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Presidential Documents

Title 3—

The President

Order of February 2, 2015

Sequestration Order for Fiscal Year 2016 Pursuant to Section 251A of the Balanced Budget and Emergency Deficit Control Act, as Amended

By the authority vested in me as President by the laws of the United States of America, and in accordance with section 251A of the Balanced Budget and Emergency Deficit Control Act (the ''Act''), as amended, 2 U.S.C. 901a, I hereby order that, on October 1, 2015, direct spending budgetary resources for fiscal year 2016 in each non-exempt budget account be reduced by the amount calculated by the Office of Management and Budget in its report to the Congress of February 2, 2015.

All sequestrations shall be made in strict accordance with the requirements of section 251A of the Act and the specifications of the Office of Management and Budget's report of February 2, 2015, prepared pursuant to section 251A(9) of the Act.

THE WHITE HOUSE,
February 2, 2015.

[FR Doc. 2015–02539
Filed 2–5–15; 8:45 am]
Billing code 3295–F5

Presidential Documents

Notice of February 4, 2015

Continuation of the National Emergency With Respect to the Situation in or in Relation to Côte d'Ivoire

On February 7, 2006, by Executive Order 13396, the President declared a national emergency, pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701–1706), to deal with the unusual and extraordinary threat to the national security and foreign policy of the United States constituted by the situation in or in relation to Côte d'Ivoire and ordered related measures blocking the property of certain persons contributing to the conflict in Côte d'Ivoire. The situation in or in relation to Côte d'Ivoire, which has been addressed by the United Nations Security Council in Resolution 1572 of November 15, 2004, and subsequent resolutions, has resulted in the massacre of large numbers of civilians, widespread human rights abuses, significant political violence and unrest, and fatal attacks against international peacekeeping forces.

The Government of Côte d'Ivoire and its people continue to make significant progress in promotion of democratic, social, and economic development. The United States also supports the advancement of impartial justice in Côte d'Ivoire as well as the Government of Côte d'Ivoire's efforts to prepare for a peaceful, fair, and transparent presidential election in 2015, which will be an important milestone in Côte d'Ivoire's progress. The United States is committed to helping Côte d'Ivoire strengthen its democracy, and we look forward to working with the Government and people of Côte d'Ivoire to ensure continued progress and lasting peace for all Ivorians. We urge all sides to work for the benefit of the country as a whole by rejecting violence and participating in the electoral process.

While the Government of Côte d'Ivoire and its people continue to make progress toward peace and prosperity, the situation in or in relation to Côte d'Ivoire continues to pose an unusual and extraordinary threat to the national security and foreign policy of the United States. For this reason, the national emergency declared on February 7, 2006, and the measures adopted on that date to deal with that emergency, must continue in effect beyond February 7, 2015. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency declared in Executive Order 13396.

This notice shall be published in the *Federal Register* and transmitted to the Congress.

THE WHITE HOUSE,
February 4, 2015.

[FR Doc. 2015–02603
Filed 2–5–15; 8:45 am]
Billing code 3295–F5

Rules and Regulations

Federal Register

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2009–1088; Directorate Identifier 2008–SW–76–AD; Amendment 39–18091; AD 2014–12–11 R1]

RIN 2120–AA64

Airworthiness Directives; Sikorsky Aircraft Corporation Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are revising Airworthiness Directive (AD) 2014–12–11 for Sikorsky Aircraft Corporation (Sikorsky) Model S–92A helicopters. AD 2014–12–11 required revising the Rotorcraft Flight Manual (RFM) to include the appropriate operating limitations for performing Class D external load-combination operations. As published, AD 2014–12–11 referenced an incorrect date for Revision No. 12 of Sikorsky RFM SA S92A–RFM–003, Part 1. This AD corrects the error while retaining the requirements of AD 2014–12–11. These actions are intended to require appropriate operating limitations to allow operators to perform Class D external load-combination operations, including human external cargo, in this model helicopter that now meets the Category A performance standard.

DATES: This AD is effective March 13, 2015.

ADDRESSES: For service information identified in this AD, contact Sikorsky Aircraft Corporation, Attn: Manager, Commercial Technical Support, mailstop S581A, 6900 Main Street, Stratford, CT, telephone (203) 383–4866, email address *tsslibrary@sikorsky.com*, or at *http://www.sikorsky.com.* You may view this referenced service information at the FAA, of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* in Docket No. FAA–2009–1088; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, any incorporated-by-reference information, the economic evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: John Coffey, Flight Test Engineer, Boston Aircraft Certification Office, 12 New England Executive Park, Burlington, MA 01803; telephone (781) 238–7173; email: *john.coffey@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to revise AD 2014–12–11, Amendment 39–17872 (79 FR 45085, August 4, 2014), which applied to Sikorsky Model S–92A helicopters. The NPRM, published in the **Federal Register** on October 27, 2014 (79 FR 63855), proposed to retain the requirements of AD 2014–12–11 and correct the date of the RFM revision that appeared in the text of the rule.

Specifically, AD 2014–12–11 included the following under paragraph (f), Credit for Actions Previously Completed: ''Incorporation of the changes contained in Sikorsky RFM SA S92A–RFM–003, Part 1, Revision No. 12, approved March 21, 2005, before the effective date of this AD is considered acceptable for compliance with the corresponding actions specified in paragraph (e) of this AD.'' As published, the reference to March 21, 2005, was incorrect. The correct approval date for Revision 12 is December 9, 2010.

The FAA has determined that it is appropriate to revise AD 2014–12–11 to correct the RFM approval date. This revision clarifies which RFM revision is acceptable to obtain credit for previous actions.

No other part of the preamble or regulatory information has been changed. The final rule is reprinted in its entirety for the convenience of affected operators.

Comments

We gave the public the opportunity to participate in developing this AD, but we received no comments on the NPRM (79 FR 63855, October 27, 2014).

FAA's Determination

We have reviewed the relevant information and determined that an unsafe condition exists and is likely to exist or develop on other helicopters of these same type designs and that air safety and the public interest require adopting the AD requirements as proposed.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

(3) Will not affect intrastate aviation in Alaska to the extent that a regulatory distinction is required, and

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2014–12–11, Amendment 39–17872 (79 FR 45085, August 4, 2014), and adding the following new AD:

2014–12–11 R1 Sikorsky Aircraft Corporation: Amendment 39–18091; Docket No. FAA–2009–1088; Directorate Identifier 2008–SW–76–AD.

(a) Applicability

This AD applies to Sikorsky Aircraft Corporation Model S–92A helicopters, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as an inaccurate Rotorcraft Flight Manual (RFM) provision, which was approved without appropriate limitations for this model helicopter for carrying Class D external rotorcraft-load combinations, including Human External Cargo (HEC), when this model helicopter was not certificated to Category A one-engine inoperative (OEI) performance standards, including fly away capabilities after an engine failure, which is required for carrying HEC.

(c) Affected ADs

This AD revises AD 2014–12–11, Amendment 39–17872 (79 FR 45085, August 4, 2014).

(d) Effective Date

This AD becomes effective March 13, 2015.

(e) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(f) Required Actions

Within 90 days, revise the Operating Limitations section of Sikorsky Rotorcraft Flight Manual (RFM) SA S92A–RFM–003, Part 1, Section I, by inserting a copy of this AD into the RFM or by making pen and ink changes, as follows:

(1) In the ''Types of Operation'' section, beneath Hoist, add the following: ''The hoist equipment certification installation approval does not constitute approval to conduct hoist operations. Operational approval for hoist operations must be granted by the Federal Aviation Administration. No cabin seats may be installed in front of station 317 when conducting Human External Cargo hoist operations, which requires Category A performance capabilities.''

(2) In the ''Flight Limits'' section, add the following: '' ''HOIST'' When conducting Human External Cargo operations, which require category 'A' performance capabilities, the minimum hover height is 20 feet AGL and the maximum hover height is 80 feet AGL. ''HOIST'' The collective axis must remain uncoupled when conducting Human External Cargo, which requires category 'A' performance capabilities, for the period of time that the person is off the ground or water and not in the aircraft. This can be accomplished by either uncoupling the collective axis or by the pilot depressing the collective trim switch during the pertinent portion of the maneuver.''

(3) In the ''Weight Limits'' section:

(i) Remove the following: ''NOTE: The 150 pound hoist decrement does not preclude Cat A operations at a gross weight of 26,500 pounds with a hoist installed. If conditions permit, the pilot may go to the right of the 26,500 line on Figure 1–2 to determine a maximum gross weight up to 26,650 and then subtract 150 pounds.''

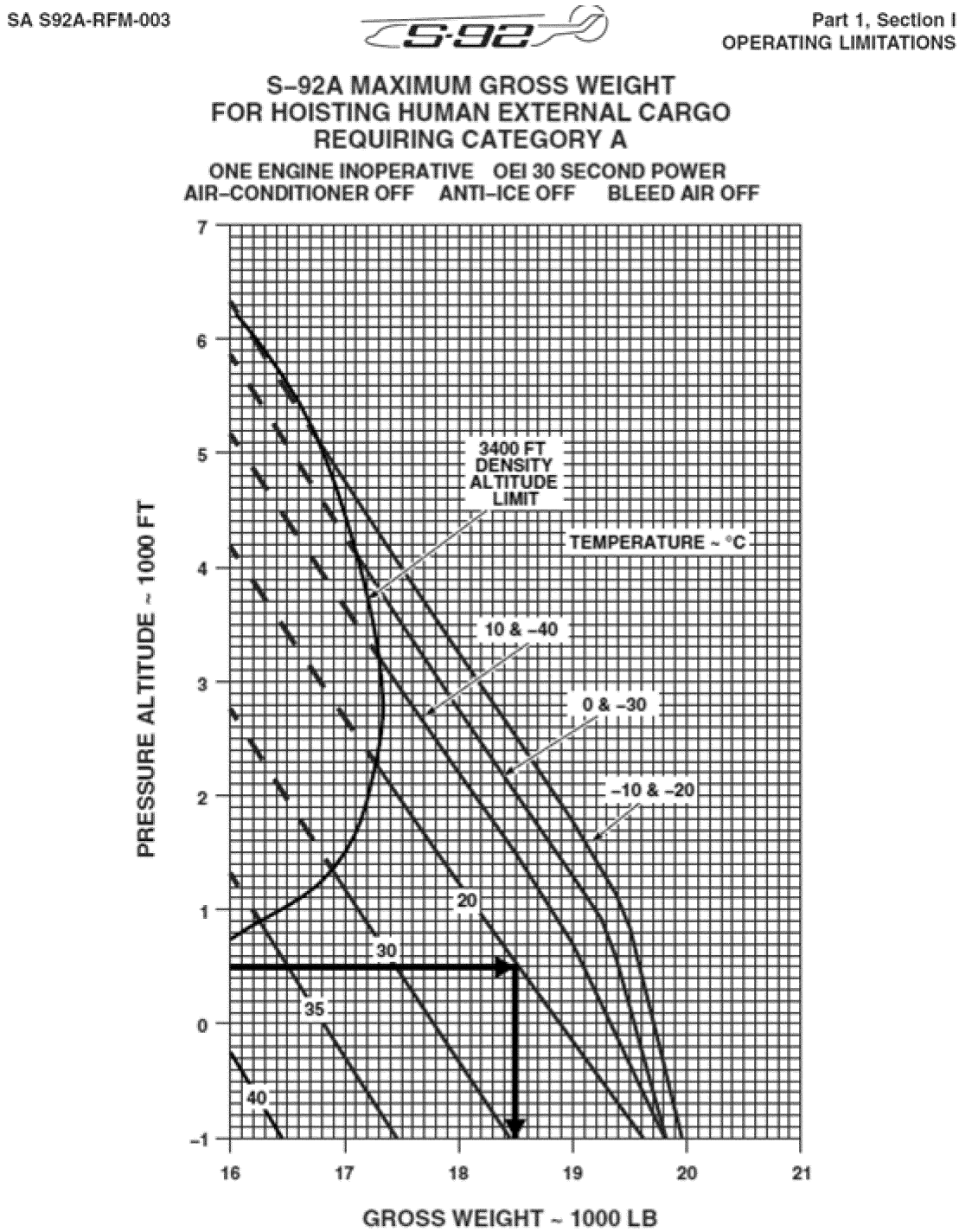
(ii) Add the following: ''NOTE: If conditions permit, the pilot may go to the right of the 26,500 pound line on Figure 1–2 to determine the maximum gross weight and then subtract a 150 pound hoist decrement. The maximum gross weight for category 'A' operations cannot exceed 26,500 pounds (12,020 kilograms).''

