animal data on dose, timing, and duration of exposure. If there are no data to assess the risk from inadvertent exposure, require the labeling to so state.

○ Require under the subheading ''Clinical Considerations'' the inclusion of information related to prescribing decisions for pregnant women, including the risk, if known, to the pregnant woman and the fetus from the disease or condition the drug is indicated to treat and the potential influence of drug treatment on that risk; information about dosing adjustments during pregnancy; if use of the drug is associated with any maternal adverse reactions that are unique to pregnancy or if known adverse reactions occur with increased frequency or severity in pregnant women, a description of such adverse reactions; if it is known or anticipated that treatment of the pregnant woman will cause a complication in the fetus or the neonate, a description of the complication, the severity and reversibility of the complication, and general types of interventions, if any, that may be needed.

○ If the drug has a recognized use during labor or delivery, whether or not that use is stated as an indication in the labeling, or is expected to affect labor or delivery, require the inclusion of available information about the effect of the drug on the mother; the fetus/neonate; the duration of labor and delivery; the possibility of complications, including interventions, if any, that may be needed; and the later growth, development, and functional maturation of the child.

○ Require the inclusion of a ''Data'' subheading that, for human data, describes positive and negative experiences during pregnancy, including developmental abnormalities, and, to the extent applicable, the number of subjects and duration of the study. For animal data, require under the subheading ''Data'' a description of the relationship of the exposure and mechanism of action in the animal species to the anticipated exposure and mechanism of action in humans.

• Replace the ''Nursing mothers'' subsection with ''Lactation'' and replace the content requirements of ''Nursing mothers'' in its entirety with the following:

○ Require that the labeling of all drugs contain a ''Lactation'' subsection.

○ Under the subheading ''Risk Summary,'' if the data demonstrate that the drug does not affect the quantity and/or quality of human milk and there is reasonable certainty either that the drug is not detectable in human milk or that the amount of drug consumed through breast milk will not adversely affect the breast-fed child, the labeling must state: The use of (*name of drug*) is compatible with breastfeeding. After this statement (if applicable), the labeling must summarize the drug's effect on milk production, what is known about the presence of the drug in human milk, and the effects on the breast-fed child.

○ The source(s) of the data (*e.g.,* human, animal, in vitro) that are the basis for the ''Risk Summary'' must be stated. When there are insufficient data or no data to assess the drug's effect on milk production, the presence of the drug in human milk, and/or the effects on the breast-fed child, the ''Risk Summary'' must so state.

○ If the drug is not systemically absorbed, require that the subheading ''Risk Summary'' contain only the following statement: (*Name of drug*) is not absorbed systemically from (*part of body*) and cannot be detected in the mother's blood. Therefore, detectable amounts of (*name of drug*) will not be present in breast milk. Breastfeeding is not expected to result in fetal exposure to the drug.

○ If the drug is absorbed systemically, require the following under the subheading ''Risk Summary'':

▪ A description of the effects of the drug's impact on milk production, including the effect of the drug on the quality and quantity of milk, including milk composition, and the implications of these changes to the breast-fed child.

▪ A description of the presence of the drug in human milk in one of the following ways: (1) The drug is not detectable in human milk, (2) the drug has been detected in human milk, (3) the drug is predicted to be present in human milk, (4) the drug is not predicted to be present in human milk, or (5) the data are insufficient to know or predict whether the drug is present in human milk.

▪ Require that if studies demonstrate that the drug is not detectable in human milk, the ''Risk Summary'' state the limits of the assay used.

▪ Require that if the drug has been detected in human milk, the ''Risk Summary'' give the concentration

detected in milk in reference to a stated maternal dose (or, if the drug has been labeled for pediatric use, in reference to the pediatric dose), an estimate of the amount of the drug consumed daily by the infant based on an average daily milk consumption of 150 milliliters per kilogram of infant weight per day, and an estimate of the percentage of the maternal dose excreted in human milk.

- Require the inclusion of information about the likelihood and seriousness of known or predicted effects on the breast-fed child from exposure to the drug in human milk based on the pharmacologic and toxicologic profile of the drug, the amount of drug detected or predicted to be found in human milk, and age-related differences in absorption, distribution, metabolism, and elimination.

○ Under the subheading ''Clinical Considerations,'' require the labeling to provide the following information to the extent it is available: Information concerning ways to minimize the exposure of the breast-fed child to the drug, such as timing the dose relative to breastfeeding or pumping and discarding milk for a specified period; information about potential drug effects in the breast-fed child that could be useful to caregivers, including recommendations for monitoring or responding to these effects; information about dosing adjustments during lactation.

○ Require that the labeling include, under the subheading ''Data,'' an overview of the data that are the basis for the ''Risk Summary'' and ''Clinical Considerations.''

2. Pregnancy Categories and Implementation

FDA proposed to require the new content and format changes for prescription drug labeling for all applications (including new drug applications (NDAs), biologics license applications (BLAs), or efficacy supplements) required to comply with the PLR, *i.e.,* for drug products for which an application was approved on or after June 30, 2001. FDA proposed that holders of applications approved before June 30, 2001 (*i.e.,* applications not subject to the PLR), would not be required to implement the new content and format changes. Instead, if the labeling for such applications contains a pregnancy category, the application holders would be required to remove the pregnancy category designation by 3 years after the effective date of the final rule.

D. Mental Models Research

In a separate but related effort, FDA contracted with a third party research firm to conduct a Mental Models Research study in 2009 to better understand the decisionmaking processes of health care providers prescribing drugs to pregnant and lactating women with chronic conditions (Ref. 1). Mental Models Research is an established risk analysis approach that evaluates, using a structured interview, decisionmaking practices that require the synthesis of complex issues. The specific objectives of this study, which involved interviews with 54 health care providers, were to understand how health care providers used FDA-approved prescribing information (in the labeling format in place at the time of the study in 2009), in order to determine the factors that influence their treatment decisions for pregnant and lactating women with chronic conditions, and to define measures that could be used to quantify the value of prescribing information as a tool for these decision makers.

The findings from the Mental Models Research were consistent with the feedback the Agency received during its work on the proposed and final rules. For example, the research showed that the pregnancy categories were relied upon by many health care providers almost to the exclusion of other information found in the labeling. It also showed that providers often relied on secondary sources to find the pregnancy category for a particular product rather than using the product's labeling. Interviewees made suggestions for improving prescribing information, including simplifying the information presented, centralizing the relevant information, and making the information included in labeling clinically relevant.

II. Overview of the Final Rule, Including Significant Changes to the Proposed Rule

A. Overview

In this rulemaking, the Agency finalizes many of the provisions in the May 2008 proposed rule. In addition, the final rule reflects revisions the Agency made in response to comments on the May 2008 proposed rule. FDA has also made editorial and organizational changes to clarify provisions. For the purposes of this rulemaking, the term ''drug'' or ''drug product'' is used to refer to human prescription drugs and biological products that are regulated as drugs.

The final rule requires that for the labeling of certain products (as described in the ''Implementation'' section of this document), the subsections ''Pregnancy,'' ''Nursing mothers,'' and ''Labor and delivery'' be replaced by three subsections entitled ''Pregnancy,'' ''Lactation,'' and ''Females and Males of Reproductive Potential.'' Information previously placed in ''Labor and delivery'' is required to be included in the ''Pregnancy'' subsection of labeling. The final rule requires ''Risk Summary'' subheadings in the ''Pregnancy'' and ''Lactation'' subsections of labeling. The ''Pregnancy Exposure Registry'' subheading under ''Pregnancy'' is only required if there is such a registry. The ''Clinical Considerations'' and ''Data'' subheadings are required under ''Pregnancy'' and under ''Lactation'' only to the extent relevant information is available. If data demonstrate that the drug is systemically absorbed, the ''Risk Summary'' in the ''Pregnancy'' subsection requires a statement regarding the background risk, in addition to certain other information, and the ''Risk Summary'' in the ''Lactation'' subsection of labeling requires the inclusion of a risk and benefit statement, unless breastfeeding is contraindicated. The ''Females and Males of Reproductive Potential'' subsection is not required if none of the subheadings are applicable. However, when pregnancy testing and/or contraception is required or recommended before, during, or after drug therapy and/or when there are human and/or animal data that suggest drug-associated fertility effects, the ''Females and Males of Reproductive Potential'' subsection requires the inclusion of such information under the subheadings ''Pregnancy Testing,'' ''Contraception,'' and ''Infertility,'' respectively. The final rule also requires statements acknowledging when data on various labeling elements either are not available or do not establish the presence or absence of drug-associated risk In addition, the final rule requires removal of pregnancy categories from all drug product labeling, including those products for which an application was approved before June 30, 2001.

B. Significant Changes to the Proposed Rule

The final rule reflects revisions to the proposed rule in response to comments received on the proposed rule, as discussed in detail in section III of this document. FDA made the following organizational and content-based changes to the proposed rule:

1. Pregnancy

• The final rule revises the proposed rule to clarify that the ''Risk Summary'' subheading is always required in the ''Pregnancy'' subsection of labeling. The subheading ''Pregnancy Exposure Registry'' is only required when such a registry exists; the ''Clinical Considerations'' and ''Data'' subheadings are required when relevant information is available. If the ''Clinical Considerations'' subheading is required, the following headings under it are also required to the extent relevant information is available: ''Disease-associated maternal and/or embryo/fetal risk,'' ''Dose adjustments during pregnancy and the postpartum period,'' ''Maternal adverse reactions,'' ''Fetal/Neonatal adverse reactions,'' and ''Labor or delivery.'' Similarly, if the ''Data'' subheading is required, the headings ''Human Data'' and ''Animal Data'' are required under it to the extent relevant information is available.

• The final rule revises the proposed ''Pregnancy Exposure Registry'' subheading as follows:

○ Requires that contact information and a standard statement on the pregnancy exposure registry will be included under its own subheading ''Pregnancy Exposure Registry'' if there is a pregnancy registry that is scientifically acceptable.

○ Eliminates the phrase ''must be stated at the beginning of the 'Pregnancy' subsection of the labeling.''

○ Revises the phrase ''telephone number or other information needed to enroll'' to ''contact information needed to enroll.''

○ Adds a requirement that the following statement be included in labeling before the contact information for the pregnancy exposure registry: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to (*name of drug*) during pregnancy.

• The final rule revises the proposed ''Fetal Risk Summary'' as follows:

○ Changes the title of the subheading ''Fetal Risk Summary'' to ''Risk Summary.''

○ Eliminates the requirement that the following background risk statement be included in the labeling before the fetal risk summary: All pregnancies have a background risk of birth defect, loss, or other adverse outcome regardless of drug exposure. The fetal risk summary below describes (*name of drug*)'s potential to increase the risk of developmental abnormalities above the background risk.

○ Replaces the proposed standardized background risk statement with the requirement that, if the drug is systemically absorbed, the labeling state the percentage range of live births in the United States with a major birth defect and the percentage range of pregnancies in the United States that end in miscarriage, regardless of drug exposure. The final rule also requires that if such information is available for the population(s) for which the drug is labeled, it must also be included.

○ Replaces the term ''developmental abnormalities'' with the term ''adverse developmental outcomes.'' The final rule defines ''adverse developmental outcomes'' as structural abnormalities, embryo-fetal and/or infant mortality, functional impairment, and alterations to growth.

○ Clarifies that, when applicable, risk statements must include a cross-reference to additional details located under the ''Data'' subheading of ''Pregnancy.''

○ Revises the statement required when a drug is not systemically absorbed as follows:

■ Replaces the phrase ''from (part of the body)'' with ''following (route of administration)'' to describe how the drug enters the body.

■ Replaces the phrase ''cannot be detected in the blood'' with ''maternal use is not expected to result in fetal exposure to the drug.''

○ Adds a requirement that when use of the drug is contraindicated during pregnancy, this must be stated first in the ''Risk Summary.''

○ Requires that risk statements be presented in the following order: Based on human data, based on animal data, based on pharmacology.

• The ''Risk conclusions based on human data'' in the ''Risk Summary'' is revised as follows:

○ Replaces the term ''risk conclusions'' with ''risk statement.''

○ Eliminates the term ''sufficient human data'' and the proposed rule's requirement that the labeling contain one of the following standardized risk conclusions about sufficient human data: Human data do not indicate that (*name of drug*) increases the risk of (*type of developmental abnormality or specific abnormality)* and Human data indicate that (*name of drug*) increases the risk of (*type of developmental abnormality or specific abnormality*).

○ Replaces the standardized risk conclusions based on human data with the requirement that when human data are available that establish the presence or absence of any adverse developmental outcome(s) associated with maternal use of the drug, the Risk Summary must summarize the specific developmental outcome, its incidence, and the effects of dose, duration of exposure, and gestational timing of exposure. The final rule also requires that if the human data indicate that there is an increased risk for a specific adverse developmental outcome in infants born to women exposed to the drug during pregnancy, this risk must be quantitatively compared to the risk for the same outcome in infants born to women who were not exposed to the drug but who have the disease or condition for which the drug is indicated to be used. When risk information is not available for women with these condition(s), then the risk for the specific outcome must be compared to the rate at which the outcome occurs in the general population.

○ Requires that the ''Risk Summary'' must state when there are no human data or when available human data do not establish the presence or absence of drug-associated risk.

○ Eliminates the term ''other human data'' and the requirement that when there are other human data, the likelihood that the drug increases the risk of developmental abnormalities must be characterized as low, moderate, or high.

• The ''Risk conclusions based on animal data'' in the ''Risk Summary'' is revised as follows:

○ Replaces the term ''risk conclusions'' with ''risk statement.''

○ Eliminates the requirement that animal data be characterized as ''not predicted to increase the risk,'' ''low likelihood of increased risk,'' ''moderate likelihood of increased risk,'' or ''high likelihood of increased risk.''

○ Requires that when animal data are available, the labeling must summarize the findings in animals and based on these findings, describe, for the drug, the potential risk of any adverse developmental outcome(s) in humans. The final rule requires that the risk statement include: The number and type(s) of species affected, the timing of exposure, animal doses expressed in terms of human exposure or dose equivalents, and outcomes for pregnant animals and offspring. When animal studies do not meet current standards for nonclinical developmental toxicity studies, the labeling must so state. The final rule requires that when there are no animal data, the ''Risk Summary'' must so state.

• Adds a ''Risk statement based on pharmacology'' to the ''Risk Summary,'' requiring that when the drug has a well-understood mechanism of action that may result in drug-associated adverse developmental outcome(s), the ''Risk Summary'' must explain the mechanism

of action and the potential associated risks.

- Eliminates the ''Narrative description of human data'' requirement from the ''Risk Summary.''
- Removes the requirement that the ''Risk Summary'' refer to the ''Contraindications'' or ''Warnings and Precautions'' sections of the labeling when those sections contain information on an increased risk to the fetus from exposure to the drug.
- The final rule revises the ''Clinical Considerations'' component as follows:
  - Requires headings, to the extent relevant information is available, for ''Disease-associated maternal and/or embryo/fetal risk,'' ''Dose adjustments during pregnancy and the postpartum period,'' ''Maternal adverse reactions,'' ''Fetal/Neonatal adverse reactions,'' and ''Labor or delivery''.
  - Eliminates the ''Inadvertent exposure during pregnancy'' heading.
  - Eliminates the ''Prescribing decisions for pregnant women'' heading.
  - Revises ''risk, if known, to the pregnant woman and the fetus from the disease or condition the drug is indicated to treat'' (which was the language used in the proposed rule under the ''Prescribing decisions for pregnant women'' heading) to ''serious known or potential risk to the pregnant woman and/or the embryo/fetus associated with the disease or condition for which the drug is indicated to be used'' and places this information under the new heading ''Disease-associated maternal and/or embryo/fetal risk.''
  - Under ''Dose adjustments during pregnancy and the postpartum period,'' requires the inclusion of information about dose adjustments during pregnancy and the postpartum period if supported by pharmacokinetic data.
  - Under ''Dose adjustments during pregnancy and the postpartum period,'' removes the requirement that, if there are no data on dosing in pregnancy, the labeling must so state.
  - Under ''Maternal adverse reactions,'' replaces the proposed requirement that the ''labeling must describe any interventions that may be needed (*e.g.,* monitoring blood glucose for a drug that causes hyperglycemia in pregnancy)'' with the requirement that the labeling include a description of available intervention(s) for monitoring or mitigating the reaction.
  - Adds a requirement that the labeling include relevant information about fetal/neonatal adverse reactions under the heading ''Fetal/Neonatal adverse reactions''.
  - Under ''Fetal/Neonatal adverse reactions,'' replaces the phrase ''will cause a complication in the neonate'' with ''increases or may increase the risk of an adverse reaction in the fetus or neonate.''
  - Under ''Fetal/Neonatal adverse reactions,'' replaces ''the severity and reversibility of the complication'' with ''the potential severity and reversibility of the adverse reaction,'' and replaces ''general types of interventions, if any, that may be needed'' with ''available intervention(s) for monitoring or mitigating the reaction.''
  - Under ''Fetal/Neonatal adverse reactions,'' adds a requirement that the labeling must describe, if known, the effect of dose, timing, and duration of exposure on the risk.
  - Revises the heading ''Drug effects during labor or delivery'' to ''Labor or delivery.''
  - Under ''Labor or delivery,'' revises ''[i]f the drug has a recognized use during labor or delivery, whether or not the use is stated as an indication in the labeling, or if the drug is expected to affect labor or delivery'' to ''[i]f the drug is expected to affect labor or delivery.''
  - Under ''Labor or delivery,'' revises ''the possibility of complications, including interventions, if any, that may be needed'' to ''the increased risk of adverse reactions, including their potential severity and reversibility.''
  - Under ''Labor or delivery,'' adds a requirement that the labeling provide information about available intervention(s) that can mitigate effects and/or adverse reactions.
  - Under ''Labor or delivery,'' clarifies that the information described under that heading is not required for drugs approved only for use during labor and delivery.
  - Under ''Labor or delivery,'' eliminates the requirement that the labeling include information about the effect of the drug on the later growth, development, and functional maturation of the child.
- The final rule revises the ''Data'' subheading of labeling as follows:
  - Replaces ''provide an overview of the data that were the basis for the fetal risk summary'' with ''describe the data that are the basis for the Risk Summary and Clinical Considerations.''
  - Requires the inclusion of the subheading ''Data,'' and the headings ''Human Data'' and ''Animal Data,'' to the extent available information is relied on in the Risk Summary and Clinical Considerations subheadings.
  - Separates the requirements for human data from the requirements for animal data.
  - For human data, requires that the labeling describe adverse developmental outcomes, adverse reactions, and other adverse effects and, to the extent applicable, the types of studies or reports, number of subjects and duration of each study, exposure information, and limitations of the data. Requires that both positive and negative study findings be included.
  - For animal data, retains the requirement that the labeling describe the types of studies, animal species, dose, duration and timing of exposure, and adds the requirement that the labeling also describe study findings, presence or absence of maternal toxicity, and limitations of the data. Adds the requirement that the description of maternal and offspring findings must include information on the dose-response and severity of adverse developmental outcomes. Requires that animal doses or exposures be described in terms of human dose or exposure equivalents and that the basis for those calculations must be included.

2. Lactation

- The final rule revises the ''Risk Summary'' as follows:
  - Requires that when relevant human or animal lactation data are available, the ''Risk Summary'' must include a cross-reference to ''Data'' in the ''Lactation'' subsection.
  - Removes the proposed standardized statement ''The use of (*name of drug*) is compatible with breastfeeding.''
  - Requires that when human data are available, animal data must not be included unless the animal model is specifically known to be predictive for humans.
  - Requires that when use of a drug is contraindicated during breastfeeding, this information must be stated first in the ''Risk Summary.''
  - Revises the standardized statement required when the drug is not absorbed systemically from (*Name of drug*) is not absorbed systemically from (*part of body*) and cannot be detected in the mother's blood. Therefore, detectable amounts of (*name of drug*) will not be present in breast milk. Breastfeeding is not expected to result in fetal exposure to the drug to (*Name of drug*) is not absorbed systemically by the mother following (*route of administration*) and breastfeeding is not expected to result in exposure of the child to (*name of drug*).
  - Revises the order of the types of information required if the drug is systemically absorbed as follows: (1) Presence of drug in human milk, (2) effects of drug on the breast-fed child, and (3) effects of drug on milk production.
  - Replaces proposed standardized statements regarding the presence of the drug in human milk with a requirement

that the ''Risk Summary'' state whether the drug and/or its active metabolites are present in human milk, and when there are no data to assess this, the ''Risk Summary'' must so state.

○ Under ''Presence of drug in human milk,'' requires that if studies demonstrate the presence of the drug and/or its active metabolites in human milk, the ''Risk Summary'' must state the concentration of the drug and/or its active metabolites in human milk and the actual or estimated daily dose for an infant fed exclusively with human milk. The estimated amount of drug and/or its active metabolites ingested by the infant must be compared to the labeled infant or pediatric dose, if available, or to the maternal dose.

○ Under ''Presence of drug in human milk,'' retains the requirement that if studies demonstrate that the drug and/or its active metabolite(s) are not detectable in human milk, the Risk Summary must state the limits of the assay used.

○ Under ''Presence of drug in human milk,'' adds the requirement that if studies demonstrate the presence of the drug and/or its active metabolite(s) in human milk but the drug and/or its active metabolite(s) are not expected to be systemically bioavailable to the breast-fed child, then the ''Risk Summary'' must describe the disposition of the drug and/or its active metabolites.

○ Adds a requirement that if only animal lactation data are available, the ''Risk Summary'' must state only whether or not the drug and/or its active metabolite(s) were detected in animal milk and specify the animal species.

○ Under ''Effects of drug on the breast-fed child,'' the final rule:

■ Adds a requirement that the ''Risk Summary'' include available information on the known or predicted effects on the child from exposure to the drug and/or its active metabolite(s) through human milk or from contact with breast or nipple skin from a topical product.

■ Requires the inclusion of information about systemic and/or local adverse reactions.

■ Requires that the ''Risk Summary'' state if there are no data to assess the effects of the drug and/or its active metabolite(s) on the breast-fed child.

○ Under ''Effects of drug on milk production,'' the final rule:

■ Replaces the proposed requirement that the ''Risk Summary'' describe the effect of the drug on the quality and quantity of milk, including milk composition, and the implications of these changes to the milk on the breast-fed child, with the requirement that the ''Risk Summary'' must describe the effects of the drug and/or its active metabolite(s) on milk production.

■ Adds a requirement that when there are no data to assess the effects of the drug and/or its active metabolite(s) on milk production, the ''Risk Summary'' must so state.

○ The final rule adds the requirement that for drugs absorbed systemically, unless breastfeeding is contraindicated during drug therapy, the following risk and benefit statement must appear at the end of the ''Risk Summary'': The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for (*name of drug*) and any potential adverse effects on the breast-fed child from the drug or from the underlying maternal condition.

• Under ''Clinical Considerations,'' the final rule:

○ Revises the provisions of the proposed rule to require that the labeling include information concerning ways to minimize exposure to the drug and/or its active metabolite(s) in the breast-fed child in situations where the following conditions are present: The drug and/or its active metabolite(s) are present in human milk in clinically relevant concentrations; do not have an established safety profile in infants; and are used either intermittently, in single doses, or for short courses of therapy.

○ Adds a requirement that, when applicable, the labeling must describe ways to minimize a breast-fed child's oral intake of topical drugs applied to the breast or nipple skin.

○ Under ''Monitoring for adverse reactions,'' replaces the proposed requirement that the labeling include information about potential drug effects in the breast-fed child that could be useful to caregivers, including recommendations for monitoring or responding to those effects, with a requirement that the labeling must describe available intervention(s) for monitoring or mitigating the adverse reaction(s) presented in the ''Risk Summary.''

○ Eliminates the proposed requirement that the labeling include information about dosing adjustments during lactation.

• Under ''Data,'' the final rule replaces the phrase ''provide an overview of the data'' with the phrase ''describe the data.''

3. Females and Males of Reproductive Potential

• Adds ''8.3 Females and Males of Reproductive Potential'' subsection requiring that when pregnancy testing and/or contraception are required or recommended before, during, or after drug therapy and/or when there are human and/or animal data that suggest drug-associated fertility effects, this subsection of labeling must contain this information under the subheadings ''Pregnancy Testing,'' ''Contraception,'' and ''Infertility,'' in that order.

III. Comments on the Proposed Rule

The Agency received 72 comments on the proposed rule. Comments were received from prescription drug manufacturers, trade organizations representing prescription drug manufacturers and other interested parties, professional associations and organizations representing health care providers, health care and consumer advocacy organizations, individual physicians, pharmacists, consumers, and others.

Most of the comments supported FDA's goal of improving the format and content of the ''Pregnancy,'' ''Labor and delivery,'' and ''Nursing mothers'' subsections of prescription drug labeling, and several of these comments stated that the proposed rule would address shortcomings of the previous labeling regulations. Other comments noted that the proposed rule would improve the accessibility of relevant information, thereby enabling better informed medical decisions regarding the risks and benefits of prescription drug use by pregnant and lactating women. Although a number of comments supported all of FDA's proposed revisions, many comments opposed particular aspects of the proposed rule.

To make it easier to identify comments and our responses, the word ''Comment'' and a comment number appear in parentheses before each comment's description, and the word ''Response'' in parentheses precedes each response. Similar comments are grouped together under the same number. Specific issues raised by the comments and the Agency's responses follow.

A. Proposed Rule as a Whole

1. Plain Language and Intended Audience

(Comment 1) Several comments suggested that the language used in the pregnancy and lactation subsections of prescription drug labeling should be clear and accessible to a variety of audiences. One comment stated that because the intended audience for prescription pregnancy and lactation labeling is females of reproductive potential and their health care providers, this portion of prescription

drug labeling should not include overly technical information. Another comment suggested that to make the information more accessible to the general public, FDA should include a plain language summary of the pregnancy and lactation subsections. Two comments suggested that because females of reproductive potential may read the ''Pregnancy'' and ''Lactation'' subsections of labeling, FDA should include a statement that encourages patients to always consult a health care provider before discontinuing medication. Another comment questioned how patients would access the proposed information and asked whether it would be included in patient-specific information that patients receive at the pharmacy. Several other comments suggested that the final rule should aim to create user-friendly labeling that contains a concise and accurate presentation of information that is of clinical relevance.

(Response) FDA acknowledges that some females of reproductive potential may use prescribing information in the ''Pregnancy'' and ''Lactation'' subsections of prescription drug labeling. The intended audience of prescription drug labeling, however, is health care providers, and it is the responsibility of the prescribing health care provider to communicate pertinent information regarding drug risks and benefits and proper use to his or her patient. For this reason, we have determined that it is not appropriate to require a summary of the ''Pregnancy'' and ''Lactation'' subsections of labeling as a mechanism for all patients to readily access full prescribing information, or a statement that encourages patients to always consult a health care provider before discontinuing medication. We note that in addition to the professional labeling that is the subject of this rulemaking, some drugs also have FDA-approved patient labeling specifically written for the consumer, such as Medication Guides (see 21 CFR part 208). Whether the information required under the final rule will be included in FDA-approved patient labeling for an individual drug will be decided on a case-by-case basis in accordance with the applicable FDA regulations and guidance.

2. Scope of the Rule

(Comment 2) Several comments suggested that FDA expand the scope of the rule in various ways. Two comments suggested that the rule be expanded to include nonprescription products. Four comments suggested that the proposed content changes also apply to drugs for which an application was approved before June 30, 2001, although a separate comment agreed with the proposal to limit the rule to drugs for which an application was approved on or after June 30, 2001. One comment suggested that the rule be expanded to include vaccine products (we discuss this suggestion later in our response to Comment 8). Two other comments suggested that the rule provide incentives to industry to perform studies on the use of drugs and biological products during pregnancy and lactation. One comment suggested that depression should not be treated pharmacologically during pregnancy, whereas a separate comment suggested that FDA ban the use of all drugs and vaccines during pregnancy. Another comment suggested that the presentation of the information required under the rule be standardized as much as possible with applicable coding schema for ease of implementation in databases or electronic health record systems.

(Response) FDA has considered these comments and declines to expand the scope of the final rule in any of the suggested ways. This final rule amends our labeling regulations in §§ 201.57 and 201.80, which apply only to prescription drug and biological products. It is therefore not within the scope of this rulemaking to address pregnancy and lactation labeling for nonprescription drug products.

The primary purpose of this final rule, and prescription drug labeling in general, is to facilitate informed prescribing and safe and effective product use. FDA recognizes the importance of use of labeling information in electronic health records and other databases and agrees that, if possible, the presentation of information in labeling should facilitate its accessibility. However, this final rule is not designed to standardize the required information with a coding schema for use in databases or electronic health record systems. It is also beyond the scope of this rule to address incentives for collecting data on the use of drugs and biological products during pregnancy and lactation.

FDA does not make recommendations about whether particular diseases or conditions should or should not be treated pharmacologically, though we specifically decline the suggestion to ban the use of all drugs during pregnancy. We note that many diseases and conditions are associated with adverse pregnancy outcomes when not appropriately managed during pregnancy, and under-treating or not treating a pregnant woman's medical condition may put the woman's health in danger, and is often associated with greater risk to the developing fetus than the risk of exposure to a maternal drug.

FDA also declines the suggestion that the content changes required by this final rule also apply to drugs for which an application was approved before June 30, 2001. In developing this rule, FDA considered the scientific, economic, and practical implications of alternative approaches, including requiring implementation of the content and format requirements for the ''Pregnancy,'' ''Lactation,'' and ''Females and Males of Reproductive Potential'' subsections of labeling for all drugs, regardless of approval date. FDA concluded that requiring the content and format changes only for drugs for which an application was approved on or after June 30, 2001, (as described in the ''Implementation'' section of this document) best balanced the public health benefits and the economic and other costs of these labeling changes. In addition, this approach provides conformity with the rest of prescription drug labeling and the scope is consistent with the scope of the PLR. FDA, however, encourages voluntary compliance with these content and format changes for drugs for which an application was approved before June 30, 2001.

3. Combining the ''Pregnancy'' and ''Lactation'' Subsections

(Comment 3) One comment suggested that the ''Pregnancy'' and ''Lactation'' subsections should be combined for certain drugs. The comment explained that combining these sections would be useful, for example, in helping health care providers counsel women who take selective serotonin reuptake inhibitors (SSRIs) for the treatment of perinatal depression because clinicians have to consider the effects of the medication during both pregnancy and the postpartum period.

(Response) FDA disagrees. The risk and benefit considerations for drug product use are different between pregnant and lactating patients, and we have determined that the information is best presented in separate but adjacent subsections of labeling. FDA believes that if the sections were combined it would be more difficult for a health care provider who has either a pregnant or a lactating patient to locate the information relevant to the prescribing decision. For anticipatory counseling, for which the health care provider is discussing the use of the drug with a pregnant patient who in the future may be lactating, we believe that having ''Lactation'' denoted in a separate, numbered, indexed, and searchable

subsection of labeling will not make it harder for a prescriber to find this information.

4. Updates

In the preamble to the proposed rule, FDA stated that under § 201.56(a) ''the labeling must be updated when new information becomes available that causes the labeling to become inaccurate, false, or misleading'' (73 FR 30831 at 30841). The Agency also explained that ''[w]hen new human data concerning the use of a drug during pregnancy becomes available, if that information is clinically relevant, FDA believes that it is necessary for the safe and effective use of the drug and, therefore, the pregnancy subsection of the labeling must be updated to include that information. Failure to include clinically relevant new information about the use of a drug during pregnancy could cause the drug's labeling to become inaccurate, false, or misleading'' (73 FR 30831 at 30841).

(Comment 4) Several comments requested that FDA clarify its expectations for the process and timing of updating the ''Pregnancy'' and ''Lactation'' subsections of labeling after new data become available. Two of these comments stated that the data should be updated regularly or continually. Another comment stated that the labeling should be updated annually. Several other comments requested that FDA define the quantity and quality of data that necessitates that the labeling be updated. One of these comments suggested that FDA state in the final rule that the labeling should be updated if the benefit-risk profile changes because of new information, and that labeling changes should be done according to ''current labeling regulations.'' Another comment questioned whether health care providers will be informed of changes to the ''Pregnancy'' and ''Lactation'' subsections of labeling. One comment suggested that sponsors electronically post supplemental information before updated printed labeling is available, and another suggested using surveillance systems to facilitate obtaining updated safety information.

Two comments expressed specific concern that the ''Lactation'' subsection of drug labeling will not be updated frequently enough to be useful for clinicians. One of these comments stated that it is critical to routinely update labeling as human lactation data becomes available. A separate comment suggested including references in labeling to online resources regarding lactation data to provide prescribers and patients with updated information.

(Response) The requirements for labeling updates described in § 201.56(a) apply to this final rule as follows: The labeling must be informative and accurate and neither promotional in tone nor false or misleading in any particular. In accordance with §§ 314.70 and 601.12 of the chapter, the labeling must be updated when new information becomes available that causes the labeling to become inaccurate, false, or misleading (§ 201.56(a)(2)). With respect to the comment about updating labeling as human lactation data becomes available, although § 201.56(a)(3) states that the labeling must be based whenever possible on data derived from human experience, it also requires that conclusions based on animal data but necessary for safe and effective use of the drug in humans must be identified as such and included with human data in the appropriate section of the labeling.

Because studies are not usually conducted in pregnant women prior to approval, most of the data regarding use in pregnancy and lactation will be collected in the postmarketing setting. Accordingly, in order that a drug product does not become misbranded, the labeling must be updated when new information becomes available that causes the labeling to become inaccurate, false, or misleading. Applicants are responsible for following the medical literature and also for updating labeling as new published and unpublished data become available. FDA declines the suggestion to include references to online resources regarding drug use during lactation because the information has not been reviewed by FDA.

5. Responsibility for Drafting and Reviewing Labeling

(Comment 5) One comment requested that FDA clarify whether industry or FDA would be responsible for writing and reviewing the new labeling. The comment also questioned whether FDA would provide staff with the training and expertise to make necessary judgments. Another comment expressed concern about the potential for inconsistent implementation of the new rule by FDA's review divisions. This comment suggested that to increase labeling consistency, the Agency should establish a group of FDA specialists that review pregnancy and lactation labeling.

(Response) As with all prescription drug labeling, both the manufacturer and FDA reviewers will play a shared role in determining the new labeling content. The Division of Pediatrics and Maternal Health (DPMH), within the Office of New Drugs at the Center for Drug Evaluation and Research, includes staff with expertise in obstetrics, lactation, pediatrics, clinical pharmacy, and regulatory science. The DPMH is available for consultation by all FDA drug product review divisions to whom the final rule applies for all issues related to labeling content and for review of data on the use of drugs during pregnancy and lactation. The DPMH, by working across review divisions, helps to ensure consistent application of FDA pregnancy and lactation labeling regulations to different drug products. The DPMH also provides consultation services to and works collaboratively with other Offices and Centers at FDA. FDA intends to provide staff with education and training on the changes in the labeling regulations.

6. Process for Development of the Proposed Rule

(Comment 6) One comment stated that FDA should have included pharmacists in the focus tests used during development of the proposed rule.

(Response) FDA acknowledges the critical role that pharmacists play in communicating drug information both to patients and health care providers. However, during the development of the proposed rule, FDA's priority was to understand the information health care providers need to most effectively make prescribing decisions that consider both the risk and benefit to the mother and her fetus or child. Therefore, the focus testing was limited to health care providers who both care for and prescribe for pregnant and lactating women.

7. Guidance on Formulating Labeling

(Comment 7) FDA received one comment requesting that the Agency provide clear guidance to manufacturers regarding how to formulate the pregnancy and lactation labeling subsections.

(Response) Concurrent with the publication of this final rule, FDA is issuing a draft guidance for industry on ''Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products—Content and Format'' (the draft guidance on pregnancy and lactation labeling).[5] The draft guidance is intended to assist applicants in drafting the ''Pregnancy,'' ''Lactation,'' and ''Females and Males of Reproductive Potential'' subsections of

[5] This guidance, when finalized, will represent FDA's current thinking on this topic.

labeling for prescription drug products. It provides recommendations for applicants revising labeling of already approved products and for applicants drafting labeling for new products that will be submitted as part of an NDA or BLA.

8. Blood Products and Vaccines

(Comment 8) FDA received two comments regarding the applicability of the proposed rule to certain biological products. One comment requested that the final rule be expanded to include vaccine products. The other comment stated that blood products are not affected by the rule and requested that this be noted when the final rule is published.

(Response) This final rule applies to vaccine products. Vaccine products are prophylactic biological products that are developed and labeled to prevent specific diseases in specific populations. The types of information that must be communicated about a vaccine, in general, parallel the types of information that must be communicated about a drug or therapeutic biologic through labeling to facilitate safe and effective use, although there are some unique considerations for vaccines addressed in the draft guidance on pregnancy and lactation labeling, which is being published concurrently with this final rule.

We disagree that blood products are not affected by the final rule. The final rule applies to any biological products, including blood products, that are subject to the PLR.

9. Numbering of ''Pregnancy'' and ''Lactation'' Subsections

(Comment 9) FDA proposed that the identifying numbers and titles for the new labeling content under the section ''8 Use in Specific Populations'' would be 8.1 for ''Pregnancy'' and 8.2 for ''Lactation.'' FDA stated in the proposed rule that the identifying number 8.3 would be available for future use (73 FR 30831 at 30838). Two comments pointed out that under this proposal, the next subsections after ''8.2 Lactation'' will be ''8.4 Pediatric Use'' and ''8.5 Geriatric Use.'' These comments stated that the absence of subsection 8.3 may be confusing and suggested that FDA renumber the subsections. One comment requested that FDA clarify whether the Agency has a specific use in mind for 8.3 and, if it does not, suggested that the Agency renumber the subheadings to ''8.3 Pediatric Use'' and ''8.4 Geriatric Use.'' The comment explained that if a future need for an additional subsection arose, it could become 8.5.

(Response) As discussed in further detail in section III.B of this document, in this final rule, FDA designates 8.3 as ''Females and Males of Reproductive Potential.'' Accordingly, we are no longer reserving 8.3 for future use.

10. International Harmonization

(Comment 10) Two comments suggested that prescription drug labeling should be consistent at an international level to reduce confusion among health care providers, patients, and regulators interpreting the risks and benefits associated with drug use during pregnancy and lactation.

(Response) FDA declines to adopt this suggestion because it is beyond the scope of this rule to address the international harmonization of prescription drug labeling. Although we acknowledge the importance of working with our international regulatory colleagues to harmonize drug development and drug regulatory science where appropriate and beneficial, we also recognize that there is great variation internationally in health care systems, access to care and drugs, and the regulation and marketing of drugs. The final rule reflects our judgment regarding the most useful pregnancy and lactation prescription drug labeling for prescribers in the United States, which may not be applicable to prescribers in all other countries.

11. Examples in an Appendix

(Comment 11) The proposed rule included an appendix containing examples, based on the proposed rule, of pregnancy and lactation labeling for fictitious drugs.

FDA received several comments suggesting that the examples be revised or expanded. One comment requested that in the final rule, FDA provide additional examples of sample labeling, including examples for which extensive data exists. Another comment suggested that the information included in the sample labeling for the fictitious drug products did not reflect the amount of data that is typically available. The comment explained that the examples would be more useful if they presented situations where there is extensive data. Several other comments pointed out that the terminology in the examples was not consistent with the terminology in the proposed rule.

(Response) FDA has not included sample drug labeling with the final rule. The draft guidance on pregnancy and lactation labeling, which is being published concurrently with this final rule, provides information about how to interpret and apply the rule to labeling development. Labeling development is a detailed and iterative process unique to each prescription drug product, a process that is driven by the product's characteristics and actions, the efficacy and safety data submitted to the Agency, and the conditions and populations for and in which the product is intended to be used. Accordingly, FDA has concluded that the development of fictitious product labeling would not be useful to drug developers or FDA reviewers who will be responsible for developing, revising, and approving product labeling under this new final rule.

12. Cross-Referencing

FDA proposed that when the risk conclusion in the fetal risk summary is based solely on animal data, it must include a cross-reference to the ''Data'' component of the ''Pregnancy'' subsection, and the effects found in animals must be described in the ''Data'' component (73 FR 30831 at 30842).

(Comment 12) One comment suggested that any cross-references to the ''Data'' or ''Clinical Considerations'' components made anywhere in labeling specify whether the cross- reference is to the component in the ''Pregnancy'' subsection or the component in the ''Lactation'' subsection. Another comment explained that the rule would benefit from extensive use of cross-referencing within the text of each section to ensure that the bases for the risk conclusions are thoroughly understood, regardless of whether the risk conclusions are based on human or animal data, for both the ''Pregnancy'' and ''Lactation'' subsections.

(Response) FDA agrees that any cross-references to components of ''8.1 Pregnancy'' or ''8.2 Lactation'' must specify whether the cross-reference is to the component in the ''Pregnancy'' subsection or the component in the ''Lactation'' subsection. Accordingly, in the final rule, when applicable, risk statements in the ''Pregnancy'' subsection must include a cross-reference to additional details in the relevant portion of the ''Data'' subheading in the ''Pregnancy'' subsection. Also in the final rule, when relevant human and/or animal lactation data are available, the ''Risk Summary'' must include a cross-reference to the relevant portion of ''Data'' in the ''Lactation'' subsection.

13. Need for Educational Campaign

(Comment 13) FDA received one comment suggesting that the Agency develop educational campaigns for patients and health care providers regarding the changes to pregnancy and

lactation drug labeling brought about by this rulemaking.

(Response) FDA is developing educational materials for FDA staff, health care providers, and patients to inform them about the changes in these labeling regulations and how these changes will have a positive impact on labeling regarding the use of drugs and biologics during pregnancy and lactation. The draft guidance on pregnancy and lactation labeling is being published concurrently with this final rule; however, additional materials may be completed following this date.

14. Inventory

(Comment 14) FDA received one comment requesting that the final rule address how distributors should manage drug products in their inventory that have outdated labeling. The comment suggested that product inventory without the revised labeling should remain in the supply chain until the labeled product's expiration date, regardless of whether the product bears the new labeling.

(Response) For previously approved products, the implementation plan gives sponsors a minimum of 3 years after the effective date of this final rule to submit labeling with the new content and format. As we explained in the preamble to the proposed rule, FDA believes that this 3-year period will allow industry sufficient time to use up any existing labeling stock such that none will remain in the supply chain after the product bears the new labeling (73 FR 30831 at 30846).

15. Highlights

FDA's regulations require that all prescription drug labeling described in § 201.56(b)(1) contain ''Highlights of prescribing information'' (§ 201.57(a)).

(Comment 15) Two comments requested that FDA clarify which elements of the ''Pregnancy'' and ''Lactation'' subsections are likely to be included in the ''Highlights of prescribing information.'' One of the comments expressed hope that adoption of the rule will promote standardization with respect to which elements are elevated to the ''Highlights of prescribing information,'' thereby facilitating consistent interpretation and implementation of the rule's requirements among FDA reviewers and review divisions.

(Response) The requirements for placement of information in the ''Highlights of prescribing information'' are specified in § 201.57(a). This final rule does not revise or change the requirements for the ''Highlights of prescribing information.'' Additional discussion of FDA's recommendations on the content of the ''Highlights of prescribing information'' may be found in FDA's guidance for industry on ''Labeling for Human Prescription Drug and Biological Products—Implementing the PLR Content and Format Requirements'' (February 2013).[6]

16. Preemption of State Law

In the preamble to the proposed rule, FDA included a discussion in the Federalism section that referred to a more extensive discussion and analysis in the PLR regarding the preemption of product liability lawsuits.

(Comment 16) Comments expressed different views about this discussion. One comment suggested that in the final rule FDA revise the preamble to eliminate any reference to the preemption of product liability lawsuits. Another comment expressed its appreciation of FDA's view that the rule would preempt state laws that conflict with its requirements. This comment also expressed its support for FDA's intention to consult with State and local officials in an effort to avoid conflict between State law and federally protected interests.

(Response) FDA's statement regarding preemption in the proposed rule relied on statements made in the preamble to the PLR (71 FR 3922). In the preamble to the PLR, FDA discussed its views on the preemptive effect of both that regulation's codified provisions and the FD&C Act. Subsequent to the publication of the May 2008 proposed rule, the Supreme Court, in *Wyeth* v. *Levine* (555 U.S. 555 (2009)), addressed the preamble to the PLR and held that a State tort claim that an NDA-approved drug should have had a stronger warning was not preempted by the FD&C Act or FDA's labeling requirements. Following the Court's decision in *Wyeth,* FDA concluded that the position on preemption we articulated in the preamble to the PLR cannot be justified under legal principles governing preemption (Preemption Review, 76 FR 61565, October 5, 2011). Based on this analysis, to the extent that the discussion in the proposed rule relied on the discussion about preemption in the preamble to the PLR, we conclude that the statements we made regarding preemption in the preamble to the proposed rule are also not justified.

B. Specific Provisions of the Proposed Rule

1. 8.1 Pregnancy

a. *Comments related to the pregnancy subsection as a whole.*

i. *Order of subsections*—FDA proposed that information appear in subsection ''8.1 Pregnancy'' in the following order: (1) Pregnancy exposure registry (if applicable), (2) general statement about background risk, (3) fetal risk summary, (4) clinical considerations, and (5) data (proposed § 201.57(c)(9)(i)). In the proposed rule, FDA sought comment on how these elements should be ordered to optimize the clinical usefulness of this labeling subsection (73 FR 30831 at 30839). Specifically, FDA asked whether the ''Fetal Risk Summary'' should precede the pregnancy exposure registry information and the statement about background risk.

(Comment 17) Comments expressed different opinions about the proposed order of information in the ''Pregnancy'' subsection of labeling. Three comments agreed with the proposed order. One of these comments explained that the proposed order will maximize a physician's ability to find and understand important pregnancy-related information about a given drug product. Another comment explained that placing the pregnancy exposure registry information first is preferable because if this information were placed after the ''Risk Summary,'' it may be interpreted to imply that the pregnancy exposure registry exists because of the data in the fetal risk summary. One comment supported placing the pregnancy exposure registry information first so that it will appear more visible in labeling.

Many comments disagreed with the proposed order and suggested a variety of alternatives. Six comments suggested that the ''Fetal Risk Summary'' subheading be placed first because it contains the most important and useful information. One of these comments pointed out that past FDA advisory committees have suggested that summary information should be placed first. Two comments suggested that the ''Background Risk Statement'' should be first followed by the ''Fetal Risk Summary.'' These comments explained

[6] U.S. Food and Drug Administration, ''Guidance for Industry, Labeling for Human Prescription Drug and Biological Products—Implementing the PLR Content and Format Requirements,'' (February 2013), available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075082.pdf.* Many guidances are referenced throughout this document. The guidance referred to in this footnote, as well as others referenced throughout the remainder of the document, can be found on the FDA Drugs guidance Web page at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.* We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA Drugs guidance Web page.

that the most important information should be placed first, as recommended by FDA advisory committees. Three comments suggested that the pregnancy exposure registry information be placed last. Another comment suggested that the information be placed in the following order: Pregnancy exposure registry information, clinical considerations, fetal risk summary, data, and background risk statement.

(Response) FDA has determined that placing the pregnancy exposure registry information first under ''8.1 Pregnancy'' best balances the objectives of this rulemaking. Although we agree that the ''Risk Summary'' information is most important to prescribers and we acknowledge that the advisory committee expressed a preference for placing the most important information first, it is also clear that stakeholders desire greater quality and quantity of human data in pregnancy labeling. FDA believes that the benefits of prominently placing information about pregnancy registry availability at the beginning of ''8.1 Pregnancy'' outweigh the downsides of a minor decreased prominence of the ''Risk Summary'' information, which appears immediately after the information under ''Pregnancy Exposure Registry.'' Many health care providers are still learning about pregnancy exposure registries and their purpose. We have concluded that routinely placing this information first in pregnancy labeling may increase pregnancy registry enrollment, the quality of human data that emerge from these studies, and the quality of pregnancy labeling (including the ''Risk Summary'') that follows. Because we agree that the information under ''Risk Summary'' is most important to prescribers, we also decline the suggestion to place the ''Risk Summary'' after ''Clinical Considerations.'' The ''Pregnancy'' subsection will include, in this order, information under ''Pregnancy Exposure Registry,'' as applicable, ''Risk Summary,'' ''Clinical Considerations,'' as applicable, and ''Data,'' as applicable.

ii. *Removal of the pregnancy categories*—FDA proposed to remove the pregnancy categories from all prescription drug labeling. As discussed in greater detail in section I of this document, in 1979 FDA adopted a pregnancy category system that was used to convey risk and benefit information related to potential or documented human teratogenic risk and potential maternal/fetal benefits associated with drug treatment during pregnancy. Under the 1979 regulations, each drug product was identified with a pregnancy category: A, B, C, D, or X. Categories were not used to characterize the risks and benefits associated with drug treatment by lactating women. FDA proposed to remove pregnancy categories from all prescription drug labeling because we determined that the categories were confusing and did not accurately and consistently communicate differences in degrees of fetal risk (73 FR 30831 at 30846).

(Comment 18) Comments expressed different opinions about whether the elimination of the pregnancy category system, in full or in part, would improve or diminish the usefulness of the Pregnancy subsection of prescription drug labeling. FDA received 11 comments from medical associations, women's and reproductive health advocacy organizations, toxicologists, individual health care practitioners, pharmacists, and drug manufacturers specifically supporting our proposal to retire the pregnancy category system. Several of these comments explained that the categories were confusing or misleading. One of the comments stated that although the use of pregnancy categories is easier for some practitioners, it results in miscommunication and errors in decisionmaking. Another comment explained that reliance on the categories may result in poorly informed clinical decisionmaking.