(iii) Add the following and insert Figure 1 to Paragraph (f)(3)(iii) of this AD:

'' ''HOIST'' Maximum gross weight for Human External Cargo, which requires category 'A' performance capabilities, is limited to the gross weight determined in accordance with the following Figure 1 to Paragraph (f)(3)(iii) of this AD for your altitude and temperature with the air-conditioner, anti-ice, and bleed air turned off.''

Note 1 to paragraph (f)(3)(iii) of this AD: Figure 1 to Paragraph (f)(3)(iii) of this AD becomes Figure 1–2A when inserted in the ''Weight Limits'' section of your RFM.

BILLING CODE 4910–13–P



NOTE 1: THIS CHART DEPICTS THE GROSS WEIGHT, PRESSURE ALTITUDE, TEMPERATURE COMBINATION WHERE OEI HOGE CAPABILITY EXISTS USING 30 SECOND OEI POWER WITH A 60 SHP MARGIN.

NOTE 2: 15 FT OF GROUND CLEARANCE IS ASSURED IN THE EVENT OF AN ENGINE FAILURE AT 20 TO 80 FT AGL.

Figure 1-2A – Maximum Gross Weight for HEC Requiring Cat 'A'

Figure 1 to Paragraph (f)(3)(iii)

(g) Credit for Actions Previously Completed

Incorporation of the changes contained in Sikorsky RFM SA S92A–RFM–003, Part 1, Revision No. 12, approved December 9, 2010, before the effective date of this AD is considered acceptable for compliance with the corresponding actions specified in paragraph (f) of this AD.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Boston Aircraft Certification Office, FAA, may approve

AMOCs for this AD. Send your proposal to: John Coffey, Flight Test Engineer, Boston Aircraft Certification Office, 12 New England Executive Park, Burlington, MA 01803; telephone (781) 238–7173; email: *john.coffey@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office, before operating any aircraft complying with this AD through an AMOC.

(i) Additional Information

For service information identified in this AD, contact Sikorsky Aircraft Corporation, Attn: Manager, Commercial Technical Support, mailstop S581A, 6900 Main Street, Stratford, CT, telephone (203) 383–4866, email address *tsslibrary@sikorsky.com,* or at *http://www.sikorsky.com.* You may review a copy of the service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

(j) Subject

Joint Aircraft Service Component (JASC) Code: 2510 Flight Compartment Equipment.

Issued in Fort Worth, Texas, on January 16, 2015.

Lance T. Gant,

Acting Directorate Manager, Rotorcraft Directorate Manager, Aircraft Certification Service.

[FR Doc. 2015–02283 Filed 2–5–15; 8:45 am]

BILLING CODE 4910–13–C

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 229, 230, and 232

[Release Nos. 33–9720; 34–74194; File No. S7–08–10]

Asset-Backed Securities Disclosure and Registration

AGENCY: Securities and Exchange Commission.

ACTION: Technical amendment.

SUMMARY: This release makes technical corrections to rules that were published in the **Federal Register** on September 24, 2014. The Commission adopted revisions to Regulation AB and other rules governing the offering process, disclosure, and reporting for asset-backed securities. These technical amendments are being published to reinstate language that was inadvertently removed and make other technical corrections.

DATES: Effective February 6, 2015.

FOR FURTHER INFORMATION CONTACT: Kayla M. Florio, Attorney-Advisor, at (202) 551–3850; Division of Corporation Finance, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–3628.

SUPPLEMENTARY INFORMATION: This release technical amendments to § 229.1100, § 230.190, and § 232.201 that were published in the **Federal Register** on September 24, 2014 (79 FR 57184).

List of Subjects

17 CFR Part 230

Advertising, Reporting and recordkeeping requirements, Securities.

17 CFR Parts 229 and 232

Reporting and recordkeeping requirements, Securities.

Text of Amendments

For the reasons set out in the preamble, Title 17, Chapter II, of the Code of Federal Regulations is amended as follows:

PART 229—STANDARD INSTRUCTIONS FOR FILING FORMS UNDER SECURITIES ACT OF 1933, SECURITIES EXCHANGE ACT OF 1934 AND ENERGY POLICY AND CONSERVATION ACT OF 1975—REGULATION S–K

■ 1. The authority citation for part 229 continues to read as follows:

Authority: 15 U.S.C. 77e, 77f, 77g, 77h, 77j, 77k, 77s, 77z–2, 77z–3, 77aa(25), 77aa(26), 77ddd, 77eee, 77ggg, 77hhh, 777iii, 77jjj, 77nnn, 77sss, 78c, 78i, 78j, 78j–3,78*l,* 78m, 78n, 78n–1, 78o, 78u–5, 78w, 78*ll,* 78mm, 80a–8, 80a–9, 80a–20, 80a–29, 80a–30, 80a–31(c), 80a–37, 80a–38(a), 80a–39, 80b–11, and 7201 *et seq.;* and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

§ 229.1100 [Amended]

■ 2. Amend § 229.1100 in paragraph (f) by removing the reference ''(§§ 229.1100 through 229.1124)'' and adding in its place ''(§§ 229.1100 through 229.1125)''.

PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

■ 3. The authority citation for part 230 continues to read, in part, as follows:

Authority: 15 U.S.C. 77b, 77b note, 77c, 77d, 77d note, 77f, 77g, 77h, 77j, 77r, 77s, 77z–3, 77sss, 78c, 78d, 78j, 78*l,* 78m, 78n, 78*o,* 78*o*–7 note, 78t, 78w, 78*ll*(d), 78mm, 80a–8, 80a–24, 80a–28, 80a–29, 80a–30, and 80a–37, and Pub. L. 112–106, sec. 201(a), 126 Stat. 313 (2012), unless otherwise noted.

* * * * *

§ 230.190 [Amended]

■ 4. Amend § 230.190 in paragraph (b)(5) by adding ''and'' after ''securities;''.

PART 232—REGULATION S–T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

■ 5. The authority citation for part 232 continues to read, in part, as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s(a), 77z–3, 77sss(a), 78c(b), 78*l,* 78m, 78n, 78o(d), 78w(a), 78*ll,* 80a–6(c), 80a–8, 80a–29, 80a–30, 80a–37, and 7201 *et seq.;* and 18 U.S.C. 1350.

* * * * *

§ 232.201 [Amended]

■ 6. Amend § 232.201 in paragraph (a) introductory text by adding ''an application for an order under any section of the Investment Company Act (15 U.S.C. 80a–1 *et seq.*),'' after ''a Form D (239.500 of this chapter),''.

Dated: February 3, 2015.

Brent J. Fields,

Secretary.

[FR Doc. 2015–02425 Filed 2–5–15; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1952

[Docket ID. OSHA 2014–0019]

RIN 1218–AC92

Arizona State Plan for Occupational Safety and Health

AGENCY: Occupational Safety and Health Administration, Department of Labor.

ACTION: Rejection of State initiated plan change.

SUMMARY: This document announces the Occupational Safety and Health Administration's (OSHA's) decision to reject Arizona's standard for fall protection in residential construction. OSHA is deferring decision on the simultaneously proposed action of reconsidering the Arizona State Plan's final approval status, pending Arizona's expected repeal of the rejected standard, by operation of law, and subsequent enforcement of a standard that is at least as effective as OSHA's standard on fall protection in residential construction.

DATES: Effective February 6, 2015.

FOR FURTHER INFORMATION CONTACT: *For press inquiries:* Francis Meilinger, OSHA Office of Communications, Room

N–3647, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–1999; email: *meilinger.francis2@dol.gov.*

For general and technical information: Douglas J. Kalinowski, Director, OSHA Directorate of Cooperative and State Programs, Room N–3700, U.S. Department of Labor, 200 Constitution Avenue NW., Washington DC 20210; telephone: (202) 693–2200; email: *kalinowski.doug@dol.gov.*

SUPPLEMENTARY INFORMATION:

Background

Arizona State Plan

Arizona administers an OSHA-approved State Plan to develop and enforce occupational safety and health standards for private sector and state and local government employers, pursuant to the provisions of Section 18 of the Williams-Steiger Occupational Safety and Health Act of 1970 (29 U.S.C. 667) (''the Act''). The Arizona State Plan received initial OSHA approval on November 5, 1974 (39 FR 39037), and the Arizona Occupational Safety and Health Division (ADOSH) of the Industrial Commission of Arizona is designated as the state agency responsible for administering the State Plan. Pursuant to Section 18(e) of the Act, OSHA granted Arizona ''final approval'' effective June 20, 1985 (50 FR 25561). Final approval under Section 18(e) requires, among other things, a finding by the Assistant Secretary for Occupational Safety and Health (''Assistant Secretary'') that the plan, in actual operation, provides worker protection ''at least as effective as'' that provided by OSHA.

OSHA's Residential Construction Fall Protection Standard

OSHA issued its current federal construction fall protection standard on August 9, 1994 (29 CFR part 1926, subpart M, 59 FR 40672). In general, subpart M requires that an employee exposed to a fall hazard at a height of six feet or more (hereinafter referred to as a ''trigger height'') be protected by conventional fall protection, specifically a guardrail system, safety net system, or personal fall arrest system. Subpart M creates an exception allowing a residential construction employer who can demonstrate that it is infeasible or creates a greater hazard to use these systems, to develop and implement a fall protection plan instead. OSHA's standard requires that fall protection plans conform to specific criteria, including that they be site-specific and specify the alternative measures that will be taken to eliminate or reduce the possibility of a fall. (29 CFR 1926.502(k)(1). As set forth in subpart M, there is a presumption that use of conventional fall protection is feasible and implementation will not create a greater hazard, and the employer has the burden of proving otherwise. It should be noted that OSHA rarely encounters real-world situations where conventional fall protection is truly infeasible.

In response to questions raised by the residential construction industry about the feasibility of subpart M, on December 8, 1995, OSHA issued interim fall protection procedures (STD 3.1) for residential construction employers that differ from those in subpart M. OSHA instruction STD 03–00–001 (a plain language rewrite and renumbering of STD 3.1) set out an interim compliance policy that permitted employers engaged in certain residential construction activities to use specified alternative procedures instead of conventional fall protection. OSHA never intended STD 03–00–001 to be a permanent policy; in issuing the Instruction, OSHA stated that the guidance provided therein would remain in effect until further notice or until completion of a new rulemaking effort addressing these concerns.

On July 14, 1999, OSHA initiated the evaluation of STD 03–00–001 by publishing an Advanced Notice of Proposed Rulemaking (ANPR) (64 FR 38078) seeking comments and data to support claims that fall protection requirements for certain construction activities were infeasible. In the ANPR, OSHA stated that the conventional fall protection requirements and six foot trigger height set forth in subpart M were established as reasonably necessary and appropriate to protect workers, and as technologically and economically feasible for employers. OSHA noted that since the promulgation of subpart M, there had been additional advances in the types and capability of commercially available fall protection equipment and, therefore, OSHA intended to rescind STD 03–00–001 unless persuasive evidence of infeasibility or significant safety hazard was presented.

After considering all comments submitted on the record, OSHA concluded that, overall, there was no persuasive evidence to show that employers in residential construction would be unable to find a safe and feasible means of protecting workers from falls in accordance with subpart M (29 CFR 1926.501(b)(13)). Therefore, on December 16, 2010, OSHA's Compliance Guidance for Residential Construction (STD 03–11–002) canceled OSHA's interim enforcement policy (STD 03–00–001) on fall protection for certain residential construction activities, and required employers engaged in residential construction to fully comply with 29 CFR 1926.501(b)(13). This new guidance informed State Plans that, in accordance with the Act, they must each have a compliance directive on fall protection in residential construction that, in combination with applicable State Plan standards, resulted in an enforcement program that is at least as effective as OSHA's program (75 FR 80315, Dec. 22, 2010).

Arizona's Residential Construction Fall Protection Standard

On June 16, 2011, ADOSH adopted STD 03–11–002, but on June 17, 2011, the Industrial Commission of Arizona (ICA) immediately stayed the enforcement of this directive. Then on November 30, 2011, the ICA lifted the stay, effective January 1, 2012. On March 27, 2012, a new bill, SB 1441, was signed into legislation, requiring conventional fall protection in residential construction whenever an employee is working at a height of 15 feet or more or whenever a roof slope is steeper than 7:12, and creating an exception where implementation of conventional fall protection is infeasible or creates a greater hazard. SB 1441 was codified as Arizona Revised Statute, Title 23, Ch. 2, Art 13 (A.R.S. 23–492), which sets forth fall protection requirements for residential construction work in the state. ADOSH then adopted the requirements of A.R.S. 23–492 as a state standard (Ariz. Admin. Code R20–5–601.01). In most instances, state standards are adopted by the designated state occupational safety and health agency, and are forwarded to OSHA as supplements to the State Plan (29 CFR 1953.4). However, in this instance the legislature itself provided the standard (Ariz. Admin. Code R20–5–601.01). Accordingly, the State Plan supplement at issue in this **Federal Register** document is referred to as the ''state statute'' rather than ''standard'' or ''supplement,'' the terms used in OSHA's procedural regulations.

After a series of discussions with the state, on March 19, 2014, OSHA sent Arizona a letter to show cause why a proceeding to reject the state statute and reconsider the state's final approval status should not be commenced. OSHA's main point of contention was the 15-foot trigger height for the use of conventional fall protection. On May 1, 2014, Arizona submitted its response, pointing to the passage of SB 1307, a new bill signed on April 22, 2014,

which makes certain revisions to A.R.S. 23–492. This revised version of the state statute makes some relatively minor changes to its fall protection requirements, but does not alter the 15-foot trigger height for conventional fall protection. The revisions in SB 1307 do mandate fall protection for heights above six feet, but in most situations, allow this protection to be in the form of a fall protection plan and do not require conventional fall protection. Further, Arizona's requirements for a fall protection plan allow employers to ''develop a single fall protection plan covering all construction operations,'' but require that a qualified person develop a supplement to the general plan for additional fall hazards at specific sites, not already included in the plan. (A.R.S. 23–492.07(A)(1)), (SB 1307 Secs. 5(A)(1), (5)). The Arizona state statute requires that the plan ''reduces or eliminates hazards,'' but does not provide specific guidance on what measures are enough to meet this threshold, and allows for only a safety monitoring system in most situations. (A.R.S. 23–492.07(A)(8)). Finally, SB 1307 also contains a conditional repeal provision stating that if OSHA does reject the state statute, and publishes that decision in the **Federal Register** pursuant to 29 CFR 1902.23, then A.R.S. 23–492 is repealed by operation of law (SB 1307 Sec. 7).

Comparison of OSHA Standards and Arizona's Residential Construction Fall Protection Statute

The OSH Act requires that State Plans develop and enforce standards that are at least as effective as OSHA's standards (29 U.S.C. 667(c)(2)). OSHA's standard for fall protection in residential construction (subpart M, 29 CFR 1926.501(b)(13)) generally requires conventional fall protection (fall arrest systems, safety nets, or guardrails) any time employees are working at heights of six feet or greater. In contrast, Arizona's state statute generally requires very limited, if any, fall protection for employees working between six and 15 feet. The 2014 revision of the Arizona statute includes a mandate for fall protection for heights above six feet, but in most situations, allows for that fall protection to be in the form of a fall protection plan only. As discussed below in response to the comments, OSHA has found that conventional fall protection is a more effective means of protecting workers than implementation of a written plan. Arizona and OSHA's requirements for a fall protection plan differ significantly.

In the limited circumstances where conventional fall protection is infeasible or creates a greater hazard, OSHA requires the employer to implement a written, site-specific fall protection plan that specifies the alternative measures that will be taken to eliminate or reduce the possibility of a fall (29 CFR 1926.501(b)(13); STD 03–11–002). (1307 Sec. 2(A) and 5(A)). In contrast, the Arizona statute generally requires that the plan ''reduces or eliminates hazards,'' but does not provide specific guidance on what measures are enough to meet this threshold, and allows for only a safety monitoring system in most situations. (A.R.S. 23–492.07(A)(8)). In addition, the Arizona state statute allows employers to develop a single fall protection plan that can cover multiple worksites. In an apparent effort to make the single fall protection plan more site-specific, the 2014 revision of the Arizona statute requires that a qualified person develop a supplement to the general plan for additional fall hazards not already included in the plan. (SB 1307 Secs. 5(A)(1), (5)). However, the state statute contains no guidance about the required level of detail of the plan, which leaves open the possibility that single plans could be general enough to meet the statutory requirement for almost all situations. Further, there is no requirement to review the plan at each site to ensure that it meets the statutory requirement of eliminating or reducing the possibility of a fall.

Finally, Arizona's statute contains several exceptions to the general requirement for conventional fall protection that will result in many circumstances in which conventional fall protection is not required, and the use of other alternative methods, *e.g.* ''eave barriers'' and parapet walls is allowed. (SB 1307 Secs. 1(6), 3(G)(2), 4(A) and 4(B)).

After reviewing the provisions of both versions of the state statute, OSHA has concluded that the Arizona statute is not at least as effective as OSHA's standard, the most notable problematic differences being Arizona's 15-foot trigger height for using conventional fall protection as opposed to OSHA's six-foot trigger height, Arizona's single fall protection plan for all worksites, and Arizona's exceptions to the requirement for conventional fall protection. On the basis of these concerns, OSHA is rejecting Arizona's statute on fall protection in residential construction.

Initial Federal Register Document and Discussion of Comments

OSHA published a **Federal Register** document proposing to reject the Arizona fall protection statute and reconsider the state's final approval on August 21, 2014 (79 FR 49465). The agency requested comments by September 25, 2014. OSHA received a total of ten comments on both rejection of the state statute and reconsideration of final approval status. OSHA has reviewed and considered the comments, and the following discussion summarizes the issues raised and OSHA's responses.

Comments were received from representatives of the American Society for Safety of Engineers (ASSE), National Safety Council (NSC), Home Builders Association of Central Arizona (HBACA), National Association of Home Builders (NAHB), Subcontractors Association of Arizona (ASA),[1] members of the Arizona State Senate, Greater Phoenix Chamber of Commerce, Safirst Corporation, Grand Canyon State Electric Cooperative Association, and the Industrial Commission of Arizona (ICA). Commenters provided mixed feedback on both the proposed rejection of the Arizona statute and proposed reconsideration of Arizona's final approval status. ASSE and NSC supported OSHA in reconsidering final approval at this time, while the Greater Phoenix Chamber of Commerce, Safirst Corporation, HBACA, NAHB, ICA, ASA, members of the Arizona State Senate, and Grand Canyon State Electric Cooperative Association all opposed reconsideration of final approval. Most of the arguments against reconsideration included a request to delay the action in order to allow the conditional repeal within SB 1307 to take effect upon rejection of the statute. OSHA has agreed to defer its decision on reconsideration of final approval status and will monitor Arizona's response to the rejection of the state statute and subsequent implementation and enforcement of residential fall protection requirements. Further discussion of the comments on reconsideration can be tabled until such time that OSHA decides whether or not to move forward on that action.

In respect to the comments on the proposed rejection of Arizona's statute, ASSE and NSC both generally supported rejection, focusing on the discrepancy in trigger heights and supporting the argument that a law requiring a plan for avoiding hazards does not ensure the same level of safety as a law requiring personal protective equipment when exposure to a hazard does occur. The HBACA, NAHB, ASA, members of the Arizona State Senate, and ICA all generally opposed rejection of the state's statute, with many overlapping arguments. One common

[1] Late comment.

contention was that the Arizona statute is ''at least as effective'' as OSHA's standard because Arizona has a holistic approach to fall protection, emphasizing fall prevention rather than simply focusing on fall protection once a fall has occurred above certain trigger heights. Commenters argued that Arizona has a more effective fall protection program by requiring the extensive use of written fall protection plans to implement work practices that reduce exposure to fall hazards. OSHA agrees that preventing falls is preferable to arresting them. For example, STD 03–11–002 notes that use of guardrails, where feasible, is preferable to personal fall arrest systems or safety nets. However, OSHA finds that a requirement to have a written fall protection plan in place is not a substitute for the proactive protection provided by guardrails, personal fall arrest systems or safety nets. In general, OSHA has found that conventional fall protection is a more effective means of protecting workers than a written plan to reduce or eliminate fall hazards. OSHA agrees that planning plays an important part in preventing falls and acknowledges that a written fall protection plan contributes to ensuring safety at a workplace, but only if it is combined with the implementation of conventional fall protection. If a worker is exposed to a fall hazard despite the implementation of a plan, that worker must be protected. Moreover, the protection afforded needs to be at least as effective as what would be required under OSHA's standard. Further, as discussed above, OSHA has concerns about Arizona's fall protection plan requirements, on its face. In sum, the state statute lacks specific guidance on the required contents of the plan, essentially allows for a fall protection plan to be a single plan for all sites, and does not require review of the plan at each site.

Commenters also argued that the exceptions to Arizona's general requirement for conventional fall protection were greatly narrowed by SB 1307 and do not undermine the statute. OSHA acknowledges that SB 1307 did limit the exceptions; however, in addition to only requiring a fall protection plan between six and 15 feet in height, there are also other exceptions above 15 feet in which conventional fall protection is not required by the Arizona statute, but would be required under OSHA's standard.

Another common thread among the comments opposing rejection is that differing trigger heights is not conclusive evidence that the state's standard is not ''at least as effective'' as OSHA's standard. OSHA's rulemaking on subpart M concluded that a six foot rule was reasonably necessary and appropriate to protect workers and technologically and economically feasible for employers, including employers in residential construction. OSHA recognizes Congressional intent in allowing State Plans to promulgate different standards and to be more effective than OSHA. State Plans are not necessarily required to adopt an identical fall protection standard as long as workers are afforded ''at least as effective'' protection under the state standard as they would have under OSHA's standard.

Several commenters objected to OSHA making a determination of effectiveness absent a publicized definition of effectiveness and known process for making the determination. The OSH Act requires a State Plan to develop and enforce safety and health standards that are ''at least as effective'' in providing safe and healthful employment and places of employment as provided by OSHA's standards. At least one commenter asserted that OSHA should rely on outcome performance measures or injury and illness rates as evidence that a State Plan is at least as effective as OSHA. However, OSHA regulations establish that effectiveness is evaluated by comparing state standards to OSHA's standards on a provision by provision basis. OSHA's regulations require that State Plans provide standards with respect to specific issues which will be at least as effective as the standards promulgated by OSHA relating to the same issues. (29 CFR 1902.4(b)(2)). OSHA's indices of effectiveness require that State Plan standards are at least as effective in containing specific provisions for the protection of employees from exposure to hazards. As such, State Plan standards must include appropriate provisions requiring use of suitable protective equipment and control or technological procedures to protect against such hazards. See 29 CFR 1902(b)(2)(vii). As explained above, OSHA's main point of contention with the Arizona statute is that Arizona employers are not required to provide conventional fall protection to workers in residential construction working at heights between six and 15 feet on slopes with a pitch that is less than 7:12, as they would be required to provide if operating in a state covered by OSHA, and the Arizona statute fails to impose any additional or different requirements or administrative controls that entirely eliminate the fall hazard at those heights.

Three other collateral issues raised by the commenters included a call for action with the other State Plans that have differing standards for fall protection in residential construction; a request for a response to NAHB's previous petition for OSHA to reopen the rulemaking on the fall protection standard; and a concern about lack of outreach to subcontractors during OSHA's discussions with Arizona. In respect to the first issue, OSHA is currently engaged in a dialogue with the other State Plans that have different fall protection trigger heights, just as OSHA engaged in dialogue with Arizona prior to beginning this formal process to reject the state statute. (See 79 FR 49465). OSHA expects these states to take steps in the near future to move forward towards ensuring they are ''at least as effective'' as OSHA. In respect to the second issue, on September 19, 2014, OSHA released an official denial in response to NAHB's petition to reopen rulemaking on the fall protection standard. In denying the petition, OSHA stated, in part:

> OSHA believes that rescinding the interim directive, and enforcing compliance with 29 CFR 1926.501(b)(13), has been effective in reducing the incidence of fatal falls among residential construction workers. OSHA believes this policy change has led to increasing numbers of residential construction employers using conventional fall protection, and expects that residential construction worksites will become even safer as more employers implement these fall protection methods.