FDA received 16 comments from physicians, pharmacists, pharmacy associations, nurses, manufacturers, drug safety consultants, and individual consumers, requesting that FDA either retain the pregnancy category system or replace the pregnancy category system with another standardized schema. Many of these comments suggested that FDA add the additional narrative information as proposed, but also retain the category system. Two of these comments explained that the pregnancy categories are simple and effective, and the new information may confuse patients or prescribers. Another comment stated that without a standardized schema, there will not be a consistent and useful format for decisionmaking. Other comments agreed that the pregnancy categories need to be revised but suggested that FDA develop new standardized statements or categories or revise the bases for the current categories. Two comments urged FDA to maintain an ''X''-like category for drugs where the risks outweigh any benefit to a pregnant or nursing patient, and one comment urged FDA to maintain an ''X''-like category so that providers and patients could easily identify those drugs that are contraindicated for the mother, fetus, and/or a breastfeeding infant.

A separate comment supported FDA's proposal to eliminate the pregnancy categories but thought they should be retained until the implementation of the final rule is complete.

(Response) FDA has determined that retaining the pregnancy categories is inconsistent with the need to accurately and consistently communicate differences in degrees of fetal risk. As discussed in the proposed rule, the current pregnancy category system has long been criticized as being confusing and overly simplistic (73 FR 30831 at 30833–30834). Through experience and stakeholder feedback, FDA learned that the pregnancy categories were heavily relied upon by clinicians but misinterpreted, misunderstood, and erroneously used as a grading system where fetal risk increased from A to X. The categories gave the incorrect impression that drugs in the same category carried the same risk or potential for human adverse developmental outcomes. In addition, the categories did not discriminate among risk information obtained from nonclinical animal studies and postmarketing human studies and did not discriminate among drugs associated with adverse outcomes of differing severity or incidence. Stakeholders also pointed out that the pregnancy categories focused on structural abnormalities and thus did not adequately address the full range of potential developmental toxicities.

As described in greater length in the preamble of the proposed rule, FDA carefully explored a multitude of models to determine whether the former pregnancy category system or a different pregnancy category system could accurately and consistently communicate differences in degrees of fetal risk (73 FR 30831 at 30833–30837). FDA found that when it applied these criteria to actual animal and human data findings for drugs with known risk profiles, none of the models produced clinically informative and reliable differentiations of risk (73 FR 30831 at 30838). Prescribing and drug-use decisions during pregnancy require consideration of not only fetal risk information, but also of various clinical and individual factors, including maternal drug effects, the severity of maternal disease, maternal tolerance of the drug, coexisting maternal conditions, the impact of maternal disease on the fetus, and available alternative therapies. FDA concluded that continuing to use a category system to characterize the risks of drug use during pregnancy would not be appropriate because of the complexity of medical decisionmaking regarding

drug use during pregnancy (73 FR 30831 at 30838).

FDA continues to believe that a narrative structure for pregnancy labeling is best able to capture and convey the potential risks of drug exposure based on animal or human data, or both. This perspective is consistent with FDA's approach to other aspects of product labeling. For example, numeric or letter or other categorical gradations of risk have never been used for safety labeling because safety and risk are complex constructs in clinical medicine. For similar reasons, FDA does not apply symbol or letter designations of risk to other potential toxicities or adverse effects expected with drug product use.

For the reasons discussed previously, FDA declines the suggestion to maintain pregnancy category X. We note, however, that labeling must clearly identify populations in which use of a drug is contraindicated. The labeling regulations in § 201.57 clearly describe the information that must be included in the ''Contraindications'' section and all contraindications from the full prescribing information are always listed in the ''Highlights of prescribing information'' (§ 201.57(c)(5)). Therefore, when use of a drug is contraindicated in pregnancy, this information must be stated in the ''Contraindications'' section and listed in the ''Highlights of prescribing information,'' as well as, per the previous discussion, stated first under the ''Risk Summary'' subheading of the ''Pregnancy'' subsection of labeling.

To the extent that the comment suggests that the pregnancy categories should be retained for applications subject to § 201.80 until the implementation of the new content and format requirements is complete, we decline this suggestion; we believe it is more consistent with the Agency's overall concerns with respect to removing the pregnancy categories to implement that change within a shorter timeframe that nevertheless provides sufficient time for compliance. We would like to clarify that for applications required to implement the new content and format requirements, the pregnancy categories are required to be removed at the time the labeling is revised regardless of whether this will result in the labeling including a pregnancy category for more than 3 years after the effective date of the final rule (as described in the ''Implementation'' section of this document in response to Comment 92). Requiring that the labeling for some applications be revised twice solely as part of the implementation of this regulation would not be consistent with the Agency's goal to avoid overburdening both the Agency and industry.

b. *Comments related to specific provisions of 8.1 Pregnancy.*

i. *Pregnancy exposure registry*—FDA proposed that if there is a pregnancy exposure registry for a product described in § 201.56(b)(1) (*i.e.,* prescription drug products for which an application was approved after June 30, 2001), the telephone number or other information necessary to enroll in the registry or to obtain information about the registry must be stated at the beginning of the ''Pregnancy'' subsection of prescription drug labeling (proposed § 201.57(c)(9)(i)(A)). For drug products that do not have a pregnancy exposure registry, the proposed rule did not require the ''Pregnancy'' subsection of prescription drug labeling to contain any statement about pregnancy exposure registries.

(Comment 19) Comments disagreed about the mandatory inclusion of pregnancy exposure registry information. Many comments supported the mandatory inclusion of pregnancy exposure registry information in the ''Pregnancy'' subsection of prescription drug labeling. These comments explained, for example, that including pregnancy exposure registry information in labeling may ''encourage patient involvement in registries'' and ''pave the way for improved registry use by clinicians leading to better documentation of drug effects and use during pregnancy.''

One comment stated that including a reference to an existing pregnancy registry should not be mandatory.

(Response) FDA believes that appropriately conducted pregnancy registries are an important mechanism for the collection of clinically relevant data concerning the effects of exposure to drugs during pregnancy. The Agency believes that including information about pregnancy exposure registries in prescription drug labeling will encourage participation in registries, thereby improving their usefulness. Thus, if there is a pregnancy registry that FDA has reviewed and found scientifically acceptable, FDA is requiring that the ''Pregnancy'' subsection of prescription drug labeling include under its own subheading, ''Pregnancy Exposure Registry,'' a standard statement concerning the existence of the registry, as well as the contact information necessary to enroll in the pregnancy exposure registry or to obtain information about the registry. The Agency generally considers a pregnancy exposure registry scientifically acceptable when it is consistent with applicable FDA guidance, including the guidance for industry on ''Establishing Pregnancy Exposure Registries'' (August 2002). If there are changes to an existing pregnancy registry or a new pregnancy registry is initiated after drug approval, labeling will need to be updated to include this new information.

(Comment 20) Two comments sought clarification regarding the standards for including contact information for a pregnancy exposure registry. One comment stated that contact information should only be included if the registry is scientifically acceptable to the sponsor and FDA. Another comment asked whether contact information for non-U.S. registries must be included.

(Response) As stated previously, if there is a scientifically acceptable pregnancy registry for a drug product, FDA is requiring a standard statement concerning the registry as well as contact information needed to enroll in the registry or obtain additional information about it. For registries that include U.S. populations, U.S. contact information should be included in the labeling, regardless of whether the registry is maintained within the United States or elsewhere.

(Comment 21) Four comments suggested that the pregnancy exposure registry information should have its own component header.

(Response) FDA agrees with the suggestion that the pregnancy exposure registry information should have its own component header. In the final rule, contact information for an existing pregnancy exposure registry and a standard statement on the registry will fall under the subheading ''Pregnancy Exposure Registry'' in the ''Pregnancy'' subsection of prescription drug labeling. Because of this change, FDA eliminated the phrase ''must be stated at the beginning of the 'Pregnancy' subsection of the labeling'' from the final rule.

(Comment 22) Two comments stated that it should be easier to enroll patients in pregnancy exposure registries.

(Response) The importance of subject recruitment into pregnancy exposure registries and the need to build awareness of pregnancy exposure registries among health care providers are both factors in FDA's decision to place information about existing pregnancy exposure registries at the beginning of § 201.57, ''8.1 Pregnancy.'' The actual process of enrolling patients, however, is beyond the scope of this rule.

(Comment 23) Comments expressed disagreement about whether the ''Pregnancy Exposure Registry''

subheading should be omitted from the ''Pregnancy'' subsection of prescription drug labeling when there is no existing registry for the drug. One comment suggested that the ''Pregnancy Exposure Registry'' subheading should not be omitted even if there is no existing registry for the drug, and that it should include a statement that there is no specific pregnancy exposure registry for the drug. Another comment requested that FDA consider incorporating a statement that the subheading may be omitted if there is no pregnancy exposure registry.

(Response) FDA concludes that the ''Pregnancy Exposure Registry'' subheading should be omitted when there is no pregnancy exposure registry. We have determined that requiring the ''Pregnancy Exposure Registry'' subheading in labeling when there is no pregnancy exposure registry for the drug product, and the inclusion of a statement indicating that no registry exists, would not further the goal of improving the collection of data in pregnant women who are exposed to a drug.

(Comment 24) One comment suggested that the labeling should state the purpose of the pregnancy exposure registry and provide the contact information necessary for enrollment.

(Response) FDA agrees that including a statement in the labeling about the purpose of the pregnancy exposure registry would be useful. In the final rule, FDA requires that if there is a scientifically acceptable pregnancy exposure registry for the drug, the labeling must include a statement that there is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to the drug during pregnancy, and include contact information needed to enroll in the registry or to obtain information about the registry. Because the purpose of all pregnancy registries is to collect clinically relevant human data that can be used in a product's labeling to provide health care providers with useful information for treating or counseling patients who are pregnant or anticipating pregnancy, we do not believe it is necessary to include a more specific statement in labeling about their purpose.

(Comment 25) Two comments suggested that pregnancy exposure registry information be included in ''Highlights'' and in the ''Patient Counseling Information'' section of labeling. One comment requested that FDA clarify in guidance whether the Agency anticipates requesting more pregnancy registries as a condition of marketing approval.

(Response) FDA believes that including information about pregnancy exposure registries in the ''Patient Counseling Information'' section of labeling would be useful. If the drug product has a pregnancy exposure registry, the availability of a pregnancy exposure registry should be noted in the ''Patient Counseling Information'' section of labeling, and a cross-reference should be included to ''8.1 Pregnancy'' for the contact information necessary to enroll. The preamble to the PLR states that ''Highlights'' summarizes the information from the ''Full Prescribing Information'' that is most important for prescribing the drug safely and effectively and organizes it into logical groups to enhance accessibility, retention, and access to the more detailed information (71 FR 3922 at 3931). Information about the availability of and contact information for a pregnancy exposure registry are not considered essential information for prescribing and should not appear in ''Highlights'' (see FDA's guidance for industry on ''Labeling for Human Prescription Drug and Biological Products—Implementing the PLR Content and Format Requirements'' (February 2013)). The question of whether FDA anticipates requesting more pregnancy exposure registries as a condition of marketing approval is outside the scope of this rule.

In the final rule, FDA revised the phrase ''telephone number or other information needed to enroll'' to ''contact information needed to enroll.'' FDA determined that this change would allow for more flexibility in the type of contact information included under this portion of the labeling.

ii. *Background risk statement*—FDA proposed that a general statement about the background risk of adverse pregnancy outcomes be included in labeling. The proposed rule stated in § 201.57(c)(9)(i)(B) that the following statement was required to be included in the labeling: All pregnancies have a background risk of birth defect, loss, or other adverse outcome regardless of drug exposure. The fetal risk summary below describes (*name of drug*)'s potential to increase the risk of developmental abnormalities above the background risk.

(Comment 26) Two comments expressed support for the inclusion of a background risk statement. One of these comments noted that the statement will be useful to clinicians when explaining the fetal risks associated with drug use during pregnancy.

Several comments suggested modifying the background risk statement. One comment suggested that applicants be given the option to identify in the background risk statement the specific risks described in the fetal risk summary. The comment proposed that the second sentence of the background statement be modified to state: ''The fetal risk summary below describes the potential of (*name of drug*) to contribute to risk of ('adverse outcomes, including developmental abnormalities' or *identify specific risks*) above background risk.''

Several comments requested clarification about whether the background risk statement refers to the general population or the population with the disease. Two other comments suggested that when the background risk of adverse outcomes in the relevant disease population is known to be higher than in the general population, this information should be included in the background risk statement. One of these comments suggested that relevant literature citations should also be included as appropriate.

One comment asked FDA to clarify how it will determine the background rate of adverse pregnancy outcomes. Another comment suggested that FDA and industry develop a standard definition of background risk that would provide a common explanation for all labeling, both for the general population and for any specific disease states or conditions. This comment explained that different reviewers may look at different criteria for assessing background risk (*i.e.,* what constitutes a developmental abnormality or a congenital malformation), and a standard definition would provide for consistency. A separate comment stated that the background risks of pregnancy can vary by demographics, location, ethnicity, and other variables. The comment suggested that to maintain uniform and standardized descriptions of background risk, FDA should provide industry with a guidance document describing background risk.

One comment recommended against requiring data in the background risk statement. The comment explained that background statistics change over time as new evidence is made available and accepted by the medical community.

Several comments suggested that FDA revise or omit the second sentence of the background risk statement. One of the comments explained that the sentence implies that the drug necessarily has the potential to increase the risk of developmental abnormalities above the background risk.

(Response) In the final rule, FDA has eliminated the proposed standardized background risk statement. In its place, the final rule requires that the labeling

state the percentage range of live births in the general population of the United States with a major birth defect and the percentage range of pregnancies in the United States that end in miscarriage, regardless of drug exposure. The final rule also requires that if such information is available for the population(s) for which the drug is labeled, it must also be included. The final rule requires that the background risk information appear in labeling under the subheading ''Risk Summary,'' rather than as a standalone statement under its own subheading (as in the proposed rule).

The Agency has determined that rather than including a standardized general statement about background risk, it is beneficial to include the approximate background rates of major birth defects and miscarriage. This will provide some context to the risk statement, and a basis for comparison with risk estimates from studies in pregnant women. Including the approximate background rates allows the prescriber to inform patients of the risk of major birth defects and miscarriage, regardless of drug exposure. Accordingly, the final rule requires that the labeling include the approximate background rates of major birth defects and miscarriage, regardless of drug exposure, in the United States. FDA agrees, however, that it is possible that these numbers may change over time. Therefore, the Agency did not include any specific numbers in the final rule. Instead, the Agency has provided information, including relevant literature citations, about current background rates of major birth defects and miscarriage in the draft guidance on pregnancy and lactation labeling, which is being published concurrently with this final rule. Although the literature citations are included in the draft guidance, the Agency does not believe it is either necessary or appropriate to include them in the labeling.

FDA agrees that the second sentence in the proposed background risk statement, which states that the fetal risk summary describes the drug's potential to increase the risk of developmental abnormalities above the background risk, could have been misinterpreted as meaning that the drug is associated with an increased risk. As discussed previously, the Agency has removed the standardized background risk statement, including the second sentence, from the final rule.

iii. *Fetal risk summary*—FDA proposed that under ''Pregnancy,'' prescription drug labeling include a subheading ''Fetal Risk Summary'' (§ 201.57(c)(9)(i)(C)). FDA proposed that the section include a risk conclusion, contain a narrative description of the risk(s) (if the risk conclusion is based on human data), and refer to any contraindications or warnings and precautions.

(Comment 27) One comment expressed support for the proposed ''Fetal Risk Summary,'' explaining that the proposed labeling requirements increase the utility of the ''Pregnancy'' subsection by expanding the teratology section to include information about specific developmental abnormalities such as incidence, seriousness, reversibility, potential for correction, and effect of dose, duration, and gestational timing of exposure. Several other comments suggested that the proposed ''Fetal Risk Summary'' be revised in various ways, discussed in detail as follows.

Sources of data. FDA proposed that all available data, including human, animal, and pharmacologic data, that are relevant to assessing the likelihood that a drug will increase the risk of developmental abnormalities and other relevant risks must be considered (Proposed § 201.57(c)(9)(i)(C)(*1*)).

(Comment 28) One comment recommended that rather than considering ''all available data,'' the data sources for the ''Fetal Risk Summary'' be limited to ''scientifically rigorous, organized data collection schemes such as clinical or preclinical studies, and registries.''

(Response) FDA declines this suggestion. For example, depending on the safety signal, valuable information may come from epidemiological studies that are not prospective pregnancy exposure registries. On occasion, adverse event reporting or case series reporting may raise enough concern about a potential increased risk for a specific structural malformation or pattern of malformations, or a serious adverse event, that the information should be included in labeling.

(Comment 29) *Maternal and neonatal risk.* One comment suggested that FDA include information regarding maternal and neonatal risks in the ''Pregnancy'' subsection of labeling. The comment suggested that FDA add a ''maternal risk subsection,'' preferably before the ''Fetal Risk Summary,'' which would address side effects and adverse reactions associated with the use of a drug, including those unique to pregnancy. The comment explained that placing this information higher on the label and making it a separate subsection would underscore the importance of the health of the mother. The comment also suggested that FDA include neonatal outcomes as well as fetal outcomes in the ''Fetal Risk Summary.''

(Response) FDA agrees that information on drug-associated maternal risk is important, and in the final rule has created a separate heading, ''Maternal adverse reactions,'' under ''Clinical Considerations,'' which requires relevant information, to the extent it is available, about drug-associated maternal adverse reactions that are unique to or more frequent or severe during pregnancy. FDA disagrees that information on neonatal outcomes as well as fetal outcomes should be included in the ''Risk Summary.'' Rather, if available, this information is included under its own heading, ''Fetal/Neonatal adverse reactions,'' under ''Clinical Considerations.'' FDA believes that consistent placement of this information under a specified heading under ''Clinical Considerations'' will allow health care providers to easily locate this information. FDA also believes that this approach ensures that maternal, fetal, and neonatal risks will be captured and clearly conveyed in prescription drug labeling.

Terms used to describe adverse fetal outcomes. FDA proposed that the fetal risk summary must characterize the likelihood that the drug increases the risk of developmental abnormalities in humans (*i.e.,* structural anomalies, fetal and infant mortality, impaired physiologic function, alterations to growth) and other relevant risks (*e.g.,* transplacental carcinogenesis) (proposed § 201.57(c)(9)(i)(C)(*1*)).

(Comment 30) Several comments suggested that the term ''developmental abnormalities'' should be replaced with a broader and more accurate term. One comment suggested FDA replace the term ''developmental abnormalities'' with the term ''adverse outcomes, including developmental abnormalities.'' This comment explained that the phrase ''developmental abnormalities'' does not include ''other relevant risks (*e.g.,* transplacental carcinogenesis)'' that are also required to be described in the ''Fetal Risk Summary.'' Several comments suggested replacing the term ''developmental abnormalities'' with the term ''developmental effects'' or ''adverse developmental effects.'' These comments explained that in the field of developmental toxicology, a developmental abnormality would imply, in general, a dysmorphogenic effect (malformation or variation), rather than the wider definition intended by the proposed rule. Several comments noted the importance of using terminology consistently in labeling.

(Response) FDA agrees that the terms used to describe various developmental effects or outcomes should be accurate and understandable, and that standard nomenclature in the field of developmental toxicology should be used to the extent that it exists. FDA also agrees that terminology should be used consistently in labeling. FDA concludes that the term ''developmental abnormalities'' is widely recognizable as referring to structural defects (malformations or variations), rather than the full range of possible manifestations of developmental toxicity as FDA had intended. Therefore, in the final rule, FDA has included the following terms that describe various developmental toxicities, as explained in the following list:

- ''Adverse developmental outcomes'' has replaced ''developmental abnormalities'' as the general term to encompass all manifestations or types of developmental toxicity.
- ''Structural abnormalities'' is used to describe dysmorphology, which includes malformations, variations, deformations, and disruptions, rather than the proposed ''structural anomalies.''
- ''Embryo-fetal and/or infant mortality'' is used to describe developmental mortality, which includes miscarriage, stillbirth, and infant death (including neonatal death), instead of the proposed ''fetal and infant mortality.''
- ''Functional impairment'' is used to describe functional toxicity, which includes such outcomes as deafness, endocrinopathy, neurodevelopmental effects, and impairment of reproduction, rather than ''impaired physiologic function.''
- ''Alterations to growth'' is used to describe such outcomes as growth restriction, excessive growth, and delayed and early maturations.

These terms and descriptions are consistent with FDA's guidance for industry on ''Reproductive and Developmental Toxicities—Integrating Study Results to Assess Concerns'' (September 2011).

Relationship between animal and human data. FDA proposed that when both human and animal data are available, risk conclusions based on human data must be presented before risk conclusions based on animal data (proposed § 201.57(c)(9)(i)(C)(*2*)).

(Comment 31) A number of comments suggested that FDA reexamine the emphasis that the ''Fetal Risk Summary'' places on human data as compared to animal data.

Several comments stated that because there will be frequent conflicts between human and animal data, FDA should develop an overall approach to characterize risk based on both human and animal data. One of these comments suggested that FDA consider the European Medicines Agency's (EMEA's) (now EMA's) Integration Table for Risk Assessment and Recommendation for Use as an example of how to integrate risk conclusions based on animal and human data.

Two comments stated that the proposed rule gives primary emphasis to human studies, if they exist, while downgrading the emphasis on animal data. One of these comments explained that the quality and statistical power of human data often fall well short of desirable, and suggested that human data be accompanied by clear acknowledgement of any deficiencies. The other comment explained that emphasizing minimal human data over strong animal data can misrepresent the fetal risk of a drug.

Two comments suggested that if human data are ''insufficient'' (*i.e.,* do not meet the standard for inclusion in proposed § 201.57(c)(9)(i)(C)(*2*)(*i*)), a risk statement based on human data should not precede a risk statement based on animal data. One of these comments explained that the most robust and clinically relevant data should always be presented first.

Several comments stated that if risk conclusions are based on sufficient human data, sponsors should not be required to include animal data, even if such data are available. One comment also suggested that if sufficient human data become available after the labeling is approved, animal data should be removed when the human data are added to the labeling. This comment explained that ''a risk conclusion based on animal data might not support, or could flatly contradict, a risk conclusion based on sufficient human data.''

One comment suggested that FDA ban all animal studies because human studies are more accurate.

(Response) We continue to believe that the ''Risk Summary'' is appropriately based on both human and animal data. Because of the importance of human data, we also have determined that when human data provide an incomplete assessment, this should be stated in the risk statement based on human data. Specifically, the ''Risk Summary'' must state when there are no human data or when available human data do not establish the presence or absence of a drug-associated risk. FDA believes that the use of narrative summaries of the data will avoid conflicting characterizations of risk magnitude.

FDA disagrees with the suggestion that animal data be presented first in cases where the human data are insufficient. FDA also disagrees that the most robust and clinically relevant data—whether human data or animal data—should always be presented first. We have determined that to promote consistency and to meet readers' expectations that information will always be found in the same place, a fixed order of presentation must be maintained. Moreover, we have determined that human data should precede animal data because it is the most clinically relevant.

We note that the purpose of this rulemaking is to facilitate informed prescribing and safe and effective drug product use; placing restrictions on or encouraging any type of studies that may be used as the basis for drug labeling is beyond the scope of this rule.

Not systemically absorbed. FDA proposed that if the drug is not systemically absorbed, the fetal risk statement must contain only the following statement: (*Name of drug*) is not absorbed systemically from (part of body) and cannot be detected in the blood. Maternal use is not expected to result in fetal exposure to the drug (proposed § 201.57(c)(9)(i)(C)(*1*)).

(Comment 32) One comment suggested that this statement should focus on the route of administration rather than the part of the body.

(Response) FDA agrees that ''part of the body'' could be misconstrued and we have determined that the use of ''route of administration'' to describe how the drug enters the body is more consistent with labeling language that addresses dosing and administration. In the final rule, FDA has replaced ''part of the body'' with ''route of administration.'' FDA has determined that ''cannot be detected in the blood'' is redundant and that the statement is clear without this phrase. In the final rule, FDA has eliminated that phrase.

(Comment 33) *Standard statement for certain drugs.* FDA received one comment suggesting that we develop a standard statement for drugs that are indicated for use only by males or by females who are not of reproductive potential.

(Response) FDA disagrees. We have determined that a standard statement is not needed. We believe it is appropriate that the ''Risk Summary'' will be included in labeling for all drugs, regardless of their indicated population. This will promote consistency in drug labeling.