In respect to the third issue, OSHA values stakeholder input, and if OSHA's discussions with other states about their fall protection in residential construction standards lead to meetings with industry representatives, OSHA will seek to welcome the involvement of subcontractors, their representatives, and other interested parties. In this proceeding, OSHA outlined its efforts to work with Arizona and other stakeholders in the initial **Federal Register** document (See 79 FR 49465), and OSHA has meet all the procedural requirements for this action. (See 29 CFR 1953.6(e)).

The public comments and questions submitted on the docket have all been addressed in this document and there are no substantial issues raised that necessitate a public hearing. Arizona specifically waived a hearing on the rejection of the state statute, and no other commenter requested a hearing. Arizona also waived the tentative decision by the Assistant Secretary that is provided in the regulations on rejection proceedings. (29 CFR 1902.21) The regulations further provide that

when the state waives the tentative decision, the Assistant Secretary ''shall issue a final decision.'' (29 CFR 1902.21(b)).

Decision on Rejecting the State's Statute

Pursuant to the procedures set forth in 29 CFR 1953.6(e) and 1902.22–23, the Assistant Secretary has made a final decision to reject the Arizona State Plan's statute for fall protection in residential construction. Thus, the Assistant Secretary rejects the changes to Arizona's State Plan prescribed by Title 23, chapter 2, article 13, section 01, Arizona Revised Statutes (A.R.S. 23–492.01) under 29 CFR 1953.6(e) and 1902.22, and now publishes that decision in the **Federal Register** pursuant to 29 CFR 1902.23. This rejection excludes the changes prescribed by A.R.S. 23–492.01 from the Arizona State Plan. The Assistant Secretary is deferring decision on the simultaneously proposed action of reconsidering the State Plan's final approval. This deferral is pending Arizona's expected repeal of the rejected statute and subsequent enforcement of a standard at least as effective as OSHA's standard. The Assistant Secretary's decision to reject the state statute is based upon the facts determined by OSHA in monitoring the Arizona State Plan and a comparative review of Arizona's statute and OSHA's standard, and was reached after opportunity for public comment.

Effect of the Decision

SB 1307 contains a conditional repeal provision stating that if OSHA does reject the state statute, and publishes that decision in the **Federal Register** pursuant to 29 CFR 1902.23, then A.R.S. 23–492 is repealed by operation of law (SB 1307 Sec. 7). Therefore, the expected effect of the Assistant Secretary's decision to reject Arizona's statute covering fall protection in residential construction is that ADOSH will revert to enforcing 29 CFR part 1926, subpart M. The Assistant Secretary will defer the decision on reconsideration to allow the state time to implement and begin enforcement of STD 03–11–002. OSHA will continue to monitor the State Plan, specifically enforcement activities in residential construction, to confirm that ADOSH is implementing and enforcing subpart M, or an at least as effective alternative, in an at least as effective manner. The lack of any such implementation or enforcement would leave a gap in the State's enforcement program for construction, but if the State Plan retained its final approval, neither the State Plan nor OSHA could cover that gap. Any such gap in the State Plan's enforcement program would serve as the basis for the Assistant Secretary's reconsideration of 18(e) final approval status. At this time, the Assistant Secretary is deferring the decision on reconsideration pending the state's enforcement of subpart M.

Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Ave. NW., Washington, DC, authorized the preparation of this document. OSHA is issuing this document under the authority specified by Section 18 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 667), Secretary of Labor's Order No. 1–2012 (77 FR 3912), and 29 CFR parts 1902 and 1953.

Signed in Washington, DC, on January 30, 2015.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2015–02302 Filed 2–5–15; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF THE TREASURY

31 CFR Part 50

Interim Guidance Concerning the Terrorism Risk Insurance Program Reauthorization Act of 2015

AGENCY: Department of the Treasury, Departmental Offices.

ACTION: Notice of interim guidance.

SUMMARY: This notice provides interim guidance concerning the Terrorism Risk Insurance Program (Program) under the Terrorism Risk Insurance Act of 2002, as amended (TRIA). In this notice, the Department of the Treasury (Treasury) addresses issues that have arisen under Treasury's regulations for the Program (Program regulations) due to the enactment of the Terrorism Risk Insurance Program Reauthorization Act of 2015 (2015 Reauthorization Act).

DATES: February 4, 2015.

FOR FURTHER INFORMATION CONTACT: Kevin K. Meehan, Policy Advisor, Federal Insurance Office, 202–622–7009; Thomas E. Scanlon, Senior Counsel, Office of General Counsel (Banking and Finance), 202–622–8170.

SUPPLEMENTARY INFORMATION: This notice provides interim guidance addressing the application of certain provisions of TRIA [1] and the Program regulations [2] following enactment of the 2015 Reauthorization Act.[3]

Treasury expects to issue a proposal to amend the Program regulations; this interim guidance may be relied upon by members of the public until superseded by the Program regulations, as amended, or by subsequent guidance.[4]

I. Background

TRIA was enacted following the attacks on September 11, 2001, to address disruptions in the market for terrorism risk insurance, to help ensure the continued widespread availability and affordability of commercial property and casualty insurance for terrorism risk, and to allow for the private markets to stabilize and build insurance capacity to absorb any future losses for terrorism events. Title I of TRIA creates the Program, requires insurers to ''make available'' terrorism risk insurance for commercial property and casualty losses resulting from certified acts of terrorism (insured losses), and provides for shared public and private compensation for such insured losses. Pursuant to TRIA, the Secretary of the Treasury administers the Program. The Federal Insurance Office assists the Secretary of the Treasury in administering the Program.

The Program was originally scheduled to terminate on December 31, 2005; however, the Terrorism Risk Insurance Extension Act of 2005 [5] extended the Program through December 31, 2007, and the Terrorism Risk Insurance Program Reauthorization Act of 2007 [6] further extended the Program through December 31, 2014. On January 12, 2015, the President signed into law the 2015 Reauthorization Act; Section 101 of that Act amends the Program's termination date to December 31, 2020.

II. Interim Guidance

Treasury considers the Program regulations to be in effect, except to the extent that any provision of the Program regulations is inconsistent with TRIA, as amended by the 2015 Reauthorization Act. In the case of an inconsistency, the provision(s) of TRIA, as amended by the 2015 Reauthorization Act, shall apply. Furthermore, Treasury recognizes that the 2015 Reauthorization Act introduces ambiguities regarding application of certain sections of the Program regulations. This interim guidance is designed to address certain requirements under the Program

[1] 15 U.S.C. 6701, note.

[2] 31 CFR part 50.

[3] Public Law 114–1, 129 Stat. 3.

[4] 31 CFR 50.7.

[5] Public Law 109–144, 119 Stat. 2660.

[6] Public Law 110–160, 121 Stat. 1839.

regulations and TRIA, as amended by the 2015 Reauthorization Act.

Interim Guidance One (Documentation)

Due to requirements under state law regulating rates and forms, an insurer may need additional time to provide disclosures and offers of coverage for insured losses in compliance with the Program regulations and TRIA, as amended by the 2015 Reauthorization Act. An insurer should provide disclosures and offers that comply with the Program regulations and TRIA, as amended by the 2015 Reauthorization Act, as soon as possible and not later than April 13, 2015.

Interim Guidance Two (Form of Disclosure)

Section 50.17(c) of the Program regulations provides that an insurer may use NAIC Model Disclosure Form No. 1 or NAIC Model Disclosure Form No. 2, or other disclosures that meet the requirements of the Program regulations. NAIC Model Disclosure Form No. 1 and NAIC Model Disclosure Form No. 2, as amended in 2015, are consistent with the disclosure requirements of the Program regulations and TRIA, as amended by the 2015 Reauthorization Act.

Interim Guidance Three (Timing of Disclosure)

As amended by the 2015 Reauthorization Act, TRIA no longer requires an insurer to provide to a policyholder certain disclosures at the time of a policy's ''purchase,'' but still requires the insurer to provide such disclosures at the time of ''offer'' and ''renewal.'' The timing of an insurer's disclosures may conform with either subpart B of the Program regulations or Section 103(b)(2) of TRIA, as amended by the 2015 Reauthorization Act.

Interim Guidance Four (Content of Disclosure)

An insurer that offered coverage for insured losses prior to January 12, 2015, using the then-current NAIC Model Disclosure Form No. 1, NAIC Model Disclosure Form No. 2, or other disclosures consistent with the Program regulations, is not required to provide a revised disclosure to the policyholder. Subject to Interim Guidance One, disclosures on or after January 12, 2015 provided in connection with a new or mid-term offer of coverage for insured losses should be based on the requirements of the Program regulations and TRIA, as amended by the 2015 Reauthorization Act.

Interim Guidance Five (New Offers of Coverage)

(a) Except as described herein, Treasury expects that an insurer will make a new offer of coverage for insured losses with respect to any in-force policy that does not provide coverage for insured losses.

(b) An insurer is not expected to make a new offer of coverage for insured losses if—

(i) the policy incorporates a conditional exclusion or change of terms and conditions relating to coverage for insured losses and, because the Program is in effect, the insurer forbears effective January 1, 2015 (or as of the effective date of the policy, if later) on the exercise of the conditional exclusion or change in terms and conditions. Not later than April 13, 2015, an insurer should provide to the policyholder written notice of the insurer's forbearance or written notice of the insurer's withdrawal of any previous exercise of the conditional exclusion or change in terms and conditions. In the written notice, the insurer should state that the insurer's forbearance or withdrawal, as applicable, is effective January 1, 2015 (or as of the effective date of the policy, if later); or

(ii) the policyholder declined coverage for insured losses, so long as the insurer's offer did not materially differ in price from that which the insurer would have offered following enactment of the 2015 Reauthorization Act.

(c) If a policyholder declined coverage for insured losses but the insurer's offer did materially differ in price from that which the insurer would have offered following enactment of the 2015 Reauthorization Act, then the insurer should consider making a new offer to that policyholder.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act,[7] the information collections contained in this document have been approved by the Office of Management and Budget (OMB) under control number 1505/0197. Any agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a valid OMB control number.

Dated: February 4, 2015.

Michael T. McRaith,

Director, Federal Insurance Office.

[FR Doc. 2015–02556 Filed 2–4–15; 4:15 pm]

BILLING CODE 4810–25–P

[7] 44 U.S.C. 3501 *et seq.*

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2015–0034]

Drawbridge Operation Regulation; Columbia River, Vancouver, WA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulations.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Burlington Northern Santa Fe (BNSF) Railway Bridge across the Columbia River, mile 105.6, at Vancouver, WA. This deviation is necessary to accommodate maintenance to replace movable rail joints. This deviation allows the bridge to remain in the closed position during maintenance activities.

DATES: This deviation is effective from 7 a.m. until 3 p.m. on February 25, 2015, and from 7 a.m. until 3 p.m. on February 26, 2015.

ADDRESSES: The docket for this deviation, [USCG–2015–0034] is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Steven Fischer, Bridge Administrator, Thirteenth Coast Guard District; telephone 206–220–7282, email *d13-pf-d13bridges@uscg.mil.* If you have questions on viewing the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: BNSF has requested that the BNSF Swing Bridge across the Columbia River, mile 105.6, remain closed to vessel traffic to facilitate replacement of movable rail joints. During this maintenance period the swing span of the BNSF Railway Bridge across the Columbia River at Vancouver, WA, will be disabled and the bridge will not be able to be open. The BNSF Swing Bridge, mile 105.6, provides 39 feet of vertical clearance

above Columbia River Datum 0.0 while in the closed position. Vessels able to pass through the bridge in the closed positions may do so at anytime. The current operating schedule for the bridge is set out in 33 CFR 117.5. The normal operating schedule for the BNSF Swing Bridge states that the bridge must open promptly and fully on request. This deviation allows the swing span of the BNSF Railway Bridge across the Columbia River, mile 105.6, to remain in the closed position, and need not open for maritime traffic from 7 a.m. until 3 p.m. on February 25, 2015, and 7 a.m. until 3 p.m. on February 26, 2015. The bridge shall operate in accordance to 33 CFR 117.5 at all other times. Waterway usage on this part of the Columbia River includes vessels ranging from commercial tug and tow vessels to recreational pleasure craft including cabin cruisers and sailing vessels. The bridge will not be able to open for emergencies and there is no immediate alternate route for vessels to pass. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessels can arrange their transits to minimize any impact caused by the temporary deviation.