Risk conclusions based on human data. In the proposed rule, under the subheading ''Fetal Risk Summary,'' FDA proposed that when human data are sufficient to reasonably determine the likelihood that the drug increases the risk of fetal developmental abnormalities or specific developmental abnormalities, the likelihood of increased risk must be characterized using one of the following risk conclusions: Human data do not indicate that (*name of drug*) increases the risk of (*type of developmental abnormality or specific developmental abnormality*) or Human data indicate that (*name of drug*) increases the risk of (*type of developmental abnormality or specific abnormality*) (proposed § 201.57(c)(9)(i)(C)(*2*)(*i*)). The proposed rule defined the sources of ''sufficient human data'' as clinical trials, pregnancy exposure registries or other large scale epidemiologic studies, or case series reporting a rare event (proposed § 201.57(c)(9)(i)(C)(*2*)(*i*)).

(Comment 34) Many comments requested that FDA more clearly define the criteria for ''sufficient human data'' and provide further guidance on the quantity and quality of evidence considered to be ''sufficient human data'' rather than ''other human data.'' One comment requested that FDA clarify the standards that constitute ''sufficient human data,'' including how those standards were developed. Another comment stated that there is no agreement among experts as to how much data are needed to reach a risk conclusion and requested that FDA clarify what is considered sufficient human data to reasonably determine the risk of developmental abnormalities. Several comments questioned whether data from an individual study could ever constitute ''sufficient human data.'' These comments explained that although individual clinical trials, pregnancy exposure registries, large-scale epidemiologic studies, and case series can provide signals for potential adverse pregnancy outcomes, an individual study is not statistically powered to fully assess the incidence and form one of the proposed risk conclusions. A separate comment stated that even if human data has multiple sources, there is often not enough human data to make a risk conclusion. This comment questioned how often the risk statements based on sufficient human data would be used. One comment stated that the proposed rule does not discuss who will determine whether the data are sufficient or how such a determination will be made. The comment suggested that to increase consistent implementation across review divisions, a dedicated group of FDA specialists should review the determination of whether the human data are sufficient or insufficient for all labeling subject to the rule. This comment also requested that FDA provide examples of sufficient and insufficient data and that FDA caution prescribers that such classifications should not be considered as scientific proof that a drug may or may not harm a particular patient.

(Response) FDA agrees that the term ''sufficient human data'' is ambiguous and has eliminated it from the final rule. FDA has also eliminated from the final rule the distinction between ''sufficient human data'' and ''other human data.'' In the final rule, FDA requires that when human data are available that establish the presence or absence of any adverse developmental outcome(s) associated with maternal use of the drug, the labeling must summarize the specific developmental outcome; its incidence; and the effects of dose, duration of exposure, and gestational timing of exposure. As stated previously, the final rule also requires that the ''Risk Summary'' state when there are no human data or when available human data do not establish the presence or absence of drug-associated risk.

FDA has also determined that the term ''risk conclusion'' is inappropriate because the available data may not always lead to a conclusion regarding the drug's risk to the fetus. Therefore, in the final rule, FDA has replaced the term ''risk conclusion'' with the term ''risk statement.''

(Comment 35) Several comments suggested that the Agency revise the proposed risk statements to make them more straightforward and appropriately qualify the nature of the data and the inability to draw definitive conclusions about an absence of risk based on them. Two of these comments suggested that the term ''human data'' be replaced with the term ''available human data.'' One comment suggested that the risk conclusion ''Human data do not indicate that (name of drug) increases the risk of (type of developmental abnormality or specific developmental abnormality)'' be replaced with ''Available human data indicate no additional risk of (type of developmental abnormality or specific developmental abnormality) with (name of drug).'' One comment suggested that the term ''indicate'' should be replaced with the term ''suggest.''

(Response) In the final rule, FDA has eliminated the requirement in the proposed rule that standardized risk conclusions be used to characterize the likelihood of increased risk. As discussed previously, in the final rule, FDA requires instead, under ''Risk statement based on human data,'' that when human data are available that establish the presence or absence of any adverse developmental outcome(s) associated with maternal use of the drug, the labeling must summarize the specific developmental outcome; its incidence; and the effects of dose, duration of exposure, and gestational timing of exposure. The final rule also requires that if the data indicate that there is an increased risk for a specific adverse developmental outcome in infants born to women exposed to the drug during pregnancy, this risk must be quantitatively compared to the risk for the same outcome in infants born to women who were not exposed to the drug but who have the disease or condition for which the drug is indicated to be used. The final rule requires that if the data indicate that there is an increased risk for a specific adverse developmental outcome in infants born to women exposed to the drug during pregnancy, but risk information is not available for women who were not exposed to the drug but who have the disease or condition for which the drug is indicated to be used, then the risk for the specific outcome must be compared to the rate at which the outcome appears in the general population.

(Comment 36) FDA also received comments about the proposed sources of sufficient human data. One comment stated that sufficient data must be based on large-scale epidemiologic studies or clinical trials, and cannot be based on pregnancy registries or case reports/series requiring further evaluation. This comment explained that most pregnancy registries can only serve to rule out a major teratogen and to generally determine the similarity in array of effects seen in large registries, and they cannot provide a quantitative estimate of population rates of individual defects or abnormalities. Another comment stated that a risk conclusion cannot always be reached based on the types of human data described in the proposed rule, and questioned whether there is a consistent approach to sufficient human data as it relates to case series reporting of a rare event. This comment explained that spontaneous reports should not be part of the basis for this subsection. One comment questioned how the labeling will summarize seemingly contradictory results of well-powered pregnancy exposure registries or studies from

which a definitive clinical conclusion cannot be reached.

(Response) FDA recognizes that because retrospective voluntary adverse event reporting may be biased and incomplete, spontaneous reports cannot rule in or out a causal relationship between drug exposure and clinical outcome. However, multiple spontaneous reports (or case series) of rare events can be useful in suggesting possible associations between adverse events and drug exposure during pregnancy that warrant further investigation. Furthermore, FDA has determined that data from studies with small numbers of pregnancy exposures may provide valuable information about potential safety signals, especially when corroborated by findings from other studies.

(Comment 37) One comment suggested that FDA eliminate the proposed rule's requirement that sponsors specify all possible types of developmental abnormalities or specific abnormalities for which human data do not indicate that the drug increases the risk. The comment explained that such a list could be lengthy and of little clinical benefit to health care providers.

(Response) FDA did not intend to imply that every potential type of developmental abnormality must be included in labeling when human data are negative. We note that it is difficult to be certain that a lack of findings equates to a lack of risk because the failure of a study to detect an association between a drug exposure and an adverse outcome may be related to many factors, including a true lack of an association between exposure and outcome, a study of the wrong population, failure to collect or analyze the right data endpoints, and/or inadequate power. The intent of this final rule is to require accurate descriptions of available data and facilitate the determination of whether the data demonstrate potential associations between drug exposure and an increased risk for developmental toxicities.

FDA proposed that when there are available human data that are not sufficient to use one of the risk conclusions for sufficient human data, the likelihood that the drug increases the risk of developmental abnormalities must be characterized as low, moderate, or high (proposed § 201.57(c)(9)(i)(C)(*2*)(*ii*)). In the preamble to the proposed rule, FDA sought comment on this subsection. Specifically, FDA sought ''comment on whether, in situations with human data that are not sufficient, rather than classifying the risk as low, moderate, or high, the risk should instead be characterized by specific statements describing the findings, or whether the findings should be described at all if they are not readily interpretable. Examples of specific statements would be: 'Limited data in humans show (describe outcomes),' or 'Limited data in humans show conflicting results (describe study types, number of cases, outcomes, and limitations)''' (73 FR 30831 at 30842).

(Comment 38) FDA received 10 comments from a variety of sources expressing strong disagreement with the proposal to use the terms ''low,'' ''moderate,'' and ''high'' to characterize the likelihood of increased risk of adverse outcomes due to drug exposure based on less than sufficient human data. FDA received only one comment supporting the proposal.

Four comments stated that the proposal to classify risk as low, moderate, or high based on insufficient human data might produce the same confusion as the current pregnancy category system. These comments explained that, as with the A, B, C, D, X category system, the use of the categories low, moderate, and high to characterize the likelihood of increased risk of adverse outcomes would oversimplify the data and lump drugs with various types and amounts of data together without describing the basis for the conclusions. Another comment suggested that these characterizations are subjective and would be confusing to health care providers.

One comment recommended that when the human data are insufficient, FDA require the inclusion of the following risk conclusion: ''Insufficient data—risk conclusion not established.'' Another comment recommended that FDA consider adopting something similar to the EMA's system. One comment suggested that the ''Risk Summary'' should include information about the findings, such as the gestational age of exposure, the target organ or organ system, and the findings should be characterized in terms of structural, developmental, growth, or functional abnormality. Another comment recommended that when the human data are not sufficient, the labeling contain statements specific to the findings rather than classifying the risk as low, moderate, or high. One comment suggested that when there are insufficient data, the labeling should include a statement explaining that it is not possible to draw conclusions based on insufficient human data. This comment also expressed a preference for referring to the data portion of the labeling rather than including a more detailed narrative discussion of insufficient human data in the fetal risk summary.

(Response) As discussed previously, FDA agrees that the term ''sufficient human data'' is ambiguous and we have removed the term from the final rule, as well as the distinction between ''sufficient human data'' and ''other human data.'' FDA also agrees that the terms ''low,'' ''moderate,'' and ''high'' are subjective and should not be used to describe human data that cannot support a statement about fetal risk. The final rule requires instead that when human data are available that establish the presence or absence of any adverse developmental outcome(s) associated with maternal use of the drug, the labeling must summarize the specific developmental outcome; its incidence; and the effects of dose, duration of exposure, and gestational timing of exposure. As discussed earlier, the final rule also requires that if the human data indicate that there is an increased risk for a specific adverse developmental outcome in infants born to women exposed to the drug during pregnancy, this risk must be quantitatively compared to the risk for the same outcome in infants born to women who were not exposed to the drug but who have the disease or condition for which the drug is indicated to be used. When risk information is not available for women with the disease or condition for which the drug is indicated, then the risk for the specific outcome must be compared to the rate at which the outcome occurs in the general population. The final rule also requires that the ''Risk Summary'' state when there are no human data or when available human data do not establish the presence or absence of drug-associated risk.

Narrative description of risk(s) based on human data. FDA proposed that when there are human data, the risk conclusion must be followed by a brief description of the risks of developmental abnormalities as well as other relevant risks associated with the drug. To the extent possible, this description must include the specific developmental abnormality (*e.g.,* neural tube defects); the incidence, seriousness, reversibility, and correctability of the abnormality; and the effect on the risk of dose, duration of exposure, and gestational timing of exposure. When appropriate, the description must include the risk above the background risk attributed to drug exposure and confidence limits and power calculations to establish the statistical power of the study to identify

or rule out a specified level of risk (proposed § 201.57(c)(9)(i)(C)(*4*)).

In the final rule, FDA has removed the ''Narrative description of risk(s)'' heading from the ''Pregnancy'' subsection. FDA has determined that much of the information required under that heading by the proposed rule was duplicative of information now required in the ''Risk Summary.'' As discussed previously, when human data are available that establish the presence or absence of any adverse developmental outcome(s) associated with maternal use of the drug, the ''Risk Summary'' in the ''Pregnancy'' subsection must summarize the specific developmental outcome; its incidence; and the effects of dose, duration of exposure, and gestational timing of exposure. Because this information is required to be included in a narrative form in the ''Risk Summary,'' we determined that including a separate ''Narrative description of risk(s)'' heading in the labeling was unnecessary. In addition, as explained in the following comments and our responses, some of the information that was required by the proposed rule to appear under ''Narrative description of risk(s)'' is required by the final rule to appear instead under ''Clinical Considerations.''

(Comment 39) One comment suggested that FDA add a statement to the ''Narrative description of risk(s)'' portion of the ''Pregnancy'' subsection of labeling that explains that spontaneous abortions caused by a drug could potentially mask the risk of developmental abnormalities.

(Response) Although FDA acknowledges that embryo-fetal death (*i.e.,* spontaneous abortion) does sometimes occur due to severe developmental abnormalities, the Agency has determined that it is not necessary to explicitly include such a statement in labeling. Any increase in spontaneous abortions attributed to drug exposure above the background risk is required to be described in the ''Risk Summary.''

(Comment 40) One comment stated that the term ''seriousness'' is ambiguous and suggested replacing it with the phrase ''impact on health.'' Two comments requested clarification of the terms ''reversibility'' and ''correctability.''

(Response) FDA agrees that the term ''seriousness'' is not clear, and it is not used in the final rule; it has been replaced with a requirement that the labeling describe the potential severity of the adverse reaction. Information about the reversibility of adverse reactions should be included under the heading, ''Fetal/Neonatal adverse reactions,'' under ''Clinical Considerations.'' This portion of the final rule requires that if it is known or anticipated that maternal drug therapy increases or may increase the risk of an adverse reaction in the fetus or neonate, the labeling must describe the adverse reaction, the potential severity and reversibility of the adverse reaction, and available interventions for monitoring or mitigating the reaction.

In response to the comments requesting clarification of the terms ''reversibility'' and ''correctability,'' FDA considers a condition to be reversible if it can self-correct with routine care and nurturing or through an intervention such as discontinuing the drug. An example of a potentially reversible drug effect in the neonate is provided in the draft guidance on pregnancy and lactation labeling, which is being published concurrently with the final rule. The term ''correctable'' has been removed from the final rule.

(Comment 41) One comment suggested that FDA include in the ''Narrative description of risk(s)'' information about precautionary measures that can be taken to prevent an adverse outcome caused by the drug.

(Response) FDA agrees that information about precautionary measures to prevent an adverse drug effect should be included in labeling. In the final rule, under ''8.1 Pregnancy,'' ''Clinical Considerations,'' ''Maternal adverse reactions,'' FDA requires that if the use of the drug is associated with a maternal adverse reaction that is unique to pregnancy or if a known adverse reaction occurs with increased frequency or severity in pregnant women, the labeling must describe the adverse reaction and available intervention(s) for monitoring or mitigating it. Also, in the final rule, FDA requires that under ''8.1 Pregnancy,'' ''Clinical Considerations,'' ''Fetal/Neonatal adverse reactions,'' if it is known or anticipated that maternal drug therapy increases or may increase the risk of an adverse reaction in the fetus or neonate, the labeling must describe the adverse reaction, the potential severity and reversibility of the adverse reaction, and available intervention(s) for monitoring or mitigating the reaction. For further discussion of these requirements, see Comment 61 and our response.

(Comment 42) One comment suggested that FDA replace the phrase ''risk attributed to drug exposure'' in the ''Narrative description of risk(s)'' with the phrase ''a drug's potential to contribute to the risk of adverse outcomes.''

(Response) As discussed previously, the ''Narrative description of risk(s)'' heading was removed from the final rule, and the phrase ''risk attributed to drug exposure'' is not used elsewhere in the final rule.

(Comment 43) Two comments stated that confidence intervals and power calculations should not be included in labeling because they are too technical and not useful for most prescribers.

(Response) FDA does not agree. Under ''Data,'' the final rule requires a description of the limitations of any data included in the labeling. Confidence intervals and power calculations are important for the review and interpretation of the data. As noted in the draft guidance on pregnancy and lactation labeling, which is being published concurrently with the final rule, the confidence intervals and power calculation, when available, should be part of that description of limitations.

(Comment 44) One comment suggested that the ''Narrative description of risk(s)'' include a discussion about the uncertainties or limitations of the ''Fetal Risk Summary'' when appropriate.

(Response) As discussed previously, FDA has removed the ''Narrative description of risk(s)'' heading from the final rule. In the final rule, any uncertainties or limitations of the data are required to be stated in ''Data.''

(Comment 45) One comment suggested that the ''Narrative description of risk(s)'' cross-reference ''Data'' to direct readers to the information upon which the narrative is based.

(Response) As discussed previously, the ''Narrative description of risk(s)'' was removed from the final rule.

Risk statement based on animal data. FDA proposed to require that when the data on which the risk conclusion is based are animal data, the ''Fetal Risk Summary'' must characterize the likelihood that the drug increases the risk of developmental abnormalities using one of the following risk conclusions: Not predicted to increase the risk, low likelihood of increased risk, moderate likelihood of increased risk, high likelihood of increased risk, or insufficient data (proposed § 201.57(c)(9)(i)(C)(*3*)(*i*)–(c)(9)(i)(C)(*3*)(*v*)). In the preamble to the proposed rule, the Agency sought comment on whether these standardized statements can adequately communicate different levels of risk based on animal data and their potential relevance to human fetal effects or whether these statements are likely to generate

confusion among prescribers (73 FR 30831 at 30843).

(Comment 46) Comments expressed different opinions about the proposal to use standardized statements to characterize animal data. FDA received 11 comments, primarily from toxicologists, teratologists, and organizations representing toxicologists and teratologists, as well as a few comments from drug manufacturers, expressing strong disagreement with the proposal to use risk statements to characterize animal data. FDA received three comments that supported using standardized statements to characterize the likelihood, based on animal data, that a drug will increase the risk for a known developmental abnormality. These comments explained, for example, that a standardized statement indicating the possible correlation between animal and human data would be helpful to clinicians.

Two comments stated that the proposed categories are confusing and subject to variable interpretation. One of these comments explained that it will be very difficult to categorize the results of multiple studies conducted for a single drug into one of the proposed categories, and there could be disagreement about whether to characterize the risk based on the animal data as ''low,'' ''moderate,'' or ''high.''

Several comments stated that the proposal to use category language to describe animal data demonstrates a misunderstanding of the function and meaning of experimental animal studies. These comments explained that although animal data can identify the potential of a therapeutic agent to cause developmental toxicity, it cannot give rise to an estimate of the probability of human harm.

Two comments expressed concern that the use of standardized risk statements would amount to a category system similar to the one that FDA currently uses and would have all of its associated problems.

Several comments expressed particular concern with the proposal to use these categories without an accompanying narrative description of the animal studies. One comment suggested that the sample labels provided in the Appendix of the proposed rule illustrate the difficulty of trying to characterize the risk to humans based on animal data. Another comment stated that ''the terms 'risk,' 'medium,' and 'high' are highly charged terms'' and expressed concern that the risk statements will be over-interpreted by anxious consumers and their clinicians.

One comment suggested that rather than using the proposed risk statements, FDA should instead use the standardized statements presented in the draft reviewer guidance on ''Integration of Study Results to Assess Concerns about Human Reproductive and Developmental Toxicities'' (October 2001).

Most of the comments that disagreed with the proposed standardized risk statements suggested that the labeling instead contain narrative statements describing the animal data and its potential relationship to human pregnancy risk. One of these comments explained that ''succinct narrative statements will promote a reasoned risk assessment, facilitate comparisons among drugs, and enhance risk communication.'' Several of these comments suggested that the labeling should describe animal data qualitatively, including the number of species with positive findings, consistency of findings, and the type of findings.

(Response) The Agency has determined that the terms ''not predicted to increase the risk,'' ''low likelihood of increased risk,'' ''moderate likelihood of increased risk,'' and ''high likelihood of increased risk'' are confusing and subject to different interpretations. The Agency believes that using standardized risk statements may give the false impression that animal data can provide a semi-quantitative assessment of human risk. The Agency also agrees that the use of standardized risk statements to characterize the risk of developmental abnormalities based on animal data would potentially have the same drawbacks as the current pregnancy category system. Therefore, in the final rule, FDA removed the requirement that a standardized risk statement be used to describe human risk based on animal data. Instead, the ''Risk Summary'' requires that when animal data are available, the labeling must summarize the findings in animals and, based on these findings, describe, for the drug, the potential risk of adverse developmental outcomes in humans. The final rule requires that the statement include the number and type(s) of species affected, timing of exposure, animal doses expressed in terms of human exposure or dose equivalents, and outcomes for pregnant animals and offspring. The final rule also requires that when animal studies do not meet current standards for nonclinical developmental toxicity studies or when there are no animal data, the labeling must so state.

(Comment 47) Two comments suggested that labeling should include language explaining the limitations of using animal data to predict the likelihood that the drug increases the risk of developmental abnormalities.

(Response) FDA declines the suggestion to include language in labeling explaining the limitations of using animal data to predict the likelihood that the drug increases the risk of developmental abnormalities, because this is beyond the scope of this rule, and is discussed in guidance documents, such as FDA's guidance for industry on ''Reproductive and Developmental Toxicities—Integrating Study Results to Assess Concerns'' (September 2011).

(Comment 48) FDA proposed that the ''Risk Summary'' contain ''risk conclusions'' based on animal data. One comment suggested that the term ''risk conclusion'' be replaced with the term ''risk statement'' because it is difficult to reach any conclusions about fetal risk posed by drugs based solely on animal data.

(Response) FDA agrees. As with human data, in the final rule, the Agency has replaced the term ''risk conclusion'' with the term ''risk statement'' when discussing risks based on animal data.

(Comment 49) *Risk statement based on pharmacology.* One comment suggested that FDA consider whether a separate approach is appropriate for a group of drugs, such as oncology products, for which the pharmacological and toxicological mechanisms are similar. The comment suggested that for cytotoxic drugs, FDA could use the following standard risk statement: ''(*Drug name*) is indicated for (*cancer type*) and is generally used in terminally ill patients. There are very limited data on exposure in pregnant patients and, therefore, no assessment of fetal or maternal risk is available. The mechanism of action of this drug is to kill growing cells and it can be anticipated that there is a risk to the fetus at all stages of development.''

(Response) FDA agrees that the ''Pregnancy'' subsection of labeling should address situations in which a drug may result in an increased risk of adverse developmental outcomes based on a well-understood mechanism of action. The final rule requires that when the drug has a well-understood mechanism of action that may result in adverse developmental outcome(s), the ''Risk Summary'' must explain the mechanism of action and the potential associated risks.

Contraindications, warnings, and precautions. FDA proposed that the

''Fetal Risk Summary'' refer to information that is included in the ''Contraindications'' or ''Warnings and Precautions'' section of labeling regarding an increased risk to the fetus from exposure to the drug (proposed § 201.57(c)(9)(i)(C)(*5*)).

(Comment 50) One comment suggested that FDA specify that any contraindications or warnings or precautions that must be included in the ''Fetal Risk Summary'' are those that relate to risk to the fetus.

(Response) In the final rule, FDA removed the requirement that the ''Risk Summary'' refer to information that is included in the ''Contraindications'' or ''Warnings and Precautions'' section of labeling regarding an increased risk to the fetus from exposure to the drug. As described in FDA's draft guidance for industry implementing the PLR, when a topic is discussed in more than one section of labeling, the section containing the most important information relevant to prescribing should typically include a succinct description and should cross-reference sections that contain additional detail (FDA's guidance for industry on ''Labeling for Human Prescription Drug and Biological Products—Implementing the PLR Content and Format Requirements'' (February 2013)). Consistent with that principle, cross-referencing of information required under the final rule will typically appear in the section where the topic is briefly summarized, *e.g.,* ''Warnings and Precautions,'' and will refer the reader to the place in labeling where it will be presented in greater detail, *i.e.,* ''Pregnancy.'' We note that because a contraindication is important information that needs to be communicated to the health care provider, the final rule requires that when use of a drug is contraindicated during pregnancy, this information must be stated first in the ''Risk Summary.''

iv. *Clinical considerations.*

FDA proposed that the ''Pregnancy'' subsection of prescription drug labeling include a ''Clinical Considerations'' component to provide guidance and information to health care providers about the use of the drug in three distinct clinical situations: (1) Counseling women who were inadvertently exposed to the drug during pregnancy, (2) making prescribing decisions for pregnant women, and (3) making prescribing decisions during labor and delivery (proposed § 201.57(c)(9)(i)(D)).

We received many comments on this proposal. Based on those comments, FDA has made some changes to the final rule. A description of each comment we received and our responses follow.

(Comment 51) *General comments.* Comments expressed different opinions about the utility and appropriateness of the proposed ''Clinical Considerations'' component. Many comments expressed general support for including this information. One comment stated that ''Clinical Considerations'' will help clinicians and patients to consider all aspects of the patient's care when deciding when and how to prescribe drugs during pregnancy and in women of childbearing potential. Another comment stated that the title ''Clinical Considerations'' encourages professionals to make their own medical judgments. A separate comment noted that FDA refrained from interfering with the physician's discretion by framing ''Clinical Considerations'' as a practical guide that assists the provider in decisionmaking.

Some comments cautioned that ''Clinical Considerations'' was too directive in its advice and requiring this information intruded on the practice of medicine and could increase physician liability for failure to adhere to labeling instructions. One comment stated that ''Clinical Considerations'' should not dictate prescribing by a physician for pregnant women. The comment requested that FDA revisit this provision to see whether the content can be made more useful without advising physicians how to practice medicine. In particular, the comment suggested that information about known alternative therapies should be included. Alternatively, the comment suggested that FDA consider the use of a general statement about clinical considerations rather than an extensive, clinically based discussion that may be unable to incorporate risk and benefit information. Another comment stated that it is the health care provider's responsibility to keep abreast of the latest information about the disease state and its effect on pregnant women and to apply that knowledge to treatment of each individual patient, and the professional labeling is not the appropriate place for this information.

(Response) FDA disagrees both that ''Clinical Considerations'' is too directive and that professional labeling is not the appropriate place for this information. As a Public Health Agency with expertise in drug regulation and safety, FDA has a responsibility to issue regulations that facilitate the development of drug labeling that communicates how to safely and effectively prescribe drugs in the clinical setting. The Agency does not regard ''Clinical Considerations'' as dictating prescribing decisions. Rather, FDA views the ''Clinical Considerations'' component of ''Pregnancy'' as providing information that supports health care providers' understanding of drug product risks and benefits and facilitates informed prescribing decisions and patient counseling.

Inadvertent exposure. FDA proposed that under the subheading ''Clinical Considerations,'' the ''Pregnancy'' subsection of labeling include information regarding known or predicted risks to the fetus from inadvertent exposure to the drug during pregnancy (proposed § 201.57(c)(9)(i)(D)(*1*)). The proposed rule would have required that: The labeling must discuss the known or predicted risks to the fetus from inadvertent exposure to the drug (exposure in early pregnancy before a woman knows she is pregnant), including human or animal data on dose, timing, and duration of exposure. If there are no human or animal data to assess the risk from inadvertent exposure, the labeling must so state.

(Comment 52) Comments expressed different opinions about the necessity and utility of including this information.

Two comments supported including information about inadvertent exposure. One of these comments explained that the proposed section improves a physician's ability to manage such cases.

Two comments, however, suggested that FDA consider removing this requirement because it will be duplicative of the information contained in the ''Fetal Risk Summary.'' One of these comments explained that assuming equal exposure to the drug, the known or predicted risks to the fetus would be the same regardless of whether the exposure was intentional or not. This comment explained that because fetal risks are already fully described in the ''Fetal Risk Summary,'' including the same information under ''inadvertent exposure during pregnancy'' would be redundant. The comment suggested that the ''inadvertent exposure during pregnancy'' component instead include a cross-reference to the ''Fetal Risk Summary'' and describe only information not already described in the ''Fetal Risk Summary,'' in particular, any information about ways to manage or mitigate the effects of inadvertent drug exposure. The other comment explained that the risk of drug exposure to the fetus early in pregnancy should not be different between women who

choose to become pregnant and those whose pregnancies were unplanned.

Another comment suggested that FDA either delete the statement ''exposure in early pregnancy before a woman knows that she is pregnant'' or retain it as an example. This comment explained that although inadvertent exposure is more likely in early pregnancy, it may occur at any time during pregnancy.

One comment asked for clarification as to what is expected to be included in this section. Specifically, this comment questioned how the risk conclusions from animal data in the ''Fetal Risk Summary'' will be used to counsel clinicians on the risk of inadvertent exposure, and requested that FDA provide examples of this section in an Appendix.

(Response) The Agency agrees that the proposed ''inadvertent exposure during pregnancy'' component would have required information about drug effects on the fetus that is largely redundant of the information that is required to be included in the ''Risk Summary'' in the ''Pregnancy'' subsection of prescription drug labeling. FDA has removed the ''inadvertent exposure during pregnancy'' component from the final rule.

Prescribing decisions for pregnant women. FDA proposed that the ''Clinical Considerations'' portion of the ''Pregnancy'' subsection of prescription drug labeling contain information about prescribing decisions for pregnant women, including the following: (1) The risk, if known, to the pregnant woman and the fetus from the disease or condition the drug is indicated to treat; (2) information about dosing adjustments during pregnancy; (3) information about maternal adverse reactions associated with use of the drug; and (4) information about any known or anticipated complications in the neonate from treatment of the pregnant woman (proposed § 201.57(c)(9)(i)(D)(*2*)).

In the final rule, FDA removed the heading ''Prescribing decisions for pregnant women.'' FDA determined that because the ''inadvertent exposure'' component was removed from the final rule, the ''Clinical Considerations'' portion of the ''Pregnancy'' subsection was shortened such that having a separate heading for ''Prescribing decisions for pregnant women'' was unnecessary.

FDA received comments about the information required in the proposed rule under the heading ''Prescribing decisions for pregnant women.'' A description of each comment and our responses follow.

FDA proposed that the ''Prescribing decisions for pregnant women'' component under ''Clinical Considerations'' include information about the risk, if known, to the pregnant woman and the fetus from the disease or condition the drug is indicated to treat (proposed § 201.57(c)(9)(i)(D)(*2*)(*i*)).

(Comment 53) Comments disagreed about whether the ''Pregnancy'' subsection of labeling should include information about the effects of not treating the woman's underlying disease or condition.

Two comments supported requiring the inclusion of information about the short- and long-term effects of not taking a necessary drug to treat a chronic disease or condition for the duration of a pregnancy, as well as information about the severity of the condition for which the drug might be prescribed.

Two other comments, however, disagreed with including information in ''Clinical Considerations'' about the risks of not treating the mother's underlying disease or condition during pregnancy. These comments stated that prescription drug labeling is not the appropriate place for health care providers to learn about the risks of diseases that drugs are indicated to treat.

(Response) FDA has determined that when relevant information is available about the serious effects of not treating conditions or diseases during pregnancy, it must be included in this section of labeling. In the final rule, this requirement appears first under ''Clinical Considerations'' under the heading ''Disease-associated maternal and/or embryo/fetal risk.'' The wording of this portion of the final rule was revised to require that when there is a serious known or potential risk to the pregnant woman and/or the embryo/fetus associated with the disease or condition for which the drug is indicated to be used, the labeling must describe the risk.

(Comment 54) Other comments suggested that the ''Clinical Considerations'' component of the proposed rule be altered in various ways.

Two comments expressed concern that descriptions of risks to the pregnant patient or fetus posed by diseases or conditions would vary among drugs that are indicated to treat the same disease or condition, thereby promoting confusion. One of these comments suggested that FDA develop disease-specific text for developmental risks of major disease classes, such as asthma, hypertension, diabetes, and epilepsy, which sponsors can use in their prescription drug labeling. This comment also requested that the information be updated on a timely basis.

(Response) FDA agrees that it is important that information provided in labeling is consistent and up-to-date, and we address this issue in our response to Comment 4. FDA is not mandating that labeling contain consistent disease-specific text, as knowledge of disease-associated risk may change over time as more data become available.

(Comment 55) One comment suggested that FDA add a statement under ''Clinical Considerations'' explicitly stating that untreated or inadequately treated health conditions (such as infections; chronic diseases such as diabetes, hypertension, renal and thyroid diseases; and psychiatric disorders such as depression) can adversely affect the health of the woman and the outcomes of the pregnancy, and that decisions about medication usage must be balanced with the risks of untreated and/or poorly managed health conditions.

(Response) FDA disagrees with this suggestion. We have determined that requiring a general standardized statement is less effective than providing drug-specific information about the risks of not treating the condition or disease for which the drug is indicated to be used.

(Comment 56) One comment suggested that ''Clinical Considerations'' should provide information about how to discontinue or switch medications during pregnancy when necessary.

(Response) FDA agrees that when such information is available, it may be appropriate to include it in ''Clinical Considerations.'' We note that this does not require a change to the final rule, because this is consistent with current labeling practices.

(Comment 57) One comment suggested that ''Clinical Considerations'' take into account the severity of the disease, disorder, or condition to the mother, and the availability and the benefits and risks of alternative therapies for which greater or lesser knowledge may be known about their use in pregnant women.

(Response) FDA disagrees with the suggestion that the labeling address the availability and the benefits and risks of alternative therapies during pregnancy. Because the comparative risks and benefits for different therapies may vary by patient, this determination must be made by the prescribing health care provider. FDA acknowledges, however, that under certain circumstances it may be appropriate to include a statement in the labeling that pregnant women

should consider alternative drug therapies, and the appropriateness of this would be evaluated on a case-by-case basis during the labeling review process for a specific application.

Dosing adjustments during pregnancy. FDA proposed that ''Clinical Considerations'' provide information about dosing adjustments during pregnancy (proposed § 201.57(c)(9)(i)(D)(*2*)(*ii*)). The proposed rule stated that this information must also be included in the ''Dosage and Administration'' and ''Clinical Pharmacology'' sections of the labeling, and that if there are no data on dosing during pregnancy, the labeling must so state.

(Comment 58) One comment suggested that dosing information should be restricted to the ''Dosage and Administration'' section of labeling and that ''Clinical Considerations'' should cross-reference the ''Dosage and Administration'' and ''Clinical Pharmacology'' sections of the labeling rather than repeat dosing adjustment information in the ''Pregnancy'' subsection of labeling. The comment also suggested replacing the phrase ''no data'' because it could become outdated and because, in some instances, there may be data but it might not be sufficient to support recommendations for dosing adjustments.

(Response) We disagree with the suggestion that all information about dosing should be restricted to the ''Dosage and Administration'' section of labeling. FDA has determined that it is important that labeling information relevant to the use of the drug during pregnancy be included in the ''Pregnancy'' subsection. These issues are discussed in the draft guidance on pregnancy and lactation labeling, which is being published concurrently with the final rule. If there are pharmacokinetic data that support dose adjustment(s) during pregnancy and the postpartum period, this information must be provided under the heading, ''Dose adjustments during pregnancy and the postpartum period'' in ''Clinical Considerations,'' and there should be a cross-reference to other sections of labeling that include more details (*e.g.,* ''Dosage and Administration'' or ''Clinical Pharmacology''). Although in the proposed rule FDA had required a cross-reference to ''Dosage and Administration'' and ''Clinical Pharmacology,'' we have removed that requirement. We believe, however, that when appropriate, a cross-reference should be included. This approach is consistent with the regulations and guidance applicable to the ''Dosage and Administration'' section of labeling (§ 201.57(c)(3)) and FDA's guidance for industry on ''Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products—Content and Format'' (March 2012), which require that the labeling provide details on how to adjust or modify the dosage in the ''Dosage and Administration'' section of labeling, including for specific patient populations.

FDA agrees with the suggestion to remove the phrase ''no data'' from the final rule. In the final rule, we have removed the requirement to state if there are no data available on dose adjustments during pregnancy and the postpartum period. In addition, as noted in the draft guidance on pregnancy and lactation labeling, which is being published concurrently with the final rule, headings under ''Clinical Considerations'' (including ''Dose adjustments during pregnancy and the postpartum period'') should be omitted if there are no data available or the available data are not relevant.

Maternal adverse reactions. FDA proposed that ''Clinical Considerations'' contain information about maternal adverse reactions that are unique to pregnancy or adverse reactions that occur with increased frequency or severity in pregnant women. The proposed rule required that the labeling also describe any interventions that may be needed, such as monitoring blood glucose for a drug that causes hyperglycemia in pregnancy (proposed § 201.57(c)(9)(i)(D)(*2*)(*iii*)).

(Comment 59) One comment suggested that a cross-reference, ''see Pregnancy,'' be added to the ''Adverse Reactions'' section of labeling to ensure that health care providers refer to this section.

(Response) FDA disagrees with this comment. The conventions for cross-referencing are explained in FDA's guidance for industry on ''Labeling for Human Prescription Drug and Biological Products—Implementing the PLR Content and Format Requirements'' (February 2013). The suggestion that this rule require a cross-reference from the ''Adverse Reactions'' section to the ''Pregnancy'' subsection of labeling is not consistent with the conventions set forth in that guidance. In addition, not every drug product will have pregnancy-related adverse reactions; thus, a required cross-reference is unnecessary.

(Comment 60) One comment suggested that ''Clinical Considerations'' refer to ''available'' interventions rather than ''needed'' interventions to avoid interfering with the practice of medicine.

(Response) FDA agrees with the suggestion to replace the phrase ''interventions that may be needed'' with the phrase ''available interventions.'' In the final rule, FDA requires that if use of the drug is associated with a maternal adverse reaction that is unique to pregnancy or if a known adverse reaction occurs with increased frequency or severity in pregnant women, the labeling must describe the adverse reaction and available intervention(s) for monitoring or mitigating the reaction. This change also allows for differences that may exist in community standards of care and available services across the United States. We note that in the final rule we removed the following language from the codified: ''*e.g.,* monitoring blood glucose for a drug that causes hyperglycemia in pregnancy.''

Fetal/Neonatal adverse reactions. FDA proposed that ''Clinical Considerations'' contain information about any known or anticipated complications in the neonate, including any interventions that might be needed (proposed § 201.57(c)(9)(i)(D)(*2*)(*iv*)).

(Comment 61) Two comments asked FDA to clarify the meaning of the term ''complication.'' One comment suggested that if FDA intended the term ''complication'' to mean adverse reaction in the neonate, the Agency should use the term ''adverse reaction.'' This comment also suggested that if an adverse reaction/complication has been described in the ''Fetal Risk Summary,'' only a cross-reference to § 201.57(c)(9)(i)(C) should be required to appear in § 201.57(c)(9)(i)(D)(*2*)(*iv*). Another comment suggested that FDA state that a ''complication'' could be an ''adverse drug reaction,'' and suggested that FDA state that the term ''adverse drug reaction'' may be used when appropriate.

(Response) FDA agrees that ''adverse reaction'' is a more appropriate term and that it is more consistent with the other portions of the final rule. In the final rule, the term ''adverse reaction'' (as defined in § 201.57(b)(7)) has replaced ''complication.'' Additionally, in the final rule FDA is requiring the inclusion of information regarding fetal adverse reactions in this section of labeling. Although the proposed rule only addressed adverse reactions (referred to there as ''complications'') in the neonate under what in the final rule is required in § 201.57(c)(9)(i)(C), FDA concludes that information intended to inform prescribing decisions for pregnant women appropriately includes information on fetal adverse reactions as well as neonatal adverse reactions. FDA does not believe that there is a

principled distinction between the importance of such information with respect to the fetus and with respect to the neonate. The consistent location under ''Clinical Considerations'' of information about potential adverse reactions in the fetus as well as in the pregnant woman and the neonate, and about available interventions, will make the information in that subsection more useful, as well as easier to identify for prescribers and other health care providers. Accordingly, the final rule requires that if it is known or anticipated that maternal drug therapy increases the risk of an adverse reaction in the fetus or the neonate, the labeling must describe the adverse reaction, the potential severity and reversibility of the adverse reaction, and available intervention(s) for monitoring or mitigating the reaction.

FDA disagrees with the suggestion that if an adverse reaction/complication has been described in the ''Fetal Risk Summary,'' only a cross-reference to § 201.57(c)(9)(i)(C) should be required to appear in § 201.57(c)(9)(i)(D)(*2*)(*iv*). As discussed in the draft guidance on pregnancy and lactation labeling, which is being published concurrently with the final rule, the ''Clinical Considerations'' portion of the labeling is intended to describe fetal/neonatal adverse reactions that are not adverse developmental outcomes. Therefore, because the two portions of the labeling address different potential reactions/outcomes, a cross-reference would not be appropriate.

Additionally, in the final rule, FDA added the requirement that the labeling must describe, if known, the effect of dose, timing, and duration of exposure on the risk of an adverse reaction in the fetus or neonate as FDA has concluded that this information is important for informing prescribing decisions.

Drug effects during labor or delivery. FDA proposed that the ''Clinical Considerations'' portion of pregnancy labeling contain information about drug effects during labor or delivery for drugs that have a recognized use during labor or delivery, whether or not the use is stated as an indication in the labeling, or are expected to affect labor or delivery (proposed § 201.57(c)(9)(i)(D)(*3*)).

(Comment 62) One comment supported the proposal to merge information about labor and delivery into the ''Pregnancy'' subsection of labeling.

Another comment expressed concern that including information about drugs used during labor or delivery, including drugs that are used off-label during labor or delivery, conflicts with FDA's long-standing position that off-label information is not to be included in labeling.

(Response) We note that, as stated in the proposed rule (73 FR 30831 at 30844), the language proposed for this heading contained only slight modifications from that in existing § 201.57(c)(9)(ii). However, because important safety information, whether for an approved or unapproved use, may be required to be included in labeling (see, *e.g.,* § 201.57(c)(6)(i)), we concluded that it is not necessary to include specific language regarding this issue. Therefore, FDA has removed the language regarding ''drugs that have a recognized use during labor or delivery, whether or not the use is stated as an indication in the labeling.'' In the final rule, FDA revised the heading ''Drug effects during labor or delivery'' to ''Labor or delivery,'' which is consistent with the level of specificity used in the other headings under ''Clinical Considerations.''

v. *Data.*

FDA proposed that the following information be included in the ''Pregnancy'' subsection of labeling under the subheading ''Data'':

(1) Under the subheading ''Data,'' the ''Pregnancy'' subsection of the labeling must provide an overview of the data that were the basis for the fetal risk summary.

(2) Human and animal data must be presented separately, and human data must be presented first.

(3) The labeling must describe the studies, including study type(s) (*e.g.,* controlled clinical or nonclinical, ongoing or completed pregnancy exposure registries, other epidemiological or surveillance studies), animal species used, exposure information (*e.g.,* dose, duration, timing), if known, and the nature of any identified fetal developmental abnormalities or other adverse effect(s). Animal doses must be described in terms of human dose equivalents and the basis for those calculations must be included.

(4) For human data, positive and negative experiences during pregnancy, including developmental abnormalities, must be described. To the extent applicable, the description must include the number of subjects and the duration of the study.

(5) For animal data, the relationship of the exposure and mechanism of action in the animal species to the anticipated exposure and mechanism of action in humans must be described. If this relationship is not known, that should be stated (proposed § 201.57(c)(9)(i)(E)).

FDA received comments about the information required under ''Data'' in the proposed rule and made some changes to the final rule. The following discussion addresses these comments, our responses, and the changes to the final rule.

(Comment 63) *References.* One comment suggested that under ''Data,'' the labeling should include references for the cited data. The comment explained that including references for the data would allow clinicians and other health care workers to further research pregnancy issues.

(Response) We decline this suggestion. FDA has determined that prescription drug labeling is intended to facilitate prescribing decisions and is not intended as a research tool. We also note that this final rule is a part of labeling regulations, found at § 201.57, which address the inclusion of references in prescription drug labeling (see § 201.57(c)(16)).

(Comment 64) *Postmarketing reporting of adverse reactions.* One comment stated that if specific numbers of adverse event reports are included in drug labeling, the labeling will need to be constantly updated. The comment suggested that the Agency instead consider using quantitative measures of frequency to produce a more stable label.

(Response) FDA acknowledges that the inclusion in labeling of actual numbers of postmarketing reports for particular adverse reactions is often not appropriate. We agree that the number of postmarketing reports of adverse reactions changes over time and labeling may become rapidly outdated. In addition, postmarketing reports of adverse reactions generally do not establish an incidence or prevalence of a particular outcome or definitively demonstrate an association between prenatal exposure to the drug in question and the adverse developmental outcome. However, FDA also recognizes that there may be isolated situations in which reporting of adverse reactions corroborates other human data and, in these situations, it may be appropriate to list a specific number of cases with the date when the reporting was collected. FDA will consider whether the labeling for a drug product should include specific numbers of reports of adverse reactions on a case-by-case basis based on evaluating all available data and principles of epidemiology and data interpretation.

In the final rule, FDA replaced the phrase ''provide an overview of the data'' with ''describe the data.'' FDA made this change to clarify our intention that under the subheading

''Data,'' the labeling must include a more detailed description of the data than might be understood from use of the term ''overview.'' In the final rule, FDA also added the requirement that under ''Data,'' the labeling describe the data that are the basis for the ''Clinical Considerations.'' The proposed rule stated that ''Data'' must describe the data that were the basis for the fetal risk summary, and did not address the data that were the basis for ''Clinical Considerations.'' FDA has determined that there is no principled reason to distinguish between the data under the fetal risk summary and that underlying ''Clinical Considerations.'' Accordingly, the final rule requires that under the subheading ''Data,'' the labeling describe the data that are the basis for both the ''Risk Summary'' and ''Clinical Considerations.'' This subheading, therefore, is only required to the extent that there are data that are the basis for these two subheadings and the headings under them.

FDA has also determined that the information in labeling would be clearer if human data and animal data appeared separately under applicable headings. In the final rule, FDA requires that human and animal data be presented separately under the headings ''Human Data'' and ''Animal Data.''

In the final rule, FDA requires that for human data, the labeling must describe adverse developmental outcomes, adverse reactions, and other adverse effects. To the extent applicable, the labeling must describe the types of studies or reports, number of subjects and the duration of each study, exposure information, and limitations of the data. The final rule requires that both positive and negative study findings be included. The proposed rule listed various types of studies. These were removed from the final rule because we determined that it is more appropriate to discuss these elements in guidance.

Animal data. FDA proposed that human and animal data must be presented separately, and human data must be presented first.

(Comment 65) One comment suggested that FDA omit the requirement that human data must be presented first. The comment explained that the most robust data should be presented first regardless of whether it is animal or human data.

(Response) FDA declines this suggestion. We have determined that to promote consistency and to meet readers' expectations that information will always be found in the same place, a fixed order of presentation must be maintained. Additionally, as discussed in the preamble to the proposed rule, the importance of human data in labeling was stressed by physicians who participated in focus group testing of the model labeling format and also by the FDA advisory committee that provided input on the proposed format (73 FR 30831 at 30841). FDA has determined that human data should always be presented first because human data are often the most relevant to prescribers, and animal data may not always be applicable to humans.

FDA also proposed that animal doses must be described in terms of human dose equivalents and the basis for those calculations must be included.

(Comment 66) Two comments suggested that the final rule remove the requirement to use ''administered dose'' as a comparator between animal and human data and to replace it with comparisons based on systemic exposure, if available. One of these comments explained that basing the comparison on systemic exposure will provide greater consistency within the labeling and will also provide a way to more easily make comparisons between drugs.

(Response) FDA declines this suggestion to restrict the comparison to only those based on systemic exposure. We agree that comparisons based on systemic exposure could provide consistency within labeling and therefore the final rule requires that they must be included when data are available, but the data are not always available for such a comparison. FDA believes that including the human dose equivalent may be more meaningful information for health care providers, particularly in the absence of data to make comparisons based on systemic exposure, and as such, in the final rule, a comparison of the animal to human doses must be included using the data available.

The proposed rule required that for animal data under the ''Data'' component the relationship of the exposure and mechanism of action in the animal species to the anticipated exposure and mechanism of action in humans be described. In the final rule, we removed this requirement because often this relationship is not known. The final rule requires that animal doses or exposures be described in terms of human dose or exposure equivalents, and that the basis for those calculations be included.

2. 8.2 Lactation

FDA proposed that the ''Nursing mothers'' subsection of prescription drug labeling be replaced with the subsection ''Lactation'' (proposed §§ 201.56(d)(1) and 201.57(c)(9)(ii)). FDA proposed that the ''Lactation'' subsection of prescription drug labeling contain the following subheadings: ''Risk Summary,'' ''Clinical Considerations,'' and ''Data'' (proposed § 201.57(c)(9)(ii)). FDA received many comments about the proposed ''Lactation'' subsection and made changes to the final rule based on these comments. The discussion that follows addresses these comments, our responses, and the changes FDA made to the final rule.

a. *General comments.*

i. *Support for ''Lactation'' subsection*

(Comment 67) FDA received many comments expressing support for the proposed ''Lactation'' subsection. One of these comments explained that it is essential for drug labeling ''to carry 'best science' information that enables clinicians to efficiently and thoroughly review what is known about the drug and any reported health effects to the breast-fed infant.'' The comment stated that the proposed rule would facilitate more efficient consideration of the data.

(Response) We agree with these comments, and our final rule requires labeling to include a subsection on lactation with risk and benefit information related to breastfeeding and the breast-fed infant.

ii. *Drug alternatives*

(Comment 68) One comment suggested that a statement should be included that many drugs for which we may not have lactation data have a suitable alternative for which we do have data.

(Response) We decline to adopt this comment. We do not believe it would be appropriate to include this type of statement in labeling. Because the comparative risks and benefits will vary among individual patients, a health care provider, in consultation with his or her patient, is in the best position to determine whether there is a ''suitable alternative'' for a particular drug.

iii. *Validating data*

(Comment 69) One comment expressed concern about the potential for bias or omissions with respect to which data the sponsor includes and the risk statements the sponsor uses to characterize such data. The comment encouraged FDA to employ all reasonable means to validate the sponsor's collection, evaluation, and subsequent conclusions regarding lactation data.

(Response) FDA agrees. FDA will review data available in literature and sponsor-submitted data used for developing the ''Lactation'' subsection of drug labeling. We note that this does not require a change to the final rule

because FDA's normal review process for prescription drug labeling includes validating the applicant's collection, evaluation, and subsequent conclusions regarding data.

b. *Risk summary*

i. *''Active metabolites''*

(Comment 70) Two comments suggested that FDA revise the ''Risk Summary'' so that it explicitly refers to active metabolites of the drug, in addition to the drug itself.