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

Dated: January 22, 2015.

Steven M. Fischer,

Bridge Administrator, Thirteenth Coast Guard District.

[FR Doc. 2015–02329 Filed 2–5–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2015–0052]

Drawbridge Operation Regulation; Atlantic Intracoastal Waterway, Wrightsville Beach, NC

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the S.R. 74 Bridge, across the Atlantic Intracoastal Waterway (AIWW), mile 283.1, at Wrightsville Beach, NC. This deviation is necessary to accommodate the 6th Annual Quintiles Wrightsville Beach Marathon. This deviation allows the bridge to remain in the closed position during the race.

DATES: This deviation is effective from 5 a.m. to 10:30 a.m. on Sunday, March 22, 2015.

ADDRESSES: The docket for this deviation, [USCG–2015–0052] is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Kashanda Booker, Bridge Administration Branch, Fifth Coast Guard District; telephone (757) 398–6227, email *Kashanda.l.booker@uscg.mil.* If you have questions on viewing the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: The 6th Annual Quintiles Wrightsville Beach Marathon committee on behalf of the North Carolina Department of Transportation (NCDOT) has requested a temporary deviation from the current operating schedule for the S.R. 74 Bascule Drawbridge across the AIWW mile 283.1, at Wrightsville Beach, NC. The requested deviation will accommodate the 6th Annual Quintiles Wrightsville Beach Marathon scheduled for Sunday, March 22, 2015. To facilitate this event, the draw of the bridge will be maintained in the closed-to-navigation position from 5 a.m. to 10:30 a.m. to allow race participants to cross during the scheduled event.

The current operating schedule for the bridge is set out in 33 CFR 117.821(a)(4). The regulation requires the bridge to open on signal for vessels at all times except that from 7 a.m. until 7 p.m. the bridge shall open on the hour; every third and fourth Saturday in September the bridge shall remain closed from 7 a.m. until 11 a.m.; and the last Saturday of October or the first or second Saturday of November the bridge shall remain closed from 7 a.m. until 10:30 a.m. The bascule drawbridge has a vertical clearance of 20 feet above mean high water (MHW) in the closed position. Vessels that can pass through the bridge in the closed position may do so at any time.

To ensure that waterway users are aware of the closure, the Coast Guard will issue a Local and Broadcast Notice to Mariners to allow mariners to schedule their transits accordingly. There are no alternate routes available to vessels. Most waterway traffic consists of recreational boats with a few barges and tugs during the daytime. The bridge is able to open for emergencies.

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

Dated: January 27, 2015.

James L. Rousseau,

Bridge Program Manager, Fifth Coast Guard District.

[FR Doc. 2015–02449 Filed 2–5–15; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 80

[EPA–HQ–OAR–2014–0283; FRL 9921–82–OAR]

RIN 2060–AS19

Regulation of Fuels and Fuel Additives: Extension of the Reformulated Gasoline Program to Maine's Southern Counties

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is extending the Clean Air Act's (CAA) prohibition against the sale of conventional gasoline in reformulated gasoline (RFG) areas to the southern Maine counties of York, Cumberland, Sagadahoc, Androscoggin, Kennebec, Knox, and Lincoln (hereinafter, the ''Southern Maine Counties''). This action is based on a request from the Governor of the State of Maine for areas within the ozone transport region established under the CAA. The CAA does not give the EPA discretion to deny a Governor's request on this matter. The scope of the EPA's discretion is limited to establishing the date that the prohibition commences. Consistent with the Governor's request, the EPA is finalizing as proposed a prohibition commencement date of May 1, 2015 for all refiners, importers, and distributors in the Maine counties referenced in the Governor's request, and June 1, 2015 for all retailers and wholesale purchaser-

consumers in those counties. The EPA is also adding in its RFG opt-out rules a provision to reflect that there is a four-year minimum opt-in period for areas that opt into the RFG program on the basis of their location within the ozone transport region. This clarification aligns the federal regulation for RFG opt-out requirements with the CAA.

DATES: This final rule is effective on March 9, 2015.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2014–0283. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air and Radiation Docket, EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW., Washington, DC 20004. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Patty Klavon, Office of Transportation and Air Quality, Environmental Protection Agency, 2000 Traverwood Drive, Ann Arbor, Michigan, 48105; telephone number: (734) 214–4476; fax number: (734) 214–4052; email address: *klavon.patty@epa.gov.*

SUPPLEMENTARY INFORMATION:

The contents of this preamble are listed in the following outline:

I. General Information
II. Background
III. Description of the Final Rule
IV. Rationale
V. Statutory and Executive Order Reviews
VI. Legal Authority and Statutory Provisions

I. General Information

A. Does this action apply to me?

Entities potentially affected by this rule are fuel producers and distributors who do business in Maine.

Examples of potentially regulated entities	NAICS [1] Codes
Petroleum refineries	324110
Gasoline Marketers and Distributors	424710 424720
Gasoline Retail Stations	447110
Gasoline Transporters	484220 484230

The above is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. The table lists the types of entities of which the EPA is aware that potentially could be affected by this rule. Other types of entities not listed on the table could also be affected by this rule. To determine whether your organization could be affected by this rule, you should carefully examine the regulations in 40 CFR 80.70. If you have questions regarding the applicability of this action to a particular entity, call the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

II. Background

A. Background on the Federal Reformulated Gasoline Program

The purpose of the federal RFG program is to improve air quality in certain areas through the use of gasoline that is reformulated to reduce motor vehicle emissions of tropospheric ozone-forming compounds, as set forth in CAA section 211(k)(1). The EPA first published regulations for the federal RFG program on February 16, 1994. (59 FR 7716). RFG makes up over 30 percent of the volume of motor vehicle gasoline consumed in the United States [2] and is used in 17 states and the District of Columbia.[3]

CAA section 211(k)(5) prohibits the sale of conventional gasoline (*i.e.,* gasoline that the EPA has not certified as reformulated) in certain ozone nonattainment areas beginning January 1, 1995. CAA section 211(k)(10)(D) defines the areas initially covered by the federal RFG program as ozone nonattainment areas having a 1980 population in excess of 250,000 and having the highest ozone design values during the period 1987 through 1989.[4] In addition, under CAA section 211(k)(10)(D), any area reclassified as a Severe ozone nonattainment area under CAA section 181(b) is also included in the federal RFG program. Finally, CAA sections 211(k)(6)(A) and (B) allow areas classified as Marginal, Moderate, Serious, or Severe ozone nonattainment areas, or areas within the ozone transport region established under CAA section 184, to opt into the RFG program at the request of the Governor of the State in which the area is located.

Maine is in the ozone transport region established under CAA section 184, and its request to opt into the RFG program was made pursuant to CAA section 211(k)(6)(B). That provision specifies that upon petition of the Governor of a State in the ozone transport region, the EPA is to apply the prohibition against selling or dispensing of conventional gasoline in RFG covered areas in any area in the State other than an area classified as Marginal, Moderate, Serious, or Severe ozone nonattainment area under subpart 2 of part D of subchapter 1 of the Clean Air Act. This prohibition is to ''commence as soon as practicable but not later than 2 years after the date of approval by the Administrator of the application of the Governor of the State.'' CAA section 211(k)(6)(B)(ii)(I). However, if the EPA determines that there is insufficient capacity to supply RFG, the EPA may extend the commencement date by no more than a year, and may renew that extension for two additional one-year periods. CAA section 211(k)(6)(B)(iii). The area may not opt out of the federal RFG program earlier than four (4) years after the RFG commencement date. CAA section 211(k)(6)(B)(ii)(II).

B. Request From the State of Maine

In 2013, the State of Maine enacted Public Law 2013 c.221 calling for the use of RFG in York, Cumberland, Sagadahoc, Androscoggin, Kennebec, Knox, and Lincoln counties beginning May 1, 2014. On July 23, 2013, the Governor of Maine formally requested, pursuant to CAA section 211(k)(6)(B), that the EPA extend the requirement for the sale of RFG to these counties beginning on May 1, 2014.

The Maine legislature subsequently enacted an emergency law, Public Law 2013 c.453, effective March 6, 2014, to postpone the requirement for the sale of RFG in these counties until June 1, 2015. Pursuant to that legislation, the

[1] North American Industry Classification System.

[2] See the U.S. Energy Information Administration statistics on consumption and sales of petroleum and other liquids at: *http://www.eia.gov/petroleum/reports.cfm?t=164.*

[3] For a map showing current RFG areas, please visit the EPA's Web site at: *http://www.epa.gov/otaq/fuels/gasolinefuels/rfg/areas.htm.*

[4] Applying these criteria, the EPA has determined the nine covered areas to be the metropolitan areas including Los Angeles, Houston, New York City, Baltimore, Chicago, San Diego, Philadelphia, Hartford, and Milwaukee.

Commissioner for the State of Maine's Department of Environmental Protection (DEP) submitted a request to the EPA dated March 10, 2014, modifying Maine's request for the implementation date for the sale of RFG in the Southern Maine Counties to coincide with June 1, 2015.[5]

Copies of the Commissioner's letter, the letter from the Governor of the State of Maine dated July 23, 2013, and the Maine legislation establishing the use of RFG in the Southern Maine Counties are available in the docket at EPA–HQ–OAR–2014–0283.

The EPA issued a proposal for public comment on August 28, 2014 (79 FR 51288), consistent with the State's request. No comments were received.

III. Description of the Final Rule

Based on our evaluation of the appropriate lead time and start dates, and pursuant to Maine's request for a June 1, 2015 implementation date and the provisions of CAA section 211(k)(6), the EPA is amending its RFG regulation at 40 CFR 80.70 to add new paragraph (n)(1) extending the CAA section 211(k)(5) prohibition against the sale of conventional (*i.e.,* non-reformulated) gasoline in RFG covered areas to the Southern Maine Counties. Based on Maine's request for a June 1, 2015 implementation date, the EPA is finalizing as proposed the prohibition on the sale of conventional gasoline in the Southern Maine Counties to commence as of May 1, 2015 for all regulated entities in these counties other than retailers and wholesale purchaser-consumers (*i.e.,* refiners, importers, and distributors), and as of June 1, 2015 for retailers and wholesale purchaser-consumers. Thus, conventional gasoline may not be sold to consumers in the Southern Maine Counties as of June 1, 2015. Only RFG may be sold to consumers in these counties as of June 1, 2015. The Southern Maine Counties are part of the ozone transport region as defined in CAA section 184. They are not currently classified under subpart 2 of Part D of CAA subchapter I as Marginal, Moderate, Serious, or Severe ozone nonattainment areas.

Further, in today's action, EPA is updating its RFG opt-out regulation at 40 CFR 80.72 to add a new paragraph (c)(8) to reflect that there is a four-year minimum opt-in period for areas that opt into the RFG program on the basis of their location within the ozone transport region. This clarification aligns the federal regulation for RFG opt-out requirements with CAA section 211(k)(6)(B)(ii)(II).

Thus, the State of Maine may not opt out of the federal RFG program for the Southern Maine Counties before May 1, 2019 for all regulated entities other than retailers and wholesale purchaser-consumers, and not before June 1, 2019 for retailers and wholesale purchaser-consumers, respectively.

IV. Rationale

The EPA has determined that the commencement dates for the prohibition of the sale of conventional gasoline in the Southern Maine Counties finalized in today's action provide a reasonable balance by achieving air quality benefits in southern Maine by the start of the 2015 peak ozone season and providing adequate lead time for industry to prepare for program implementation. The dates are consistent with the State's request that the EPA require RFG to be sold in the Southern Maine Counties to coincide with the beginning of the high ozone season, which begins June 1 of each year. Thus, the dates provide environmental benefits by allowing southern Maine to achieve volatile organic compound (VOC) reduction benefits for the 2015 VOC control season. The dates are also consistent with the statutory requirement that the EPA set the date for commencement of the prohibition within two years of the EPA's approval of the application by the Governor.