(Response) FDA agrees with this comment. We also have determined that it is appropriate to include information about the effects of a drug and/or its active metabolite(s) not only in the ''Risk Summary,'' but under other subheadings in the ''Lactation'' subsection of labeling. Therefore, the final rule has been revised to refer explicitly to drugs and/or their active metabolites.

ii. *''Compatible with breastfeeding''*

FDA proposed that under the subheading ''Risk Summary,'' if, as described under § 201.57(c)(9)(ii)(A)(*1*) through (c)(9)(ii)(A)(*3*) of the section, the data demonstrate that the drug does not affect the quantity and/or quality of human milk and there is reasonable certainty either that the drug is not detectable in human milk or that the amount of drug consumed via breast milk will not adversely affect the breast-fed child, the labeling must state: The use of (*name of drug*) is compatible with breastfeeding. After this statement (if applicable), the risk summary must summarize the drug's effect on milk production, what is known about the presence of the drug in human milk, and the effects on the breast-fed child (proposed § 201.57(c)(9)(ii)(A)).

(Comment 71) Two comments suggested that FDA eliminate the statement, ''The use of (*name of drug*) is compatible with breastfeeding'' from the ''Lactation'' subsection of the final rule. One of the comments explained that it will be difficult to determine whether a drug is compatible with breastfeeding with such definitive certainty, especially since the term ''compatible'' implies safety. Another comment suggested that in the final rule FDA should replace the statement ''compatible with breastfeeding'' with a standardized statement that ''sufficient'' human data exist to indicate that the drug does or does not adversely affect the breast-fed child, followed by a supportive narrative.

(Response) FDA agrees that the term ''compatible'' is not clearly defined and implies that the use of a drug during lactation is ''safe.'' No drug is completely safe even in a person who is not pregnant or breastfeeding. In addition to offering potential therapeutic benefit(s), all drugs have potential side effects and risks involved with their use. The balance between those benefits and risks is taken into account not just at the approval stage, but also helps direct diagnostic and treatment recommendations for a particular patient in a particular clinical scenario. Accordingly, in the final rule FDA removed the statement ''The use of (*name of drug*) is compatible with breastfeeding.''

Breastfeeding offers significant health benefits to both the child and mother. Different drugs and/or their active metabolites pass into breast milk in different concentrations; they may or may not be orally bioavailable in the infant, and they may or may not result in significant adverse reactions in the short term or adverse outcomes in the long term. Often, all of the potential risks related to drug treatment during lactation are not known even though the benefits of breastfeeding are known and substantial.

FDA declines the suggestion to include a standardized statement that ''sufficient'' human data exist to indicate that the drug does or does not adversely affect the breast-fed child, followed by a supportive narrative. However, the final rule requires that if the drug is absorbed systemically, the labeling must include, under ''Risk Summary,'' available information, if relevant, on the known or predicted effects on the breast-fed child from exposure to the drug and/or its active metabolite(s), including systemic and/or local adverse reactions. If the available information is sufficient to determine that use of the drug is contraindicated during breastfeeding, this significant information is required at the beginning of the ''Risk Summary.'' The ''Risk Summary'' must state when there are no data to assess the effects of the drug on the child.

FDA also revised the final rule to require that if studies demonstrate the presence of the drug and/or its active metabolite(s) in human milk but the drug and/or its active metabolite(s) are not expected to be systemically bioavailable to the breast-fed child, then the ''Risk Summary'' must describe the disposition of the drug and/or its active metabolite(s). FDA added this requirement to the final rule to identify situations in which a drug and/or its active metabolite(s) are present in human milk but the breast-fed child does not have any systemic exposure because of degradation in the gastrointestinal tract.

iii. *Not systemically absorbed*

FDA proposed that if data demonstrate that a drug is not systemically absorbed, the fetal risk summary must contain only the following statement: (*Name of drug*) is not absorbed systemically from (*part of body*) and cannot be detected in the mother's blood. Therefore, detectable amounts of (*name of drug*) will not be present in milk. Breastfeeding is not expected to result in fetal exposure to the drug (proposed § 201.57(c)(9)(ii)(A)).

(Comment 72) One comment suggested that the statement be revised to focus on the route of administration rather than on the part of the body where the drug is administered. The comment also suggested that the language ''cannot be detected in blood'' could be omitted because it is redundant with ''not systemically absorbed.''

(Response) FDA agrees with this comment and we removed the phrase ''cannot be detected in blood'' from the final rule.

We also agree with the suggestion to focus on the route of administration. FDA agrees that ''part of the body'' could be misconstrued and we have determined that the use of ''route of administration'' to describe how the drug enters the body is more consistent with labeling language that addresses dosing and administration. In the final rule, FDA has replaced ''part of the body'' with ''route of administration.''

(Comment 73) Another comment suggested revising the language ''systemically absorbed'' to ''has a systemic effect'' to include the action of biological products (vaccines) that are immune stimulants rather than chemicals that are absorbed.

(Response) FDA declines the suggestion to change the language ''systemically absorbed'' to ''has a systemic effect.'' The terms ''systemically absorbed'' and ''absorbed systemically'' refer to the absorption of the drug or biological product from its site of administration into serum and/or other body tissues where the drug or biological product, including a vaccine, can reach its receptor or target cell and exert its pharmacological or immunological effect. A drug or biological product that is not systemically absorbed will not be excreted into human milk and, therefore, breastfeeding should not result in the child's exposure to the drug. In the final rule, FDA has deleted the sentence, ''Therefore, detectable amounts of (*name of drug*) will not be present in breast milk.'' The final rule also replaces the sentence, ''Breastfeeding is not expected to result in fetal exposure to the drug'' with

''breastfeeding is not expected to result in exposure of the child to (*name of drug*).''

(Comment 74) Two comments noted that the term ''fetal'' was used improperly in this section of the proposed rule.

(Response) FDA agrees and has removed the term ''fetal'' from the ''Lactation'' subsection and replaced it with the term ''child.''

iv. *Presence of drug in human milk*

FDA proposed that under the heading ''Presence of drug in human milk'':

(1) The risk summary must describe the presence of the drug in human milk in one of the following ways: The drug is not detectable in human milk; the drug has been detected in human milk; the drug is predicted to be present in human milk; the drug is not predicted to be present in human milk; or the data are insufficient to know or predict whether the drug is present in human milk;

(2) If studies demonstrate that the drug is not detectable in human milk, the risk summary must state the limits of the assay used; and

(3) If the drug has been detected in human milk, the risk summary must give the concentration detected in milk in reference to a stated maternal dose (or, if the drug has been labeled for pediatric use, in reference to the labeled pediatric dose), an estimate of the amount of the drug consumed daily by the infant based on an average daily milk consumption of 150 milliliters per kilogram of infant weight per day, and an estimate of the [percentage] of the maternal dose excreted in human milk (proposed § 201.57(c)(9)(ii)(A)(*2*)(*i*)–(c)(9)(ii)(A)(*2*)(*iii*)). We received comments about this portion of the ''Lactation'' subsection of the proposed rule. The discussion that follows addresses these comments, our responses, and the changes FDA made to this portion of the ''Lactation'' subsection of the final rule.

(Comment 75) *Predicting whether drug is present in human milk.* Several comments objected to the proposal that the ''Risk Summary'' state that the drug is ''predicted'' or ''not predicted'' to be present in human milk. One of these comments stated that avoiding predictions and relying instead on clinical data would better assist providers. Two comments suggested that the statements about whether the drug is predicted or not predicted to be present in human milk should be omitted because the other proposed descriptions effectively cover the range of potential options.

(Response) FDA agrees that the terms ''predicted'' and ''not predicted'' should not be used in the ''Risk Summary,'' and that a description of available data, if relevant, on the presence of the drug and/or its active metabolite(s) in human milk should be used instead. In addition, FDA has determined that, in order to provide clarity in the ''Risk Summary,'' in situations where there are no data to assess whether the drug and/or its active metabolite(s) are present in human milk, the ''Risk Summary'' must so state.

(Comment 76) *Limits of the assay used.* Two comments suggested omitting assay information if the presence of drug in milk is not detectable. The comments stated that assay information is overly technical and unfamiliar for many health care providers. In addition, the comments explained that it would be presumed that during its review of the data, the review division at FDA would consider the validity of studies, including the assay's reliability and sensitivity, before approving the inclusion in labeling of a statement that the drug is not detectable in human milk.

(Response) FDA declines this comment. We have determined that the limit of the assay is critical to understanding the amount of the drug and/or its active metabolite(s) that may or may not be present in human milk. We also believe that most health care providers are capable of interpreting this data when presented in labeling and that health care providers are familiar with the importance of assay limits for all types of laboratory testing. In the final rule, FDA has retained the requirement from the proposed rule that if studies demonstrate that the drug and/or its active metabolite(s) are not detectable in human milk, the ''Risk Summary'' must state the limits of the assay used.

(Comment 77) *Concentration of the drug detected in human milk.* Two comments expressed support for FDA's proposal that the ''Lactation'' subsection of prescription drug labeling provide the concentration of the drug detected in human milk in reference to a stated adult or labeled pediatric dose. One of these comments suggested that the labeling should also include the milligrams per kilogram received per day and the percentage of the weight-equivalent therapeutic dose administered to the mother. This comment requested that the doses be presented according to infant age ranges when possible. A separate comment suggested providing a calculation of the estimated infant daily dose consumed as compared to available pediatric dosing rather than to maternal dosing, but added that clinicians may have difficulty interpreting the calculations.

One comment stated that the concentration of the drug detected in milk should not be made in reference to the maternal dose or the labeled pediatric dose. The comment explained that the concentration of a drug in milk may vary widely depending upon whether it reflects steady-state or a single dose, and could vary based on the timing between the ingestion of the drug and taking the sample. The comment suggested that an estimate of the amount of the drug consumed daily by the infant could be made in reference to the maximum maternal daily dose or the maximum labeled pediatric dose and that ''an estimate of the [percentage] of the maternal dose excreted in human milk'' could be omitted.

One comment suggested that FDA standardize the approach to presenting drug concentrations in breast milk and stated that this would ensure that uniform data are presented by all manufacturers, allowing for easy comparisons between prescription products. The comment also suggested that FDA provide a guidance document highlighting the value of breast milk area under the curve (AUC) concentrations, explaining that providing standardized ways of calculating weight-normalized drug doses and average breast milk consumption could better guide manufacturers and help create a unified approach to describing drug concentrations in breast milk.

(Response) FDA addresses these issues in the draft guidance for industry on ''Clinical Lactation Studies—Study Design, Data Analysis, and Recommendations for Labeling'' (February 2005) (the draft guidance on clinical lactation studies).

FDA agrees that it would be helpful to clinicians to provide infant drug exposure dosing in milligrams per kilograms received per day so that a clinician may compare it to a labeled infant or pediatric dose if available. However, because of the technical considerations for calculating drug and/or active metabolite levels in milk, FDA is not requiring this in the final rule.

FDA has determined that the actual or calculated infant daily dose must be compared to the labeled infant or pediatric dose, when available, and to the maternal dose when pediatric dosing is not available. When infant or pediatric dosing is available for a drug and pediatric pharmacokinetic data are available for a drug and/or its active metabolite(s), these data provide an effective way to estimate comparative exposure (and potentially comparative

safety) of a breast-fed child versus a child receiving a drug therapeutically.

Although not required by the final rule, FDA agrees that data presented according to infant age groups could be useful given the changes in infant hepatic and renal function during the first few months of life, and infants' increasing ability with age to metabolize and clear drugs and/or their active metabolites. These data may not always be available, but when they are, their presentation stratified by age would be clinically relevant and should be included in labeling.

(Comment 78) *''No data.''* One comment suggested removing the phrase ''no data'' from the ''Risk Summary'' in the ''Lactation'' subsection, because there are rarely no data for a drug.

(Response) FDA disagrees with the suggestion to remove the phrase ''no data'' from the ''Risk Summary.'' Often, there are no lactation data (either human or animal) at the time of approval of NDAs and BLAs.

v. *Effects on milk production and quality*

FDA proposed that if the drug is absorbed systemically, the risk summary must describe the effect of the drug on the quality and quantity of milk, including milk composition, and the implications of these changes to the milk on the breast-fed child (proposed § 201.57(c)(9)(ii)(A)(*1*)).

(Comment 79) Several comments stated that it is seldom feasible to adequately study the effects of a drug on the quality and quantity of breast milk, and this information should only be provided when available. One comment explained that to be scientifically valid, such evaluation requires a study before, during, and after drug exposure. This comment explained that further complicating factors are substantial inter- and intra-individual variation and small study sample size.

One comment requested that FDA include information about the effects of the drug on the woman's milk supply and other issues that affect the process of breastfeeding. The comment stated that many women are advised against taking medications that affect milk supply while lactating but are not informed that this is the reason they should avoid these medications.

(Response) Although FDA agrees that it is not always possible to determine the effects of a drug and/or its active metabolite(s) on milk production, we have determined that when the relevant data are available, this information must be included in the labeling. In the final rule, FDA requires that the ''Risk Summary'' describe the effects of the drug and/or its active metabolite(s) on milk production, and if there are no data to assess the effects of the drug and/or its active metabolite(s) on milk production, the ''Risk Summary'' must so state.

With respect to milk quality and composition, there are currently no established standards or documented population variability for milk content. It is also not known how much change in various milk components would reduce the known benefits of breastfeeding relative to the risks of exposure to a drug and/or its active metabolite(s) through breast milk combined with any potential effects on milk composition and quality. Accordingly, in the final rule, FDA has removed the requirement that the ''Risk Summary'' describe the effect of the drug on the quality and composition of milk, and the implications of these changes to the milk on the breast-fed child.

vi. Sufficient Data

(Comment 80) One comment noted that the proposed rule does not require sufficient data to reach conclusions in the ''Risk Summary'' in the ''Lactation'' subsection, and suggested that FDA discuss what constitutes sufficient data, as it does in the ''Pregnancy'' subsection.

(Response) As discussed previously, many comments disagreed with FDA's proposed use of the term ''sufficient'' in the ''Pregnancy'' subsection of labeling. The comments stated that the term was not clearly defined in the proposed rule, and suggested that it would be difficult to apply the term consistently across drug labeling. Based on FDA's consideration of these comments, the final rule does not refer to ''sufficient'' data in either the ''Pregnancy'' or the ''Lactation'' subsection.

vii. Risk and Benefit Statement

(Comment 81) FDA received seven comments noting that the proposed ''Lactation'' subsection did not require the inclusion in labeling of any information about the benefits of breastfeeding. Some of these comments recommended that FDA add such a statement to the final rule to prevent patients from unnecessarily foregoing or discontinuing breastfeeding.

(Response) FDA acknowledges that the proposed rule did not require the inclusion of information about the benefits of breastfeeding. The Agency has determined that the inclusion in the ''Lactation'' subsection of labeling of a risk and benefit statement will provide a useful framework for health care providers to use when making prescribing decisions for lactating patients. In the final rule, FDA requires that for drugs absorbed systemically, unless breastfeeding is contraindicated during drug therapy, a statement that the developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for the drug and any potential adverse effects on the breast-fed child from the drug or from the underlying maternal condition, must be included at the end of the ''Risk Summary'' in the ''Lactation'' subsection of labeling.

c. Clinical Considerations

FDA proposed that under the subheading ''Clinical Considerations,'' the labeling must provide the following information to the extent it is available: (1) Information concerning ways to minimize the exposure of the breast-fed child to the drug, such as timing the dose relative to breastfeeding or pumping and discarding milk for a specified period; (2) information about potential drug effects in the breast-fed child that could be useful to caregivers, including recommendations for monitoring or responding to these effects; and (3) information about dosing adjustments during lactation. This information must also be included in the 'Dosage and Administration' and 'Clinical Pharmacology' sections (proposed § 201.57(c)(9)(ii)(B)(*1*)–(c)(9)(ii)(B)(*3*)). FDA received comments about the proposed ''Clinical Considerations'' subheading. The discussion that follows addresses these comments, our responses, and FDA's changes to the final rule.

i. Other Therapies

In the Proposed rule, FDA included sample labeling for several fictitious drugs. In the ''Clinical Considerations'' portion of the ''Lactation'' subsection, the ALPHAZINE sample stated that ''Other medical therapies are available for treatment of maternal hypertension.''

(Comment 82) Two comments disagreed with the inclusion of this statement. The comments explained that the statement is confusing because although no comparator data are presented, clinicians may infer that other drugs in the class are safe and effective.

(Response) We note that the language to which these comments refer was included in sample labeling included with the proposed rule, and not in the proposed rule itself. FDA included sample labeling with the proposed rule to serve as examples of how to apply the requirements of the proposed rule in different scenarios. We note that the final rule does not include sample labeling. FDA agrees, however, that

statements such as, ''Other medical therapies are available for treatment of maternal hypertension,'' may be confusing, and should not be included in the ''Pregnancy'' or ''Lactation'' subsections of labeling.

ii. Minimizing Exposure to the Breast-Fed Child

(Comment 83) *General comments.* Four comments disagreed with the proposal to include information regarding minimizing exposure of the breast-fed child in the ''Clinical Considerations'' portion of the ''Lactation'' subsection. These comments explained that inclusion of this information could discourage women from breastfeeding even when there is no reason for concern. One comment noted that this information should only be included when there is information that breastfeeding should be withheld during drug therapy and the timing of pumping and discarding of breast milk can be provided. Alternatively, the comment suggested stating when information regarding the timing of pumping and discarding breast milk cannot be provided. Another comment noted that this information should not be obligatory when data suggest that there is not sufficient excretion of the drug in milk to cause concern for the infant. The comment explained that including this information when the ''Risk Summary'' and ''Data'' components have already stated that the drug is compatible with breastfeeding could give the false impression that the drug is unsafe for the child and may encourage women to discontinue breastfeeding. One comment noted that in cases when the drug disappears from breast milk with a known half-life, it is possible to minimize infant exposure by recommending dosing occur at certain times related to feeding.

(Response) FDA notes that information concerning minimizing exposure to the breast-fed child must be provided only to the extent it is available and relevant. In addition, the final rule was revised to clarify that information concerning minimizing drug exposure in the breast-fed child must be included only if the drug and/or its active metabolite(s) are present in human milk in clinically relevant concentrations; the drug does not have an established safety profile in infants; and the drug is used either intermittently, in single doses, or for short courses of therapy. As discussed further in our response to Comment 84, the final rule also requires that, when applicable, the labeling describe ways to minimize a breast-fed child's oral intake of topical drugs applied to the breast or nipple skin.

(Comment 84) *Topical products.* In the proposed rule, FDA did not provide for inclusion of data regarding topical drugs that are not absorbed systemically by the mother but that may transfer to infants during breastfeeding. One comment requested that FDA include a standardized statement in the ''Risk Summary'' about such drug products.

(Response) Situations in which a topical pharmaceutical product can result in infant exposure without systemic absorption of the product into maternal serum are limited to topicals applied to the skin of the breast, especially that of the nipple and areola. For prescription drug products, these topicals would most likely include corticosteroids and anti-infectives. FDA acknowledges that the proposed rule did not accommodate a situation in which a drug product does not result in maternal systemic exposure but could result in infant systemic exposure. In response to this comment, FDA revised the ''Minimizing exposure'' portion of ''Clinical Considerations'' to accommodate the inclusion of information about such products. In the final rule, FDA added a requirement that, when applicable, the labeling must also describe ways to minimize a breast-fed child's oral intake of topical drugs applied to the breast or nipple skin.

iii. Drug Effects in the Breast-Fed Child and Monitoring for Adverse Reactions

FDA proposed that the ''Clinical Considerations'' portion of the ''Lactation'' subsection of prescription drug labeling include information about potential drug effects in the breast-fed child that could be useful to caregivers, including recommendations for monitoring or responding to these effects (proposed § 201.57(c)(9)(ii)(B)(*2*)).

(Comment 85) FDA received one comment about this portion of the proposed ''Clinical Considerations.'' The comment suggested that FDA omit the first part of this provision—''information about potential drug effects in the breast-fed child''—because this information duplicates the information required to appear in the ''Risk Summary'' under proposed § 201.57(c)(9)(ii)(A)(*3*), ''Effects of drug on the breast-fed child.'' The comment also stated that the term ''recommendations'' in the second part of this provision could interfere with the practice of medicine. The comment suggested the following language: ''Information about ways to monitor for, or respond to, potential drug effects in the breast-fed child that could be useful to caregivers.''

(Response) FDA acknowledges that this portion of the proposed rule appeared to require information duplicative of information in the ''Risk Summary.'' We removed the language, ''information about potential drug effects in the breast-fed child,'' from the ''Clinical Considerations'' portion of the ''Lactation'' subsection of the final rule. In the final rule, when relevant information is available about potential adverse effects in an infant due to exposure to the maternal drug and/or its active metabolite(s) through human milk, this information must be included in the ''Risk Summary.'' FDA also concluded that it was not necessary to characterize information about the potential effects of a drug and/or its active metabolite(s) on a breast-fed child as being useful to caregivers because, although caregivers sometimes read prescription drug labeling, it is not directed at them, and individual health care providers are in the best position to discuss with their patients information that may be useful for the patients to share with other caregivers. Therefore, the reference to information that may be useful to caregivers also has been removed.

FDA acknowledges the comment concerning the use of the term ''recommendations'' in the second part of this provision, and in the final rule has removed the term ''recommendations for monitoring'' and replaced it with ''available interventions for monitoring or mitigating.'' The final rule requires that under ''Clinical Considerations'' the labeling describe information about available interventions for monitoring or mitigating the adverse reactions described in the ''Risk Summary.'' We note that this language is consistent with the language in the ''Pregnancy'' subsection.

iv. Dose Adjustments

(Comment 86) One comment stated that dose adjustment information should not be included in the ''Lactation'' subsection. The comment suggested that dosing information generally should be restricted to the ''Dosage and Administration'' section of labeling.

(Response) FDA agrees with the suggestion that we omit information about dose adjustments from the ''Lactation'' subsection of prescription drug labeling, although this decision is not based on a conclusion (as suggested in the comment) that dosing information generally should be restricted to the ''Dosage and Administration'' section of

labeling. FDA has determined that other than during the immediate postpartum period when a woman's physiology is reverting from a pregnant to a nonpregnant state, a lactating woman is unlikely to require dose adjustments for drugs. The physiological changes associated with lactation are unlikely to result in pharmacokinetic changes significant enough to warrant maternal dose adjustments. Therefore, FDA has determined that all available and relevant information about dose adjustments during pregnancy and the postpartum period must be included in the ''Pregnancy'' subsection of labeling. In the final rule, FDA has removed the requirement that information about dosing adjustments during lactation be included in the ''Lactation'' subsection of labeling.

d. Data

FDA proposed that under the subheading 'Data,' the 'Lactation' subsection of the labeling must provide an overview of the data that are the basis for the risk summary and clinical considerations (proposed § 201.57(c)(9)(ii)(C)). FDA received comments about this portion of the rule. One comment expressed support for presenting lactation data under ''Data'' when available. The other comments and changes we made in response to those comments are explained in this section of the document.

(Comment 87) FDA received comments requesting that the Agency clarify when animal lactation data should be included in labeling. Several comments questioned the usefulness of animal lactation data in the absence of clinical data. One comment stated that extrapolation of animal data to humans may not be helpful without stating what is known about the correlation to humans.

Several comments stated that only human data should be presented when it is available. Two comments requested that if, in cases where both human and animal data are available, FDA decides to retain the requirement that both kinds of data be presented, the ''Lactation'' subsection be revised to state that clinical data are to be presented before preclinical data.

One comment requested additional clarification regarding the quantity and quality of animal data that would support inclusion of the data in labeling, and asked that FDA provide sample labeling for a drug for which only animal lactation data are available. Another comment suggested that the labeling state when there is an absence of available or sufficient human and/or animal data in the ''Lactation'' subsection.

(Response) The preamble to the proposed rule did not include a discussion of animal lactation data, and the inclusion of animal lactation data was not addressed in the codified section of the proposed rule. In the final rule, under ''Risk Summary,'' FDA defines situations for which animal lactation data must and must not be included in the ''Lactation'' subsection. Animal lactation data can be helpful in predicting whether a drug and/or its active metabolite(s) will be present in human milk; however, because of species-specific differences in lactation physiology, animal lactation data typically do not reliably predict drug levels in human milk. FDA added a requirement to the final rule that when relevant human lactation data are available, animal data must not be included unless the animal model is specifically known to be predictive for humans. In addition, under ''Risk Summary,'' ''Presence of drug in human milk,'' FDA clarified that if only animal lactation data are available, the ''Risk Summary'' must state only whether or not the drug and/or its active metabolite(s) were detected in animal milk and specify the animal species. Although animal data do not reliably predict whether a drug and/or its active metabolite(s) will be present in human milk, in the absence of human data, FDA determined that the fact that a drug and/or its active metabolite(s) were or were not detected in animal milk may nevertheless be useful in informing prescribing decisions.

In the final rule, FDA revised the ''Data'' portion of the ''Lactation'' subsection to require that the labeling ''describe the data that are the basis for the Risk Summary and Clinical Considerations'' and removed the requirement that the labeling ''provide an overview of the data.'' FDA made this change to clarify that under ''Data,'' the labeling must include a more detailed description of the data than might be understood from use of the term ''overview,'' as well as to maintain consistency between the ''Data'' portions of the ''Lactation'' and ''Pregnancy'' subsections. Furthermore, this subheading is only required to the extent that there are data that are the basis for the Risk Summary and Clinical Considerations subheadings, and the headings under them.

3. 8.3 Females and Males of Reproductive Potential

In the final rule, FDA is adding a requirement that information regarding pregnancy testing, contraception, and infertility be relocated in labeling under subsection ''8.3 Females and Males of Reproductive Potential.'' FDA is adding this requirement to the final rule based on public comments regarding these issues, and based on the Agency's conclusion that this information should be presented in labeling in a consistent location. Subsection ''8.3 Females and Males of Reproductive Potential'' includes three subheadings, ''Pregnancy Testing,'' ''Contraception,'' and ''Infertility.'' Each subheading should only be included if it is applicable or if relevant information is available, and Section 8.3 should be omitted in its entirety if none of the subheadings are applicable. The comments are discussed in detail in our responses to Comments 88, 89, and 90.

Information concerning pregnancy testing, contraception, and infertility is important for informing decisions made by patients, in consultation with their health care providers, regarding the use of prescription drugs before or during pregnancy. This information is in many ways inherently linked to the scientific and medical rationale underpinning the Pregnancy subsection of prescription drug labeling. However, in the course of developing this final rule, and in particular in evaluating comments 88, 89, and 90, FDA concluded that because there was no consistent placement in the labeling of information about pregnancy testing, contraception, and infertility, it was difficult for health care providers to find this important information. For example, clinical advice on infertility might be found with the discussion of animal data in the ''Nonclinical Toxicology'' section, in the ''Adverse Reactions'' section, or in the ''Warnings and Precautions'' section. Contraception and pregnancy testing recommendations for known or suspected teratogens might be found in the ''Pregnancy'' subsection or in the ''Warnings and Precautions'' section.

(Comment 88) FDA received one comment suggesting that the new labeling explicitly state that a woman taking drugs with potential or known adverse effects on pregnancy outcomes should (1) consider using reliable contraception if she does not intend to become pregnant or (2) if she does intend to become pregnant, seek consultation with her health care provider to discuss medical management of her health condition before becoming pregnant, if possible.

(Response) FDA agrees that when a drug has a potential or known adverse effect on pregnancy outcomes (*e.g.,* is a known or suspected human teratogen), information regarding recommendations or requirements regarding contraception

use must be included in prescription drug labeling. In the final rule, FDA requires that when contraception is required or recommended before, during, or after drug therapy, this information must be included under the subheading ''Contraception'' in subsection ''8.3 Females and Males of Reproductive Potential.'' In addition, it may be appropriate to include in this subsection information concerning counseling females of reproductive potential about pregnancy planning.

Furthermore, the concerns expressed in the comment regarding the inclusion of information about contraception use when taking a drug with potential or known adverse effects on pregnancy outcomes apply equally to information about pregnancy testing, particularly when a drug is a known or suspected human teratogen. Therefore, FDA has determined that information regarding recommendations or requirements concerning pregnancy testing before, during, or after drug therapy must also be included in prescription drug labeling. In the final rule, FDA requires that this information be included under the subheading ''Pregnancy Testing'' in subsection ''8.3 Females and Males of Reproductive Potential.''

(Comment 89) FDA received three comments noting that the ''Pregnancy'' subsection of the proposed rule only addresses risks to the fetus when the drug is administered to a pregnant woman, and it does not address the potential for manifestations of developmental toxicity associated with fetal drug exposure from transfer of drug through semen to the maternal and fetal circulations. One of the three comments noted that the proposed rule does not address the potential for manifestations of developmental toxicity associated with exposure resulting from transfer through the semen or the need for male contraception when a compound is determined to have a predicted risk of developmental toxicity and the transfer of semen is unknown. This comment suggested that statements addressing this issue be added when the information is required for the product. One of the comments suggested that FDA add a section to the final rule that addresses prescribing information for male patients with a partner of reproductive potential or a pregnant partner. Another comment suggested that the risk conclusion statement specify whether it is based on maternal or paternal exposure when that information is available.

(Response) FDA agrees that when relevant information is available, this information should be included in labeling. In the final rule, FDA requires that information about recommended or required use of contraception by men be included under the subheading ''Contraception'' in subsection ''8.3 Females and Males of Reproductive Potential.''

(Comment 90) FDA received one comment requesting that the Agency clarify how and when animal data described in subsection 13.1 of labeling (''Carcinogenesis, Mutagenesis, Impairment of Fertility'') that raises concerns about mutagenesis, impairment of fertility, or pre-implantation loss should be included in subsection ''8.1 Pregnancy.'' The comment also requested that FDA clarify when it would be appropriate to move information from subsection 13.1 to subsection 8.1 or to cross-reference subsection 13.1 in subsection 8.1.

(Response) As stated previously, FDA concluded that it is important to include information about drug-associated fertility effects in labeling in a consistent location and manner. In the final rule, animal data that raise concerns about drug-associated impairment of fertility and/or pre-implantation loss effects must be included under ''Infertility'' in subsection ''8.3. Females and Males of Reproductive Potential.'' In addition, when there are contraception recommendations based on animal mutagenesis data, this information must be included in subsection 8.3 under the Contraception subheading. Because the same concerns about drug-associated fertility effects apply to human data, FDA has determined that human data that raise such concerns also must be included in the ''Infertility'' subsection. With respect to the question about cross-referencing, subsection 8.3 should cross-reference the applicable animal data included in subsection 13.1, consistent with FDA's cross-referencing regulations (*e.g.,* § 201.57(c)(1), (c)(6)(iv), and (c)(15)(ii)). The draft guidance on pregnancy and lactation labeling, which is being published concurrently with this final rule, addresses these issues.

IV. Implementation

FDA proposed that holders of applications (including an NDA, BLA, or efficacy supplement) approved before June 30, 2001, would be required to remove the pregnancy category from their labeling within 3 years after the effective date of this rule. These applications are those that are not subject to the requirements of the PLR. For drugs with applications (including an NDA, BLA, or efficacy supplement) approved on or after June 30, 2001, FDA proposed a phased-in implementation plan that would stagger the required dates these products would be required to replace the content and formatting of the pregnancy and lactation subsections of their labeling with the new content and formatting required by this rule. These applications are those that are subject to the requirements of the PLR.

Table 1 contains the implementation plan that was included in the proposed rule. In table 1, ''Applications'' includes NDAs, BLAs, and efficacy supplements.

TABLE 1—IMPLEMENTATION PLAN

Applications required to conform to new pregnancy/lactation content requirements	Time by which labeling with new pregnancy/lactation content must be submitted to FDA for approval
New or Pending Applications	
Applications submitted on or after the effective date of the pregnancy final rule.	Time of submission.
Applications pending on the effective date of the pregnancy final rule ...	4 years after the effective date of pregnancy final rule or at time of approval, whichever is later.
Approved Applications Subject to the Physician Labeling Rule	
Applications approved any time from June 30, 2001, up to and including June 29, 2002, and from June 30, 2005, up to and including June 29, 2007.	3 years after the effective date of pregnancy final rule.
Applications approved any time from June 30, 2007, up to and including the effective date of the pregnancy final rule.	4 years after the effective date of pregnancy final rule.

TABLE 1—IMPLEMENTATION PLAN—Continued

Applications required to conform to new pregnancy/lactation content requirements	Time by which labeling with new pregnancy/lactation content must be submitted to FDA for approval
Applications approved from June 30, 2002, up to and including June 29, 2005.	5 years after the effective date of pregnancy final rule.

(Comment 91) Two comments stated that the proposed implementation plan was confusing. One of these comments requested that FDA explain the rationale supporting the implementation schedule. Another comment stated the proposed phased-in approach for previously approved drugs may generate confusion. The comment explained that if drug labeling information and drug reference materials contain pregnancy information that is inconsistent between newly approved and previously approved drugs through a 3- to 5-year period, confusion may limit the understanding of the new labeling.

Comments disagreed about whether the length of the implementation schedule was reasonable. One comment stated that the long implementation timeline will delay the delivery of complete information. Another comment stated that FDA should expedite the implementation schedule for licensed drugs that are necessary to maintain the health status of the mother and could harm the fetus if the mother is left untreated. This comment also suggested that the Agency should make supplemental information available in advance of the printed label. Another comment, however, expressed support for the proposal to give sponsors 3 years after the effective date of the rule to remove the pregnancy categories.

(Response) The Agency has taken all of these comments into consideration, and has decided to maintain the implementation schedule that was published in the proposed rule. The implementation schedule follows the timetable used for implementation of the PLR and works to balance the anticipated workload for the review of labels. The purpose of having a staggered approach is to avoid overburdening both the Agency and industry. The implementation plan for the final rule (also referred to as the Pregnancy and Lactation Labeling Rule (PLLR)) is modeled from the implementation plan for the PLR and experience acquired from that plan. The PLLR implementation timeline also depends on the PLR implementation and the extent to which applications are subject to the PLR.

(Comment 92) One comment expressed concern that under the proposed implementation schedule, the pregnancy categories will be removed from the labeling for some drugs before the new content required by the rule will be added to the labeling, and this could cause confusion among doctors and patients.

(Response) We would like to clarify that a holder of an application that is not subject to the PLR, and thus, not subject to the new content and format requirements of this final rule, must remove the pregnancy category from its labeling within 3 years after the effective date of this rule. A holder of an application that is subject to the PLR and thus, subject to the new content and format requirements of this rule, is not required to remove the pregnancy category until such time that it is required to submit revised labeling with the new content and format, even if that occurs more than 3 years after the effective date of the final rule. FDA did not intend to suggest that application holders of previously approved applications subject to the PLR might, in some circumstances, be required to revise labeling twice as a part of implementation. Therefore, if a holder of an application is subject to the PLR, FDA does not anticipate that the pregnancy category will be removed from the labeling prior to submitting the revised labeling with the new content and format for that product under the PLLR implementation schedule. In conjunction with the publication of the final rule, the Agency is planning to launch an education campaign for all stakeholders, including health care providers and professional organizations, to ensure that they are well informed about the changes.

V. Legal Authority

A. Statutory Authority

FDA is revising its regulations on the format and content of the ''Pregnancy,'' ''Labor and delivery,'' and ''Nursing mothers'' subsections of the ''Use in Specific Populations'' section (under § 201.57) and the ''Precautions'' section (under § 201.80) of the labeling for human prescription drugs (in addition to the list of headings and subheadings under § 201.56(d)(1)).

FDA's revisions to the content and format requirements for prescription drug labeling are authorized by the FD&C Act and by the PHS Act. Section 502(a) of the FD&C Act deems a drug to be misbranded if its labeling is false or misleading ''in any particular.'' Under section 201(n) of the FD&C Act (21 U.S.C. 321(n)), labeling is misleading if it fails to reveal facts that are material with respect to consequences that may result from the use of the drug under the conditions of use prescribed in the labeling or under customary or usual conditions of use. Section 502(f) of the FD&C Act deems a drug to be misbranded if its labeling lacks adequate directions for use and adequate warnings against use in those pathological conditions where its use may be dangerous to health, as well as adequate warnings against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users. Section 502(j) of the FD&C Act deems a drug to be misbranded if it is dangerous to health when used in the dosage or manner, or with the frequency or duration, prescribed, recommended, or suggested in its labeling.

In addition, the premarket approval provisions of the FD&C Act authorize FDA to require that prescription drug labeling provide the practitioner with adequate information to permit safe and effective use of the drug product. Under section 505 of the FD&C Act, FDA will approve an NDA only if the drug is shown to be both safe and effective for use under the conditions set forth in the drug's labeling. Section 701(a) of the FD&C Act (21 U.S.C. 371(a)) authorizes FDA to issue regulations for the efficient enforcement of the FD&C Act.

Under 21 CFR 314.125, FDA will not approve an NDA unless, among other things, there is adequate safety and effectiveness information for the labeled uses and the product labeling complies with the requirements of part 201. Under § 201.100(d) of FDA's regulations, a prescription drug product must bear labeling that contains adequate information under which licensed practitioners can use the drug safely for their intended uses. This final rule amends the regulations specifying the format and content for such labeling.

Section 351 of the PHS Act (42 U.S.C. 262) provides legal authority for the Agency to regulate the labeling and

shipment of biological products. Licenses for biological products are to be issued only upon a showing that they meet standards ''designed to insure the continued safety, purity, and potency of such products'' prescribed in regulations (section 351(d) of the PHS Act). The ''potency'' of a biological product includes its effectiveness (21 CFR 600.3(s)). Section 351(b) of the PHS Act prohibits false labeling of a biological product. FDA's regulations in part 201 apply to all prescription drug products, including biological products.

B. First Amendment

FDA's requirements for the content and format of the ''Pregnancy'' and ''Lactation'' subsections of labeling for prescription drug products are constitutionally permissible because they are reasonably related to the government's interest in ensuring the safe and effective use of prescription drug products and because they do not impose unjustified or unduly burdensome disclosure requirements. In the PLR, FDA explained in greater depth why that rule passes muster under the First Amendment (see 71 FR 3922 at 3964, January 24, 2006). That analysis is equally applicable to this final rule, and we hereby adopt that discussion by reference.

VI. Environmental Impact

The Agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Summary of Final Regulatory Impact Analysis

A. Introduction

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because our analysis suggests that some small prescription drug manufacturers and prescription drug repackagers and relabelers will incur costs that total more than 1 percent of their annual income in some years, the Agency finds that the final rule will have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $141 million, using the most current (2013) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

The first regulations on the content and format of prescription drug labeling were established in 1979, including the requirement to assign drugs to one of five pregnancy categories. Over time, however, labeling became long, repetitive, and difficult to use. With the PLR in 2006, the Agency began to apply modern principles of effective communication to improve the quality of prescription drug labeling. However, the PLR left the content of the ''Pregnancy,'' ''Labor and delivery,'' and ''Nursing mothers'' subsections of the ''Use in Specific Populations'' section untouched. This decision gave the Agency sufficient time to meet with experts and stakeholders to develop a regulatory framework that encourages applicants to prepare content that clearly communicates available information about prescription drug use during pregnancy and lactation, and in females and males of reproductive potential. With this final rule, the Agency specifically addresses the content and format of these subsections.

B. Summary of Costs and Benefits

The final regulatory impact analysis of the final rule (Ref. 2) is available at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.* Table 2 presents a summary of the annualized costs and benefits of the final rule over 10 years. With a 7 percent discount rate, annualized costs equal about $9.5 million; with a 3 percent discount rate, annualized costs equal about $9.2 million.

The final rule will require that applicants comply with new labeling content and format requirements for affected subsections for prescription drug and biological product labeling subject to the PLR under § 201.57(c)(9) (PLR labeling) and will require that applicants remove the pregnancy category from all prescription drug and biological product labeling subject to § 201.80(f)(6)(i) (non-PLR labeling). The ''Pregnancy,'' ''Labor and delivery,'' and ''Nursing mothers'' subsections of the ''Use in Specific Populations'' section will be replaced by the ''Pregnancy,'' ''Lactation,'' and ''Females and Males of Reproductive Potential'' subsections. New information will be required to summarize the key information needed by health care providers treating females and males of reproductive potential. The information in these subsections will be presented in a narrative, following a standardized order and format with clear subheadings.

The primary objectives of the final rule are to improve labeling by updating the content and format of these subsections of prescription drug product labeling, and to remove the pregnancy category system. The Agency concluded that following a standardized structure is essential for effective communication. The final rule is needed to ensure that these subsections contain the most up-to-date information available and provide prescribers with clinically relevant data that they can use in their decisionmaking processes. Consistent with the approach taken by the PLR, the Agency intends to provide applicants with clear guidance about the required content and format. Concurrent with the publication of this final rule, FDA is issuing a draft guidance for industry on ''Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products—Content and Format.''

The level of effort needed to comply with the requirements of the final rule will depend on the type of labeling (PLR or non-PLR labeling) and the length of time the product has been marketed. Applicants and persons responsible for existing prescription drug and biological product labeling will incur one-time costs to revise existing labeling in years 3, 4, and 5. Applicants submitting new BLAs, NDAs, and certain efficacy supplements will incur one-time costs to gather and organize new content required by the final rule at the time they prepare labeling for the application or supplement. In addition, we estimate the additional annual printing costs for

longer PLR labeling that will include new content.

We estimate that the total cost of the rule over 10 years will equal about $88.7 million. The present value of the total costs will equal $78.2 million with a 3 percent discount rate and $66.8 million with a 7 percent discount rate. Over 10 years, the annualized present value will equal $9.2 million with a 3 percent discount rate and $9.5 million with a 7 percent discount rate.

TABLE 2—ECONOMIC DATA: COSTS AND BENEFITS ACCOUNTING STATEMENT

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (percent)	Period covered (years)	
Benefits:							
Annualized					7		
Monetized $millions/year					3		
Annualized					7		
Quantified					3		
Qualitative	Improved quality of prescription drug labeling for health care providers						
Costs:							
Annualized	$9.5			2011	7	10	
Monetized $millions/year	9.2			2011	3	10	
Annualized					7		
Quantified					3		
Qualitative							
Transfers:							
Federal Annualized					7		
Monetized $millions/year					3		
From/To:	From:			To:			
Other Annualized					7		
Monetized $millions/year					3		
From/To:	From:			To:			
Effects:							
State, Local or Tribal Government: No effect							
Small Business: The final rule will have significant impacts on some small pharmaceutical manufacturers and prescription drug repackagers and relabelers.							
Wages: No effect							
Growth: No effect							

VIII. Paperwork Reduction Act of 1995

This final rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the total reporting and disclosure burdens. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling

Description: The final rule amends FDA regulations concerning the content and format of the ''Pregnancy,'' ''Labor and delivery,'' and ''Nursing mothers'' subsections of the ''Use in Specific Populations'' section of the labeling for human prescription drugs. The final rule requires that labeling include, among other things, a summary of the risks of using a drug during pregnancy and lactation and a discussion of the data supporting that summary. The labeling also includes relevant information to help health care providers make prescribing decisions and counsel women about the use of drugs during pregnancy and lactation. The final rule eliminates the current pregnancy categories A, B, C, D, and X. In addition, the ''Labor and delivery'' subsection has been eliminated because information on labor and delivery is included in the ''Pregnancy'' subsection. The final rule also requires that the labeling include relevant information about pregnancy testing, contraception, and infertility for health care providers prescribing for females and males of reproductive potential. The final rule is intended to create a consistent format for providing information about the risks and benefits of prescription drug and/or biological product use during

pregnancy and lactation and by females and males of reproductive potential.

Under § 201.57(c)(9)(i) and (c)(9)(ii), holders of approved applications are required to provide new labeling content in a new format—that is, to rewrite the pregnancy and lactation portions of each drug's labeling. Under § 201.57(c)(9)(iii), these application holders are also required to include a new subsection 8.3, ''Females and Males of Reproductive Potential,'' which requires that when pregnancy testing or contraception is required or recommended before, during, or after drug therapy or when there are human or animal data that suggest drug-associated fertility effects, this subsection must contain this information. These application holders are required to submit supplements requiring prior approval by FDA before distribution of the new labeling, as required in § 314.70(b) or § 601.12(f)(1).

Under § 201.80(f)(6)(i), holders of approved applications are required to remove the pregnancy category designation (*e.g.,* ''Pregnancy Category C'') from the ''Pregnancy'' subsection of the ''Precautions'' section of the labeling. These application holders must report the labeling change in their annual reports, as required in § 314.70(d) or § 601.12(f)(3).

The new content and format requirements of the final rule apply to all applications that are required to comply with the PLR, including: (1) Applications submitted on or after the effective date of the final rule; (2) applications pending on the effective date of the final rule; and (3) applications approved from June 30, 2001, to the effective date of the final rule.

The following submissions under the final rule are subject to the PRA:

- Applications submitted on or after the effective date of the final rule (§§ 314.50, 314.70(b), 601.2, 601.12(f)(1));
- Amendments to applications pending on the effective date of the final rule (§§ 314.60, 601.2, 601.12(f)(1));
- Supplements to applications approved from June 30, 2001, to the effective date of the final rule (§§ 314.70(b), 601.12(f)(1));
- Annual reports for applications approved before June 30, 2001, that contain a pregnancy category, to report removal of the pregnancy category letter in their labeling (§§ 314.70(d), 601.12(f)(3)).

The information collection requirements and burden estimates are summarized in tables 3 and 4 of this document. The burden estimates are based on data and timeframes used for section VII of this document (Summary of Final Regulatory Impact Analysis) and for the final regulatory impact analysis of the final rule (available at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm*). FDA estimates that approximately 4,000 applications containing labeling consistent with this rulemaking will be submitted to FDA during the 10-year period on or after the effective date of the final rule by approximately 390 applicants and repackagers and relabelers. The estimate of 4,000 applications includes labeling for approximately 800 applications submitted under section 505(b) of the FD&C Act or section 351 of the PHS Act, and 1,200 applications submitted under section 505(j) of the FD&C Act, and revised labeling from repackagers and relabelers for approximately 2,000 drug products. This estimate also includes labeling amendments submitted to FDA for applications pending on the effective date of the final rule. Based on data provided in section VII of this document and in the final regulatory impact analysis of the final rule, FDA estimates that for future approvals it will take applicants approximately 40 hours to prepare and submit labeling consistent with this rulemaking. The estimate of 40 hours applies only to the requirements of this rulemaking and does not indicate the total hours required to prepare and submit complete labeling for these applications. The information collection burden to prepare and submit labeling in accordance with §§ 201.56, 201.57, and 201.80 is approved by OMB under control numbers 0910–0572 and 0910–0001.

In addition, FDA estimates that approximately 10,150 supplements to applications approved from June 30, 2001, to the effective date of the final rule, or pending on the effective date, will be submitted to FDA during the third, fourth, and fifth years after the effective date to update labeling in accordance with this final rule. This estimate includes approximately 1,080 NDA, BLA, and efficacy supplements, approximately 1,320 ANDA supplements, and labeling supplements from repackagers and relabelers for approximately 7,750 drug products. FDA estimates that approximately 390 application holders and repackagers and relabelers will submit these supplements, and that it will take approximately 120 hours to prepare and submit each supplement.

FDA also estimates that approximately 5,500 annual reports will be submitted to FDA during the third year after the effective date for applications approved before June 30, 2001, that contain a pregnancy category (5,500 includes annual reports for approximately 1,340 NDAs and BLAs and approximately 4,160 ANDAs containing labeling changes resulting from this rulemaking). FDA estimates that approximately 320 application holders will submit these annual reports, and that it will take approximately 40 hours for each submission.

As indicated in tables 3 and 4 of this document, we estimate that the total hours resulting from the information collection in this rulemaking will be approximately 1,598,000 hours. The costs associated with this rulemaking, including labor costs, are discussed in section VII of this document and in the final regulatory impact analysis of the final rule.

Description of Respondents: Persons and businesses, including small businesses and manufacturers.

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of submission (21 CFR section)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Supplements to applications approved 6/30/01 to effective date (§§ 314.70(b), 601.12(f)(1)).	390	26	10,150 (Submitted 3rd, 4th, and 5th years after effective date).	120	1,218,000
Annual report submission of revised labeling for applications approved before 6/30/01 that contain a pregnancy category (§§ 314.70(d), 601.12(f)(3)).	320	17	5,500 (Submitted 3rd year after effective date).	40	220,000

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Type of submission (21 CFR section)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total					1,438,000

[1] There are no capital costs or operating and maintenance costs associated with this information collection.

TABLE 4—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Type of submission (21 CFR section)	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total ours
New NDAs/ANDAs/BLAs/efficacy supplements submitted on or after effective date, including amendments to applications pending on effective date (§§ 314.50, 314.60, 314.70(b), 601.2, 601.12(f)(1)).	390	10	4,000 (Submitted during 10-year period after effective date).	40	160,000

[1] There are no capital costs or operating and maintenance costs associated with this information collection.