Today's final action has no effect on the approved Maine State Implementation Plan (SIP). The State of Maine intends to submit a proposed SIP revision requesting the removal of its existing 7.8 Reid Vapor Pressure fuel requirements for the Southern Maine Counties. The EPA will consider Maine's request when it is received.

As stated previously, the EPA received no comments on the proposed rulemaking.

V. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a ''significant regulatory action'' under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under Executive Orders 12866 and 13563. (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act

This action does not impose any new information collection burden under the provisions of the *Paperwork Reduction Act,* 44 U.S.C. 3501 *et seq.* Burden is defined at 5 CFR 1320.3. The OMB has approved the information collection requirements that apply to the RFG program (see 59 FR 7716, February 16, 1994), and has assigned OMB control number 2060–0277 (EPA ICR No. 1591.25).

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's final rule on small entities, small entity is defined as: (1) Defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's final rule on small entities, I certify that this action will not have a significant adverse impact on a substantial number of small entities. In promulgating the RFG regulations for conventional gasoline, the EPA analyzed the impact of the regulations on small entities. The EPA concluded that the regulations may possibly have some economic effect on a substantial number of small refiners, but that the regulations may not significantly affect other small entities, such as gasoline blenders, terminal operators, service stations and ethanol blenders. See 59 FR 7810–7811 (February 16, 1994). As stated in the preamble to the final 1994 RFG rule, exempting small refiners from the RFG regulations would not meet CAA requirements. 59 FR 7810. However, since most small refiners are located in the mountain states or in California, which has its own RFG program, the vast majority of small refiners are unaffected by the federal RFG requirements (although all refiners of conventional gasoline are potentially

[5] The EPA has determined that the original petition from the Governor of Maine, together with the revised Maine legislation and the Commissioner's letter, serve as a petition from the Governor under CAA section 211(k)(6)(B) seeking commencement of the prohibition in CAA 211(k)(5) in the Southern Maine Counties on June 1, 2015.

subject to the RFG requirements). Moreover, all businesses, large and small, maintain the option to produce conventional gasoline to be sold in areas not obligated by the CAA to receive RFG or those areas which have not chosen to opt into the federal RFG program. A complete analysis of the effect of the RFG regulations on small businesses is contained in the Regulatory Flexibility Analysis which was prepared for the 1994 RFG regulations, and can be found in the docket for that rulemaking. The docket number is: EPA Air Docket A–92–12.

Today's final rule affects only those refiners, importers or blenders of gasoline that choose to produce or import RFG for sale in the Southern Maine Counties, and gasoline distributors and retail stations in those areas. As discussed above, the EPA determined that, because of their location, the vast majority of small refiners will be unaffected by the RFG requirements. For the same reason, most small refiners will be unaffected by today's action. Other small entities, such as gasoline distributors and retail stations located in the Southern Maine Counties, which will become a covered area under today's final rule, will be subject to the same requirements as those small entities which are located in current RFG covered areas. The EPA did not find the previous RFG regulations to significantly affect these entities.

D. Unfunded Mandates Reform Act (UMRA)

This final rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. Thus, this final rule is not subject to the requirements of sections 202 and 205 of the UMRA. Although the EPA does not believe that UMRA imposes requirements for this rulemaking, the EPA notes that the environmental and economic impacts of the federal RFG program were assessed in the EPA's Regulatory Impact Analysis for the 1994 RFG regulations.

This final rule is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments.

E. Executive Order 13132 (Federalism)

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. The final rule imposes requirements only on certain refiners and other entities in the gasoline distribution system, and not on States. The requirements of the final rule will be enforced by the federal government at the national level. Thus, Executive Order 13132 does not apply to this final rule.

F. Executive Order 13175

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). Today's final rule affects only those refiners, importers or blenders of gasoline that choose to produce or import RFG for sale in the Southern Maine Counties, and gasoline distributors and retail stations in those areas. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not economically significant as defined in Executive Order 12866, and because the Agency does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer Advancement Act

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

This action does not involve technical standards. Therefore, the EPA did not consider the use of any voluntary consensus standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations of the United States.

The EPA has determined that this final rule does not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A Major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective March 9, 2015.

VI. Legal Authority and Statutory Provisions

The statutory authority for this action is granted to the EPA by Sections 211(k) and 301(a) of the Clean Air Act, as amended; 42 U.S.C. 7545(k), 7601(a).

List of Subjects in 40 CFR Part 80

Environmental protection, Air pollution control, Fuel additives, Gasoline, Motor vehicle pollution.

Dated: January 23, 2015.

Gina McCarthy,

Administrator.

For the reasons discussed in the preamble, the Environmental Protection Agency is amending 40 CFR part 80 as follows:

PART 80—REGULATION OF FUELS AND FUEL ADDITIVES

■ 1. The authority citation for part 80 continues to read as follows:

Authority: 42 U.S.C. 7414, 7521, 7542, 7545, and 7601(a).

■ 2. Section 80.70 is amended by adding paragraph (n) to read as follows:

§ 80.70 Covered areas.

* * * * *

(n) The areas included in paragraph (n) of this section are located within the ozone transport region established under Clean Air Act section 184(a), are not classified as a Marginal, Moderate, Serious, or Severe ozone nonattainment area, and have opted into the reformulated gasoline program. They are covered areas for the purposes of subparts D, E, and F of this part.

(1) The southern Maine counties of York, Cumberland, Sagadahoc, Androscoggin, Kennebec, Knox, and Lincoln are a covered area beginning June 1, 2015. The prohibitions of Clean Air Act section 211(k)(5) apply to all persons other than retailers and wholesale purchaser-consumers in these counties beginning May 1, 2015. The prohibitions of section 211(k)(5) of the Clean Air Act apply to retailers and wholesale purchaser-consumers in these counties beginning on June 1, 2015.

(2) [Reserved]

■ 3. Section 80.72 is amended by adding paragraph (c)(8) to read as follows:

§ 80.72 Procedures for opting out of the covered areas.

* * * * *

(c) * * *

(8) Notwithstanding any other provision of paragraph (c) of this section, for an area that opted in pursuant to Clean Air Act section 211(k)(6)(B), the Administrator shall not set the effective date for removal of the area earlier than four years after the commencement date of opt-in.

* * * * *

[FR Doc. 2015–02185 Filed 2–5–15; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 140811659–5070–02]

RIN 0648–XD437

Fisheries Off West Coast States; Coastal Pelagic Species Fisheries; Annual Specifications

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

ACTION: Final rule.

SUMMARY: NMFS implements the annual catch limit (ACL), harvest guideline (HG), and associated annual reference points for Pacific mackerel in the U.S. exclusive economic zone (EEZ) off the Pacific coast for the fishing season of July 1, 2014, through June 30, 2015. This rule is implemented according to the Coastal Pelagic Species (CPS) Fishery Management Plan (FMP). The 2014–2015 HG for Pacific mackerel is 29,170 metric tons (mt). This is the primary commercial fishing target level. The annual catch target (ACT), which will be the directed fishing harvest target, is 24,170 mt. If the fishery attains the ACT, the directed fishery will close, reserving the difference between the HG (29,170 mt) and ACT as a 5,000 mt set-aside for incidental landings in other CPS fisheries and other sources of mortality. This final rule is intended to conserve and manage the Pacific mackerel stock off the U.S. West Coast.

DATES: Effective March 9, 2015 through June 30, 2015.

FOR FURTHER INFORMATION CONTACT: Joshua Lindsay, West Coast Region, NMFS, (562) 980–4034.

SUPPLEMENTARY INFORMATION: During public meetings each year, the estimated biomass for Pacific mackerel is presented to the Pacific Fishery Management Council's (Council) CPS Management Team (Team), the Council's CPS Advisory Subpanel (Subpanel) and the Council's Scientific and Statistical Committee (SSC), where the biomass and the status of the fisheries are reviewed and discussed. The biomass estimate is then presented to the Council along with the calculated overfishing limit (OFL), acceptable biological catch (ABC), ACL, HG and ACT recommendations and comments from the Team, Subpanel and SSC. Following review by the Council and after hearing public comment, the Council adopts a biomass estimate and makes its catch level recommendations to NMFS.

The purpose of this final rule is to implement the 2014–2015 ACL, HG, ACT and other annual catch reference points, including OFL and an ABC that takes into consideration uncertainty surrounding the current estimate of biomass for Pacific mackerel in the U.S. EEZ off the Pacific coast. The CPS FMP and its implementing regulations require NMFS to set these annual catch levels for the Pacific mackerel fishery based on the annual specification framework in the FMP. This framework includes a harvest control rule that determines the HG, the primary management target for the fishery for the current fishing season. The HG is based, in large part, on the current estimate of stock biomass. The harvest control rule in the CPS FMP is HG = [(Biomass − Cutoff) * Fraction * Distribution] with the parameters described as follows:

1. *Biomass.* The estimated stock biomass of Pacific mackerel for the 2014–2015 management season is 157,106 mt.

2. *Cutoff.* This is the biomass level below which no commercial fishery is allowed. The FMP established this level at 18,200 mt.

3. *Fraction.* The harvest fraction is the percentage of the biomass above 18,200 mt that may be harvested.

4. *Distribution.* The average portion of the Pacific mackerel biomass estimated in the U.S. EEZ off the Pacific coast is 70 percent and is based on the average historical larval distribution obtained from scientific cruises and the distribution of the resource according to the logbooks of aerial fish-spotters.

In June 2014 the Council adopted and recommended to NMFS for the 2014–2015 Pacific mackerel fishing season an OFL of 32,992 metric tons (mt), an ABC and ACL of 30,138 mt each, a HG of 29,170 mt, and an ACT of 24,170 mt. These catch specifications are based on the control rules established in the CPS FMP and a biomass estimate of 157,106 mt; the biomass estimate is the result of a 2011 full stock assessment as updated with a catch-only projection estimate. The annual biomass estimates are an explicit part of the various harvest control rules for Pacific mackerel, and as the estimated biomass decreases or increases from one year to the next, the resulting allowable catch levels similarly trend. The Pacific mackerel fishing season runs from July 1 to June 30.

Upon attainment of the ACT, directed fishing would close, reserving the difference between the HG and ACT (5,000 mt) as a set-aside for incidental

landings in other CPS fisheries and other sources of mortality. For the remainder of the fishing year, incidental landings would also be constrained to a 45-percent incidental catch allowance when Pacific mackerel are landed with other CPS (in other words, no more than 45 percent by weight of the CPS landed per trip may be Pacific mackerel), except that up to 1 mt of Pacific mackerel could be landed without landing any other CPS. Upon attainment of the HG (29,170 mt), no retention of Pacific mackerel would be allowed in CPS fisheries. The purpose of the incidental set-aside and allowance of an incidental fishery is to allow for the restricted incidental landings of Pacific mackerel in other fisheries, particularly other CPS fisheries, when the directed fishery is closed to reduce potential discard of Pacific mackerel and allow for continued prosecution of other important CPS fisheries.

The NMFS West Coast Regional Administrator will publish a notice in the **Federal Register** announcing the date of any closure to either directed or incidental fishing. Additionally, to ensure the regulated community is informed of any closure, NMFS will also make announcements through other means available, including fax, email, and mail to fishermen, processors, and state fishery management agencies.

On October 20, 2014, a proposed rule was published for this action and public comments solicited (79 FR 62590). No comments were received.

Detailed information on the fishery and the stock assessment are found in the reports ''Pacific Mackerel (*Scomber japonicus*) Stock Assessment for USA Management in the 2011–12 Fishing Year'' and ''Pacific Mackerel Biomass Projection Estimate for USA Management (2014–15)'' (see **ADDRESSES**).

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Fishery Conservation and Management Act, the Assistant Administrator, NMFS, has determined that this final rule is consistent with the CPS FMP, other provisions of the Magnuson-Stevens Fishery Conservation and Management Act, and other applicable law.

These specifications are exempt from review under Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. No comments were received regarding this certification. As a result, a regulatory flexibility analysis was not required and none was prepared.