The information collection provisions of this final rule have been submitted to OMB for review, as required by section 3507(d) of the PRA. Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

IX. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that this final rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

X. References

In addition to the references placed on display in the Division of Dockets Management for the proposed rule under Docket No. FDA–2006–N–0515 (formerly Docket No. 2006N–0467), the following references are on display in the Division of Dockets Management under Docket No. FDA–2006–N–0515 (formerly Docket No. 2006N–0467) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified all Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Decision Partners, LLC, ''Evaluation of How Best to Communicate to Healthcare Providers about the Risks and Benefits of Prescription Drug Use for Pregnant and Nursing Women: A Mental Models Research Report,'' September 2009 (available at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm*).
2. Final Regulatory Impact Analysis for Docket No. FDA–2006–N–0515 (formerly Docket No. 2006N–0467) (available at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm* and at *http://www.regulations.gov).*
3. U.S. Food and Drug Administration, ''Guidance for Industry, Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products—Content and Format,'' 2011.
4. Kweder, S.L., ''Drugs and Biologics in Pregnancy and Breastfeeding: FDA in the 21st Century.'' *Birth Defects Research Part A: Clinical and Molecular Teratology.* 82(9):605–609, September 2008.
5. Adam, M.P., J.E. Polifka, and J.M. Friedman, ''Evolving Knowledge of the Teratogenicity of Medications in Human Pregnancy.'' *American Journal of Medical Genetics Part C: Seminars in Medical Genetics.* 157C(3):175–182, August 15, 2011.
6. Law, R., P. Bozzo, G. Koren, et al. ''FDA Pregnancy Risk Categories and the CPS. Do They Help or Are They a Hindrance?'' *Canadian Family Physician.* 56:239–241, March 2010.
7. U.S. Food and Drug Administration ''Guidance for industry, Establishing Pregnancy Exposure Registries,'' 2002.
8. U.S. Food and Drug Administration ''Guidance for Industry, Reproductive and Developmental Toxicities—Integrating Study Results to Assess Concerns,'' 2011.
9. Rynn, L., J. Cragan, and A. Correa, ''Update on Overall Prevalence of Major Birth Defects—Atlanta, Georgia, 1978–2005.'' *Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report.* 57(01):1–5, January 11, 2008.
10. American College of Obstetricians and Gynecologists Frequently Asked Questions: Miscarriage and Molar Pregnancy, 2011 (available at *http://www.acog.org/~/media/For%20Patients/faq090.pdf?dmc=1&ts=20140130T1655496642*).
11. U.S. Food and Drug Administration, ''Reviewer Guidance, Evaluating the Risks of Drug Exposure in Human Pregnancies,'' 2005.
12. U.S. Food and Drug Administration, ''Guidance for industry, Considerations for Developmental Toxicity Studies for Preventive and Therapeutic Vaccines for Infectious Disease Indications,'' 2006.
13. U.S. Food and Drug Administration, ''Guidance for industry, M3 (R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals and the International Conference on Harmonisation S5 (R2) Guideline: Detection of Toxicity to Reproduction for Medicinal Products and Toxicity to Male Fertility,'' 2010.
14. Tracy, T.S., et al. ''Temporal Changes in Drug Metabolism (CYP1A2, CYP2D6 and CYP3A Activity) During Pregnancy.'' *American Journal of Obstetrics and Gynecology.* 192(2):633–639, February 2005.
15. Anderson, G.D., ''Pregnancy-Induced Changes in Pharmacokinetics.'' *Clinical Pharmacokinetics.* 44(10):989–1008, 2005.

16. American Academy of Pediatrics Policy Statement. ''Breastfeeding and the Use of Human Milk.'' *Pediatrics.* 129(3):e827–841, 2012.
17. Sachs, H.C. and Committee on Drugs. ''The Transfer of Drugs and Therapeutics Into Human Breast Milk: An Update on Selected Topics.'' *Pediatrics.* 132(3):e796–809, September 2013.
18. U.S. Food and Drug Administration, ''Draft Guidance for industry Clinical Lactation Studies—Study Design, Data Analysis, and Recommendations for Labeling,'' 2005.
19. Proposed Pregnancy and Lactation Labeling Rule (available at *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Labeling/ucm093307.htm*).
20. Public Comments on Proposed Pregnancy and Lactation Labeling Rule (available at *http://www.regulations.gov/#!docketDetail;D=FDA-2006-N-0515*).

List of Subjects in 21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 201 is amended as follows:

PART 201—LABELING

■ 1. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

§ 201.56 [Amended]

■ 2. Amend § 201.56 in paragraph (d)(1) by removing from the list of headings and subheadings the subheadings ''8.2 Labor and delivery'' and ''8.3 Nursing mothers'' and adding in their places the subheadings ''8.2 Lactation'' and ''8.3 Females and Males of Reproductive Potential'', respectively.

■ 3. Amend § 201.57 by revising paragraphs (c)(9)(i), (ii), and (iii) to read as follows:

§ 201.57 Specific requirements on content and format of labeling for human prescription drug and biological products described in § 201.56(b)(1).

* * * * *

(c) * * *

(9) * * *

(i) *8.1 Pregnancy.* This subsection of the labeling must contain the following information in the following order under the subheadings ''Pregnancy Exposure Registry,'' ''Risk Summary,'' ''Clinical Considerations,'' and ''Data'':

(A) *Pregnancy exposure registry.* If there is a scientifically acceptable pregnancy exposure registry for the drug, contact information needed to enroll in the registry or to obtain information about the registry must be provided following the statement: ''There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to (*name of drug*) during pregnancy.''

(B) *Risk summary.* The Risk Summary must contain risk statement(s) based on data from all relevant sources (human, animal, and/or pharmacologic) that describe, for the drug, the risk of adverse developmental outcomes (*i.e.,* structural abnormalities, embryo-fetal and/or infant mortality, functional impairment, alterations to growth). When multiple data sources are available, the statements must be presented in the following order: Human, animal, pharmacologic. The source(s) of the data must be stated. The labeling must state the percentage range of live births in the United States with a major birth defect and the percentage range of pregnancies in the United States that end in miscarriage, regardless of drug exposure. If such information is available for the population(s) for which the drug is labeled, it must also be included. When use of a drug is contraindicated during pregnancy, this information must be stated first in the Risk Summary. When applicable, risk statements as described in paragraphs (c)(9)(i)(B)(*1*) and (*2*) of this section must include a cross-reference to additional details in the relevant portion of the ''Data'' subheading in the ''Pregnancy'' subsection of the labeling. If data demonstrate that a drug is not systemically absorbed following a particular route of administration, the Risk Summary must contain only the following statement: ''(*Name of drug*) is not absorbed systemically following (route of administration), and maternal use is not expected to result in fetal exposure to the drug.''

(*1*) *Risk statement based on human data.* When human data are available that establish the presence or absence of any adverse developmental outcome(s) associated with maternal use of the drug, the Risk Summary must summarize the specific developmental outcome(s); their incidence; and the effects of dose, duration of exposure, and gestational timing of exposure. If human data indicate that there is an increased risk for a specific adverse developmental outcome in infants born to women exposed to the drug during pregnancy, this risk must be quantitatively compared to the risk for the same outcome in infants born to women who were not exposed to the drug but who have the disease or condition for which the drug is indicated to be used. When risk information is not available for women with the disease or condition for which the drug is indicated, the risk for the specific outcome must be compared to the rate at which the outcome occurs in the general population. The Risk Summary must state when there are no human data or when available human data do not establish the presence or absence of drug-associated risk.

(*2*) *Risk statement based on animal data.* When animal data are available, the Risk Summary must summarize the findings in animals and based on these findings, describe, for the drug, the potential risk of any adverse developmental outcome(s) in humans. This statement must include: The number and type(s) of species affected, timing of exposure, animal doses expressed in terms of human dose or exposure equivalents, and outcomes for pregnant animals and offspring. When animal studies do not meet current standards for nonclinical developmental toxicity studies, the Risk Summary must so state. When there are no animal data, the Risk Summary must so state.

(*3*) *Risk statement based on pharmacology.* When the drug has a well-understood mechanism of action that may result in adverse developmental outcome(s), the Risk Summary must explain the mechanism of action and the potential associated risks.

(C) *Clinical considerations.* Under the subheading ''Clinical Considerations,'' the labeling must provide relevant information, to the extent it is available, under the headings ''Disease-associated maternal and/or embryo/fetal risk,'' ''Dose adjustments during pregnancy and the postpartum period,'' ''Maternal adverse reactions,'' ''Fetal/Neonatal adverse reactions,'' and ''Labor or delivery'':

(*1*) *Disease-associated maternal and/or embryo/fetal risk.* If there is a serious known or potential risk to the pregnant woman and/or the embryo/fetus associated with the disease or condition for which the drug is indicated to be used, the labeling must describe the risk.

(*2*) *Dose adjustments during pregnancy and the postpartum period.* If there are pharmacokinetic data that support dose adjustment(s) during pregnancy and the postpartum period, a summary of this information must be provided.

(*3*) *Maternal adverse reactions.* If use of the drug is associated with a maternal adverse reaction that is unique to pregnancy or if a known adverse reaction occurs with increased frequency or severity in pregnant

women, the labeling must describe the adverse reaction and available intervention(s) for monitoring or mitigating the reaction. The labeling must describe, if known, the effect of dose, timing, and duration of exposure on the risk to the pregnant woman of experiencing the adverse reaction.

(*4*) *Fetal/Neonatal adverse reactions.* If it is known or anticipated that treatment of the pregnant woman increases or may increase the risk of an adverse reaction in the fetus or neonate, the labeling must describe the adverse reaction, the potential severity and reversibility of the adverse reaction, and available intervention(s) for monitoring or mitigating the reaction. The labeling must describe, if known, the effect of dose, timing, and duration of exposure on the risk.

(*5*) *Labor or delivery.* If the drug is expected to affect labor or delivery, the labeling must provide information about the effect of the drug on the pregnant woman and the fetus or neonate; the effect of the drug on the duration of labor and delivery; any increased risk of adverse reactions, including their potential severity and reversibility; and must provide information about available intervention(s) that can mitigate these effects and/or adverse reactions. The information described under this heading is not required for drugs approved for use only during labor and delivery.

(D) *Data*—(*1*) *''Data'' subheading.* Under the subheading ''Data,'' the labeling must describe the data that are the basis for the Risk Summary and Clinical Considerations.

(*2*) *Human and animal data headings.* Human and animal data must be presented separately, beneath the headings ''Human Data'' and ''Animal Data,'' and human data must be presented first.

(*3*) *Description of human data.* For human data, the labeling must describe adverse developmental outcomes, adverse reactions, and other adverse effects. To the extent applicable, the labeling must describe the types of studies or reports, number of subjects and the duration of each study, exposure information, and limitations of the data. Both positive and negative study findings must be included.

(*4*) *Description of animal data.* For animal data, the labeling must describe the following: Types of studies, animal species, dose, duration and timing of exposure, study findings, presence or absence of maternal toxicity, and limitations of the data. Description of maternal and offspring findings must include dose-response and severity of adverse developmental outcomes. Animal doses or exposures must be described in terms of human dose or exposure equivalents and the basis for those calculations must be included.

(ii) *8.2 Lactation.* This subsection of the labeling must contain the following information in the following order under the subheadings ''Risk Summary,'' ''Clinical Considerations,'' and ''Data'':

(A) *Risk summary.* When relevant human and/or animal lactation data are available, the Risk Summary must include a cross-reference to the ''Data'' subheading in the ''Lactation'' subsection of the labeling. When human data are available, animal data must not be included unless the animal model is specifically known to be predictive for humans. When use of a drug is contraindicated during breastfeeding, this information must be stated first in the Risk Summary.

(*1*) *Drug not absorbed systemically.* If data demonstrate that the drug is not systemically absorbed by the mother, the Risk Summary must contain only the following statement: ''(*Name of drug*) is not absorbed systemically by the mother following (route of administration), and breastfeeding is not expected to result in exposure of the child to (*name of drug*).''

(*2*) *Drug absorbed systemically.* If the drug is absorbed systemically, the Risk Summary must describe the following to the extent relevant information is available:

(*i*) *Presence of drug in human milk.* The Risk Summary must state whether the drug and/or its active metabolite(s) are present in human milk. If there are no data to assess this, the Risk Summary must so state. If studies demonstrate that the drug and/or its active metabolite(s) *are* not detectable in human milk, the Risk Summary must state the limits of the assay used. If studies demonstrate the presence of the drug and/or its active metabolite(s) in human milk, the Risk Summary must state the concentration of the drug and/or its active metabolite(s) in human milk and the actual or estimated daily dose for an infant fed exclusively with human milk. The actual or estimated amount of the drug and/or its active metabolite(s) ingested by the infant must be compared to the labeled infant or pediatric dose, if available, or to the maternal dose. If studies demonstrate the presence of the drug and/or its active metabolite(s) in human milk but the drug and/or its active metabolite(s) are not expected to be systemically bioavailable to the breast-fed child, the Risk Summary must describe the disposition of the drug and/or its active metabolite(s). If only animal lactation data are available, the Risk Summary must state only whether or not the drug and/or its active metabolite(s) were detected in animal milk and specify the animal species.

(*ii*) *Effects of drug on the breast-fed child.* The Risk Summary must include information, on the known or predicted effects on the child from exposure to the drug and/or its active metabolite(s) through human milk or from contact with breast or nipple skin (for topical products). The Risk Summary also must include information on systemic and/or local adverse reactions. If there are no data to assess the effects of the drug and/or its active metabolite(s) on the breast-fed child, the Risk Summary must so state.

(*iii*) *Effects of drug on milk production.* The Risk Summary must describe the effects of the drug and/or its active metabolite(s) on milk production. If there are no data to assess the effects of the drug and/or its active metabolite(s) on milk production, the Risk Summary must so state.

(*3*) *Risk and benefit statement.* For drugs absorbed systemically, unless breastfeeding is contraindicated during drug therapy, the following risk and benefit statement must appear at the end of the Risk Summary: ''The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for (*name of drug*) and any potential adverse effects on the breast-fed child from (*name of drug*) or from the underlying maternal condition.''

(B) *Clinical considerations.* Under ''Clinical Considerations,'' the following information must be provided to the extent it is available and relevant:

(*1*) *Minimizing exposure.* The labeling must describe ways to minimize exposure in the breast-fed child if: The drug and/or its active metabolite(s) are present in human milk in clinically relevant concentrations; the drug does not have an established safety profile in infants; and the drug is used either intermittently, in single doses, or for short courses of therapy. When applicable, the labeling must also describe ways to minimize a breast-fed child's oral intake of topical drugs applied to the breast or nipple skin.

(*2*) *Monitoring for adverse reactions.* The labeling must describe available intervention(s) for monitoring or mitigating the adverse reaction(s) presented in the Risk Summary.

(C) *Data.* Under the subheading ''Data,'' the labeling must describe the data that are the basis for the Risk Summary and Clinical Considerations.

(iii) *8.3 Females and males of reproductive potential.* When pregnancy

testing and/or contraception are required or recommended before, during, or after drug therapy and/or when there are human and/or animal data that suggest drug-associated fertility effects, this subsection of labeling must contain this information under the subheadings ''Pregnancy Testing,'' ''Contraception,'' and ''Infertility,'' in that order.

* * * * *

§ 201.80 [Amended]

■ 4. Amend § 201.80 as follows:

■ a. Remove the paragraph heading ''Pregnancy category A.'' and the words ''Pregnancy Category A.'' from paragraph (f)(6)(i)(*a*);

■ b. Remove the paragraph heading ''Pregnancy category B.'' and the words ''Pregnancy Category B.'' both times they appear from paragraph (f)(6)(i)(*b*);

■ c. Remove the paragraph heading ''Pregnancy category C.'' and the words ''Pregnancy Category C.'' both times they appear from paragraph (f)(6)(i)(*c*);

■ d. Remove the paragraph heading ''Pregnancy category D.'' and the words ''Pregnancy Category D.'' from paragraph (f)(6)(i)(*d*); and

■ e. Remove the paragraph heading ''Pregnancy category X.'' and the words ''Pregnancy Category X.'' from paragraph (f)(6)(i)(*e*).

Dated: November 25, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–28241 Filed 12–3–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1551]

Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products—Content and Format; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products—Content and Format.'' This draft guidance is intended to assist applicants in complying with the new content and format requirements in the Pregnancy, Lactation, and Females and Males of Reproductive Potential subsections of labeling for human prescription drug and biological products, as described in the final rule, *Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling.* The rule, which is being published concurrently with this draft guidance, is referred to as the ''Pregnancy and Lactation Labeling Rule'' (PLLR). The draft guidance will assist applicants in developing labeling for new products, revising existing labeling, and implementing the content and format requirements of the PLLR for human prescription drug and biological products.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 2, 2015.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., 4th Floor, Silver Spring, MD 20993, or Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. G102, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the draft guidance 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.

FOR FURTHER INFORMATION CONTACT: Division of Pediatric and Maternal Health, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6312, Silver Spring, MD 20993–0002, 301–796–2200; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products—Content and Format.'' The draft guidance provides recommendations on how to develop and revise professional labeling that meets the new content and format requirements of the Pregnancy, Lactation, and Females and Males of Reproductive Potential subsections of labeling for human prescription drug and biological products. Specifically, it provides information to assist applicants in preparing subsections 8.1 Pregnancy, 8.2 Lactation, and 8.3 Females and Males of Reproductive Potential of the USE IN SPECIFIC POPULATIONS section of the full prescribing information under 21 CFR 201.56(d)(1) and 201.57(c)(9)(i) through (iii), as described in the PLLR.

The PLLR provides a framework to clearly communicate information on the benefits and risks of drug use during pregnancy and lactation to help facilitate prescribing decisions. The PLLR also includes a subsection on females and males of reproductive potential to address issues in these populations that are linked to pregnancy either directly or indirectly. The draft guidance provides recommendations to applicants submitting new drug applications (NDAs), efficacy supplements to approved NDAs, biologics license applications (BLAs) (for biological products that are regulated as drugs), and efficacy supplements to BLAs, as well as to applicants that have previously submitted such applications during the time periods specified in the implementation plan set out in the preamble to the PLLR. FDA may revise other Agency guidances as needed and appropriate to reflect the PLLR content and format requirements and the recommendations in this guidance, once it has been finalized.

This draft guidance is one of a series of guidances FDA is developing, or has developed, to assist applicants with the content and format of the labeling for human prescription drug and biological products. In the **Federal Register** of January 24, 2006 (71 FR 3999), FDA announced the availability of final guidances on the content and format of the ''Adverse Reactions'' (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075057.pdf*) and ''Clinical Studies'' (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075059.pdf*) sections of labeling. In the **Federal Register** of October 19, 2009 (74 FR 53507), FDA announced the availability of final guidance on determining established pharmacologic class for use in the ''Highlights of Prescribing Information'' (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM186607.pdf*). In the **Federal Register** of March 23, 2010 (75 FR 13766), FDA announced the availability of final guidance on the content and format of the ''Dosage and Administration'' section of labeling (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075066.pdf*). In the **Federal Register** of October 12, 2011 (76 FR 63303), FDA announced the availability of final guidance on the content and format of the ''Warnings and Precautions,'' ''Contraindications,'' and ''Boxed Warning'' sections of labeling (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075096.pdf*),and in the **Federal Register** of March 3, 2009 (74 FR 9250), FDA announced the availability of draft guidance on the content and format of the ''Clinical Pharmacology'' section of labeling (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM109739.pdf*). In the **Federal Register** of February 25, 2013 (78 FR 12760), FDA announced the availability

of final guidance implementing the ''Physician Labeling Rule'' (January 24, 2006, 71 FR 3922) content and format requirements of labeling for human prescription drug and biological products under §§ 201.56(d) and 201.57 (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075082.pdf*). In the **Federal Register** of February 28, 2013 (78 FR 13686), FDA announced the availability of draft guidance on the placement and content of pediatric information in the labeling for human prescription drug and biological products in accordance with the Physician Labeling Rule (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM341394.pdf*).

The labeling requirements and these guidances are intended to make information in prescription drug labeling easier for health care practitioners to access, read, and use.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on implementing the PLLR content and format requirements for labeling for human prescription drug and biological products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of 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, and will be posted to the docket at *http://www.regulations.gov.*

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in 21 CFR 201.56 and 201.57 has been approved under OMB control number 0910–0572. The collection of information in 21 CFR 314.70 and 314.97 for submitting supplements to an approved application, the collection of information in 21 CFR 314.50(e) for submitting labeling for an application, and the collection of information in 21 CFR 314.90 for submitting waiver requests for an application have been approved under OMB control number 0910–0001. The collection of information in 21 CFR 601.12 for submitting supplements to an approved application has been approved under OMB control number 0910–0338. In addition, the information collection provisions of the PLLR have been submitted to OMB for review, as required by section 3507(d) of the Paperwork Reduction Act. Prior to the effective date of the PLLR, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in the final rule.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov.*

Dated: November 25, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–28242 Filed 12–3–14; 8:45 am]

BILLING CODE 4164–01–P

Reader Aids

Federal Register

Vol. 79, No. 233

Thursday, December 4, 2014

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations	
General Information, indexes and other finding aids	**202–741–6000**
Laws	**741–6000**
Presidential Documents	
Executive orders and proclamations	**741–6000**
The United States Government Manual	**741–6000**
Other Services	
Electronic and on-line services (voice)	**741–6020**
Privacy Act Compilation	**741–6064**
Public Laws Update Service (numbers, dates, etc.)	**741–6043**
TTY for the deaf-and-hard-of-hearing	**741–6086**

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **www.fdsys.gov.**

Federal Register information and research tools, including Public Inspection List, indexes, and Code of Federal Regulations are located at: **www.ofr.gov.**

E-mail

FEDREGTOC-L (Federal Register Table of Contents LISTSERV) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to **http://listserv.access.gpo.gov** and select *Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings);* then follow the instructions.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html** and select *Join or leave the list (or change settings);* then follow the instructions.

FEDREGTOC-L and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

CFR Checklist. Effective January 1, 2009, the CFR Checklist no longer appears in the Federal Register. This information can be found online at **http://bookstore.gpo.gov/.**

FEDERAL REGISTER PAGES AND DATE, DECEMBER

70995–71294 1
71295–71620 2
71621–71954 3
71955–72106 4

CFR PARTS AFFECTED DURING DECEMBER

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:
9214 71621
9215 71951
9216 71953
Administrative Orders:
Presidential Determinations:
No. 2015–02 of November 21, 2014 71619

5 CFR

2641 71955
Proposed Rules:
890 71695
892 71695

7 CFR

1423 70995
Proposed Rules:
318 71973
319 ..... 71703, 71973
915 71031

9 CFR

93 70997
94 70997
95 70997
145 71623
146 71623
317 71007
381 71007

10 CFR

52 71295
429 71624
431 71624
1708 71009
Proposed Rules:
430 ..... 71705, 71894
431 71710

12 CFR

46 71630

13 CFR

121 71296

14 CFR

39 ..... 71296, 71300, 71302, 71304, 71308
61 71634
71 ..... 71309, 71310, 71311, 71312
97 ..... 71639, 71641, 71646, 71652
141 71634
Proposed Rules:
39 ..... 71031, 71033, 71037, 71363
71 ..... 71364, 71365, 71710

15 CFR

730 71013
734 71013
736 71013
742 71013
744 71013
745 71013
748 71014
902 ..... 71313, 71510

16 CFR

Proposed Rules:
1422 71712

17 CFR

Proposed Rules:
1 71973
15 71973
17 71973
19 71973
32 71973
37 71973
38 71973
140 71973
150 71973

21 CFR

11 ..... 71156, 71259
101 ..... 71156, 71259
201 72064

29 CFR

4044 71019

33 CFR

110 71654
165 ..... 71020, 71022

34 CFR

600 71957
668 71957
Proposed Rules:
263 71930
612 71820
686 71820

37 CFR

381 71319

38 CFR

12 71319
17 71653
Proposed Rules:
3 71366

40 CFR

51 71663
52 ..... 71025, 71663, 71672
97 ..... 71663, 71674
180 71676

300.....71679
Proposed Rules:
52 .....71040, 71057, 71061, 71369, 71712
122.....71066
123.....71066
127.....71066
180.....71713
403.....71066
501.....71066
503.....71066

42 CFR
409.....71320
447.....71679
Proposed Rules:
409.....71081
410.....71081
418.....71081
440.....71081
484.....71081
485.....71081
488.....71081

46 CFR
Proposed Rules:
401.....71082

47 CFR
2.....71321
90.....71321
Proposed Rules:
25.....71714

48 CFR
Proposed Rules:
1.....71975
4.....71975
9.....71975
22.....71975
52.....71975

50 CFR
300.....71327
622.....71959
635 .....71029, 71331, 71510
648.....71339, 71960
660.....71340
679 .....71313, 71344, 71350
Proposed Rules:
17.....71373
226.....71714
300.....71729

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List December 3, 2014

Public Laws Electronic Notification Service (PENS)

PENS is a free electronic mail notification service of newly enacted public laws. To subscribe, go to *http://listserv.gsa.gov/archives/publaws-l.html*

Note: This service is strictly for E-mail notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.