There are no reporting, recordkeeping, or other compliance requirements required by this rule. Additionally, no other Federal rules duplicate, overlap or conflict with this rule.

This action does not contain a collection-of-information requirement for purposes of the Paperwork Reduction Act.

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

Dated: February 3, 2015.

Samuel D. Rauch III,

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

[FR Doc. 2015–02421 Filed 2–5–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 665

RIN 0648–XD745

Pacific Island Fisheries; 2015 Harvest Guideline; Northwestern Hawaiian Islands Lobster

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

ACTION: Notification of lobster harvest guideline.

SUMMARY: NMFS establishes the annual harvest guideline for the commercial lobster fishery in the Northwestern Hawaiian Islands for calendar year 2015 at zero lobsters.

DATES: February 6, 2015.

FOR FURTHER INFORMATION CONTACT: Bob Harman, NMFS PIR Sustainable Fisheries, tel 808–725–5170.

SUPPLEMENTARY INFORMATION: The Northwestern Hawaiian Islands (NWHI) commercial lobster fishery is managed under the Fishery Ecosystem Plan for the Hawaiian Archipelago. The regulations at 50 CFR 665.252(b) require NMFS to publish an annual harvest guideline for lobster Permit Area 1, comprised of Federal waters around the NWHI. Regulations governing the Papahanaumokuakea Marine National Monument in the NWHI prohibit the unpermitted removal of monument resources (50 CFR 404.7), and establish a zero annual harvest guideline for lobsters (50 CFR 404.10(a)). Accordingly, NMFS establishes the harvest guideline for the NWHI commercial lobster fishery for calendar year 2015 at zero lobsters. Thus, no harvest of NWHI lobster resources is allowed.

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

Dated: February 3, 2015

H. Menashes,

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

[FR Doc. 2015–02419 Filed 2–5–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 131021878–4158–02]

RIN 0648–XD758

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific cod by Pot Catcher/Processors in the Bering Sea and Aleutian Islands Management Area

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by catcher/processors using pot gear in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the A season apportionment of the 2015 Pacific cod total allowable catch allocated to catcher/processors using pot gear in the BSAI.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), February 4, 2015, through 1200 hours, A.l.t., September 1, 2015.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The A season apportionment of the 2015 Pacific cod total allowable catch

(TAC) allocated to catcher/processors using pot gear in the BSAI is 1,698 metric tons (mt) as established by the final 2014 and 2015 harvest specifications for groundfish in the BSAI (79 FR 12108, March 4, 2014) and inseason adjustment (80 FR 188, January 5, 2015).

In accordance with § 679.20(d)(1)(iii), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the A season apportionment of the 2015 Pacific cod TAC allocated as a directed fishing allowance to catcher/processors using pot gear in the BSAI will soon be reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by pot catcher/processors in the BSAI.

After the effective date of this closure the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Acting Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement 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 requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of directed fishing for Pacific cod by pot catcher/processors in the BSAI. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of February 2, 2015.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

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

Dated: February 3, 2015.

Emily H. Menashes,

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

[FR Doc. 2015–02417 Filed 2–3–15; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 80, No. 25
Friday, February 6, 2015

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 March 10, 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. On December 4, 2014, we published in the **Federal Register** (79 FR 71973) a notice of reopening of the comment period for an additional 60 days. Comments were required to be received on or before January 9, 2015.

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 January 10, 2015 (the day after the close of the initial extended 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 2nd day of February 2015.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2015–02404 Filed 2–5–15; 8:45 am]

BILLING CODE 3410–34–P

INTERNATIONAL TRADE COMMISSION

19 CFR Parts 201, 206, 208, and 213, and Chapter II

Rules of General Application; Investigations Relating to Global and Bilateral Safeguard Actions, Market Disruption, Trade Diversion, and Review of Relief Actions; Investigations With Respect to Commercial Availability of Textile Fabric and Yarn in Sub-Saharan African Countries; Trade Remedy Assistance

AGENCY: International Trade Commission.

ACTION: Notice of proposed rulemaking; retrospective analysis of rules.

SUMMARY: The United States International Trade Commission (''Commission'') proposes to amend provisions of its Rules of Practice and Procedure concerning the Freedom of Information Act, the Privacy Act, the Government in the Sunshine Act, certain investigations, and trade remedy assistance. The proposed amendments are part of the agency's retrospective analysis of its Rules that attempts to determine whether rules should be modified, streamlined, expanded, or repealed so as to make the agency's regulatory program more effective or less burdensome in achieving regulatory objectives. The Commission requests public comment both on the proposed amendments and on its rules in general.

DATES: To be assured of consideration, written comments must be received by 5:15 p.m. on April 7, 2015.

ADDRESSES: You may submit comments, identified by docket number MISC–038, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Agency Web site: https://edis.usitc.gov. Follow the instructions for submitting comments on the Web site.

Mail: For paper submission. U.S. International Trade Commission, 500 E Street SW., Room 112A, Washington, DC 20436.

Hand Delivery/Courier: U.S. International Trade Commission, 500 E Street SW., Room 112A, Washington, DC 20436. During the hours of 8:45 a.m. to 5:15 p.m.

Instructions: All submissions received must include the agency name and docket number (MISC–038), along with a cover letter stating the nature of the commenter's interest in the proposed rulemaking. All comments received will be posted without change to *https://edis.usitc.gov,* including any personal information provided. For paper copies, a signed original and 8 copies of each set of comments should be submitted to Lisa R. Barton, Secretary, U.S. International Trade Commission, 500 E Street SW., Room 112A, Washington, DC 20436.

Docket: For access to the docket to read background documents or comments received, go to *https://edis.usitc.gov* and/or the U.S. International Trade Commission, 500 E Street SW., Room 112A, Washington, DC 20436.

A person seeking to submit a comment that includes confidential business information should follow the procedures set out in 19 CFR 201.6.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary, telephone (202) 205–2000, or Paul R. Bardos, Office of the General Counsel, telephone (202) 205–3061, United States International Trade Commission. Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal at (202) 205–1810. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.*

SUPPLEMENTARY INFORMATION: The preamble below is designed to assist readers in understanding these proposed amendments to the Commission's Rules. This preamble provides background information, a section-by-section explanation of the proposed amendments, and a regulatory analysis of the proposed amendments. The Commission encourages members of the public to comment on the proposed amendments as well as on whether the language of the proposed amendments is sufficiently clear for users to understand.

Background

Section 335 of the Tariff Act of 1930 (19 U.S.C. 1335) authorizes the Commission to adopt such reasonable procedures, rules, and regulations as it deems necessary to carry out its functions and duties. This rulemaking seeks to improve provisions of the Commission's existing Rules of Practice and Procedure. The Commission invites the public to comment on all of these proposed rules amendments. In any comments, please consider addressing whether the language of the proposed amendments is sufficiently clear for users to understand. In addition please consider addressing how the proposed rules amendments could be improved, and/or offer specific constructive alternatives where appropriate.

Consistent with its ordinary practice, the Commission is issuing these proposed amendments in accordance with provisions of section 553 of the Administrative Procedure Act (''APA'') (5 U.S.C. 553), although such provisions are not mandatory with respect to this rulemaking. The APA procedure entails the following steps: (1) Publication of a notice of proposed rulemaking; (2) solicitation of public comments on the proposed amendments; (3) Commission review of public comments on the proposed amendments; and (4) publication of final amendments at least thirty days prior to their effective date.

This notice of proposed rulemaking is a result of the Commission's Plan for Retrospective Analysis of Existing Rules, which was published on February 14, 2012, at 77 FR 8114. The plan was issued in response to Executive Order 13579 of July 11, 2011, and established a process under which the Commission will periodically review its significant rules to determine whether any such rules should be modified, streamlined, expanded, or repealed so as to make the agency's regulatory program more effective or less burdensome in achieving regulatory objectives. On August 9, 2012, at 77 FR 47572, the Commission published a notice seeking public comment on its existing Rules as part of the retrospective review. Several comments were received, and are being taken into account as the Commission continues to review its Rules.

The Commission has in the past two years issued a number of notices of rulemaking designed to improve the Commission's existing Rules. With respect to proceedings conducted under section 337 of the Tariff Act of 1930 (19 U.S.C. 1337), the Commission most recently published a notice of final rulemaking on May 21, 2013 (78 FR 29618). Concerning proceedings conducted under title VII of the Tariff Act of 1930 (19 U.S.C. 1671 *et seq.*), the agency published a notice of final rulemaking on June 25, 2014 (79 FR 35920). In addition, the Commission updated its Rules concerning national security information by notice published on August 8, 2014 (79 FR 46350).

The Commission's Plan calls for the agency to seek public input on its Rules every two years. As a result, the Commission is seeking input by this notice to assist it in determining whether, in addition to the proposed amendments set out below, any of the agency's Rules should be modified, streamlined, expanded, or repealed so as to make the agency's regulatory program more effective or less burdensome in achieving regulatory objectives. The public is invited to comment both on the proposed amendments and any other of the Commission's Rules.

As discussed more fully below, the Commission proposes to revise provisions of its Rules concerning the Freedom of Information Act, the Privacy Act, the Government in the Sunshine Act, certain investigations, and trade remedy assistance.

Section-by-Section Analysis

The Commission proposes to amend the authority citation for part 201 to conform to the recommendation of the Office of the Federal Register with respect to statutory citation.

Section 201.17(a)(5) directs members of the public to make inquiries of the Publications Office in the Office of the Secretary when writing or calling for copies of documents. The Commission proposes to revise this provision to reflect the fact that there is no longer a Publications Office in the Secretary's Office and that many documents are available online.

Section 201.19(f) currently states that, in general, the Commission has ten (10) working days in which to respond to a Freedom of Information Act request. The Commission proposes to revise this paragraph to remove it in conformity with the applicable statutory provision (5 U.S.C. 552(a)(6)(A)(i)), which gives agencies twenty (20) working days to respond to requests. In addition, the

paragraph would be revised to increase flexibility by replacing a specific deadline for filing objections to disclosure of information with a provision for the Secretary to set the deadline.

Section 201.20(j)(8) defines the term ''representative of the news media.'' The Commission proposes to replace the existing definition with the statutory one set out at 5 U.S.C. 552(a)(4)(A)(ii).

Section 201.23(e) states that the Privacy Act Officer for the Commission is the Director of the Office of Administration. The Commission proposes to amend this provision to reflect the fact that this responsibility has been transferred to the Secretary to the Commission.

Section 201.34(a)(3) states that conference telephone calls among Commissioners generally are considered meetings under the Government in the Sunshine Act. The Commission proposes to more closely accord this statement with the statute by clarifying that this is only the case where the deliberations of the Commissioners ''determine or result in the joint conduct or disposition of official [Commission] business.'' *See* 5 U.S.C. 552b(a)(2).

Section 206.2 sets out how a petition or request for a safeguard investigation should be identified. The Commission proposes to amend the provision to add procedures for filing such documents.

The Commission proposes to remove part 208 of its Rules, which governs investigations with respect to commercial availability of textile fabric and yarn in sub-Saharan African countries. Such investigations were provided for under section 112(c) of the African Growth and Opportunity Act (19 U.S.C. 3721(c)), which was repealed by Section 3(a)(2) of the Andean Trade Preference Act, Public Law 110–436.

Part 213 implements 19 U.S.C. 1339 by establishing a Trade Remedy Assistance Office (TRAO) and assigning duties to that office. The Commission proposes to move part 213 to a new subchapter D. This move would clarify that part 213 applies to proceedings under several trade statutes. Currently part 213 is located in subchapter C, which is intended to cover only unfair practices in import trade.

The Commission proposes to amend the authority citation for part 213 to conform to the recommendation of the Office of the Federal Register with respect to statutory citation.

The Commission proposes to amend section 213.2 to update and simplify the definition of the term ''SBA size standards.'' A reference to frivolous petitions and complaints would be removed as unnecessary because, although TRAO has the statutory authority to determine that a petition or application is frivolous, the office has not received such documents. In addition, the Commission proposes to clarify that technical assistance is provided under 19 U.S.C. 1339(b), so that persons seeking information and assistance under 19 U.S.C. 1339(a) need not file the formal application required by section 213.3; a conforming change would be made to section 213.3. Also, a typographical error would be corrected.

The Commission proposes to amend sections 213.3 and 213.6 to inform the public that the agency provides information relating to trade remedy assistance on its Web site.

Regulatory Analysis of Proposed Amendments to the Commission's Rules

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) is inapplicable to this rulemaking because it is not one for which a notice of final rulemaking is required under 5 U.S.C. 553(b) or any other statute. Although the Commission has chosen to publish a notice of proposed rulemaking, these proposed regulations are ''agency rules of procedure and practice,'' and thus are exempt from the notice requirement imposed by 5 U.S.C. 553(b). Moreover, the proposed rules are certified as not having a significant economic impact on a substantial number of small entities.

The proposed rules do not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

No actions are necessary under title II of the Unfunded Mandates Reform Act of 1995, Public Law 104–4 (2 U.S.C. 1531–1538) because these amended rules will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and will not significantly or uniquely affect small governments.

The Commission has determined that these amended rules do not constitute a ''significant regulatory action'' under section 3(f) of Executive Order 12866 (58 FR 51735, October 4, 1993).

The proposed rules do not have Federalism implications warranting the preparation of a federalism summary impact statement under Executive Order 13132 (64 FR 43255, August 4, 1999).

The proposed amendments are not ''major rules'' as defined by section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et. seq.). Moreover, they are exempt from the reporting requirements of the Act because they concern rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties.

List of Subjects in 19 CFR Parts 201, 206, 208, and 213

Administrative practice and procedure; imports; foreign trade.

For the reasons stated in the preamble, under the authority of 19 U.S.C. 1335, the United States International Trade Commission proposes to amend 19 CFR parts 201, 206, 208, and 213 as follows:

PART 201—RULES OF GENERAL APPLICATION

■ 1. Revise the authority citation for part 201 to read as follows:

Authority: 19 U.S.C. 1335; 19 U.S.C. 2482, unless otherwise noted.

■ 2. Revise paragraph (a)(5) of § 201.17 to read as follows:

§ 201.17 Procedures for requesting access to records.

(a) * * *

(5) Copies of public Commission reports and other publications are available online at *http://www.usitc.gov,* or can be requested by calling or writing the Office of the Secretary. Certain Commission publications are sold by the Superintendent of Documents, U.S. Government Printing Office, and are available from that agency at the price set by that agency.

* * * * *

■ 3. Revise paragraph (f) of § 201.19 to read as follows:

§ 201.19 Notification regarding requests for confidential business information.

* * * * *

(f) *Opportunity to object to disclosure.* Through the notice described in paragraph (c) of this section, the Commission will afford a submitter an opportunity, within the period afforded to the Commission to make its decision in response to the FOIA request, to provide the Commission with a detailed written statement of any objection to disclosure. Such statement shall be filed by a deadline set by the Secretary, and it shall specify all grounds for withholding any of the information under any exemption of FOIA. In the case of FOIA Exemptions 3 or 4, it shall demonstrate why the information should continue to be considered confidential business information within the meaning of § 201.6 of this part and should not be disclosed. The submitter's claim of continued confidentiality should be supported by a certification by an officer or authorized representative of the

submitter. Information provided by a submitter pursuant to this paragraph may itself be subject to disclosure under FOIA.

* * * * *

■ 4. Revise paragraph (j)(8) of § 201.20 to read as follows:

§ 201.20 Fees.

* * * * *

(j) * * *

(8) The term *representative of the news media* refers to any person or entity that gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience. The term 'news' means information that is about current events or that would be of current interest to the public. Examples of news-media entities are television or radio stations broadcasting to the public at large and publishers of periodicals (but only if such entities qualify as disseminators of 'news') who make their products available for purchase by or subscription by or free distribution to the general public. These examples are not all-inclusive. Moreover, as methods of news delivery evolve (for example, the adoption of the electronic dissemination of newspapers through telecommunications services), such alternative media shall be considered to be news-media entities. A freelance journalist shall be regarded as working for a news-media entity if the journalist can demonstrate a solid basis for expecting publication through that entity, whether or not the journalist is actually employed by the entity. A publication contract would present a solid basis for such an expectation; the Government may also consider the past publication record of the requester in making such a determination.

* * * * *

■ 5. Revise paragraph (e) of § 201.23 to read as follows:

§ 201.23 Definitions.

* * * * *

(e) The term Privacy Act Officer refers to the Secretary, United States International Trade Commission, 500 E Street SW., Washington, DC 20436, or his or her designee.

■ 6. Revise paragraph (a)(3) of § 201.34 to read as follows:

§ 201.34 Definitions.

* * * * *

(a) * * *

(3) Conference telephone calls among the Commissioners are considered meetings as defined by paragraph (a)(1) of this section if they involve the number of Commissioners requisite for Commission action, and where the deliberations of the Commissioners determine or result in the joint conduct or disposition of official Commission business.

* * * * *

PART 206—INVESTIGATIONS RELATING TO GLOBAL AND BILATERAL SAFEGUARD ACTIONS, MARKET DISRUPTION, TRADE DIVERSION, AND REVIEW OF RELIEF ACTIONS

■ 7. The authority citation for part 206 continues to read as follows:

Authority: 19 U.S.C. 1335, 2112 note, 2251–2254, 2436, 2451–2451a, 3351–3382, 3805 note, 4051–4065, and 4101.

■ 8. Revise § 206.2 to read as follows:

§ 206.2 Identification of type of petition or request.

An investigation under this part may be commenced on the basis of a petition, request, resolution, or motion as provided for in the statutory provisions listed in §§ 206.1 and 206.31. Each petition or request, as the case maybe, filed by an entity representative of a domestic industry under this part shall state clearly on the first page thereof ''This is a [petition or request] under section [citing the statutory provision] and Subpart [B, C, D, E, F, or G] of part 206 of the rules of practice and procedure of the United States International Trade Commission.'' A paper original and eight (8) true paper copies of a petition, request, resolution, or motion shall be filed. One copy of any exhibits, appendices, and attachments to the document shall be filed in electronic form on CD–ROM, DVD, or other portable electronic format approved by the Secretary.

PART 208—[REMOVED AND RESERVED]

■ 9. Remove and reserve part 208.

Subchapter D—Special Provisions

■ 10. Under the authority of 19 U.S.C. 1335, add subchapter D with the heading set forth above, and transfer part 213, consisting of §§ 213.1 through 213.6, into new subchapter D.

PART 213—TRADE REMEDY ASSISTANCE

■ 11. Revise the authority citation for part 213 to read as follows:

Authority: 19 U.S.C. 1335, 1339.

■ 12. Revise paragraphs (d), (e), (f), and (g) of § 213.2 to read as follows:

§ 213.2 Definitions.

* * * * *

(d) *Technical Assistance.* Technical assistance is informal advice and assistance, including informal legal advice, provided under 19 U.S.C. 1339(b) and intended to enable eligible small businesses to determine the appropriateness of pursuing particular trade remedies, to prepare petitions and complaints and to seek to obtain the remedies and benefits available under the trade laws identified in § 213.2(b). Technical assistance is available to eligible small businesses at any time until the completion of administrative review or of an appeal to the administering agency regarding proceedings under the trade laws listed in § 213.2(b). Technical assistance does not include legal representation of an eligible small business or advocacy on its behalf and receipt of technical assistance does not ensure that the recipient will prevail in any trade remedy proceeding. The Office provides such technical assistance independently of other Commission staff but may consult with other staff as appropriate.

(e) *Applicant.* An applicant is an individual, partnership, corporation, joint venture, trade or other association, cooperative, group of workers, or certified or recognized union, or other entity that applies for technical assistance under this part.

(f) *Eligible small business.* An eligible small business is an applicant that the Office has determined to be entitled to technical assistance under 19 U.S.C. 1339(b) in accordance with the SBA size standards and the procedures set forth in this part.

(g) *SBA size standards.* The Office has adopted for its use SBA size standards, which are the small business size standards of the Small Business Administration set forth in 13 CFR part 121.

■ 13. Revise paragraph (a) of § 213.3 to read as follows:

§ 213.3 Determination of small business eligibility.

(a) *Application for technical assistance from small businesses.* An applicant for technical assistance under 19 U.S.C. 1339(b) must certify that it qualifies as a small business under the appropriate size standard(s) and that it is an independently owned and operated company. An application for technical assistance is available from the Office and on the Commission's Web site. The application must be signed under oath by an officer or principal of the applicant. The completed application should be submitted to the Office at the address set forth in § 213.2(a).

* * * * *

■ 14. Revise § 213.6 to read as follows:

§ 213.6 Information concerning assistance.

Any person may contact the Office with questions regarding eligibility for technical assistance. Summaries of the trade laws and the SBA size standards can be obtained by writing to the Trade Remedy Assistance Office, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Information is also provided on the Commission's Web site at *http://www.usitc.gov.*

By order of the Commission.

Issued: February 2, 2015.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015–02388 Filed 2–5–15; 8:45 am]

BILLING CODE 7020–02–P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

29 CFR Part 1614

RIN 3046–AB00

Federal Sector Equal Employment Opportunity

AGENCY: Equal Employment Opportunity Commission.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Equal Employment Opportunity Commission (''EEOC'' or ''Commission'') is issuing an Advance Notice of Proposed Rulemaking (''ANPRM'') inviting the public to submit comments regarding the Federal sector EEO complaint process. The Commission primarily is interested in suggestions that will make the process more efficient and user-friendly, and more effective in identifying and redressing prohibited employment discrimination.

DATES: Comments and suggestions in response to the Advance Notice of Proposed Rulemaking must be received on or before April 7, 2015.

ADDRESSES: You may submit comments, identified by RIN Number, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- Fax: (202) 663–4114. (There is no toll free FAX number). Only comments of six or fewer pages will be accepted via FAX transmittal, in order to assure access to the equipment. Receipt of FAX transmittals will not be acknowledged, except that the sender may request confirmation of receipt by calling the Executive Secretariat staff at (202) 663–4070 (voice) or (202) 663–4074 (TTY). (These are not toll free numbers).
- Mail: Bernadette Wilson, Acting Executive Officer, Executive Secretariat, Equal Employment Opportunity Commission, U.S. Equal Employment Opportunity Commission, 131 M Street NE., Washington, DC 20507.
- Hand Delivery/Courier: Bernadette Wilson, Acting Executive Officer, Executive Secretariat, Equal Employment Opportunity Commission, 131 M Street NE., Washington, DC 20507.

Instructions: The Commission invites comments from all interested parties. All comment submissions must include the agency name and the Regulatory Information Number (RIN) for this ANPRM. Comments need be submitted in only one of the above-listed methods. All comments received will be posted without change to *http://www.regulations.gov*, including any personal information you provide.

Comments: For access to the comments received, go to *http://www.regulations.gov.* Copies of the received comments also will be available for review by pre-arranged appointment at the Commission's library, 131 M Street NE., Suite 4NW08R, Washington, DC 20507, between the hours of 9:30 a.m. and 5 p.m., from April 7, 2015 until the Commission publishes a Notice of Proposed Rulemaking (''NPRM'') addressing the Federal sector EEO complaint process.

FOR FURTHER INFORMATION CONTACT: Thomas J. Schlageter, Assistant Legal Counsel, (202) 663–4668, or Gary John Hozempa, Senior Staff Attorney, (202) 663–4666, or (202) 663–7026 (TTY), Office of Legal Counsel, U.S. Equal Employment Opportunity Commission. (These are not toll free numbers). Requests for this advance notice in an alternative format should be made to the Office of Communications and Legislative Affairs at (202) 663–4191 (voice) or (202) 663–4494 (TTY). (These are not toll free numbers).

SUPPLEMENTARY INFORMATION: As discussed more fully below, Federal sector EEO complaint processing procedures did not originate with EEOC in 1979, when EEOC was given oversight authority over the Federal sector EEO process. Rather, formal, regulatory procedures first were promulgated by the Civil Service Commission (''CSC'') in 1966, codified at 5 CFR part 713, and the basic framework contained in those procedures was adopted by EEOC in 1979. Although EEOC has revised the procedures a number of times, the original structure inherited from the CSC—counseling, complaint, investigation, hearing, final agency action, and appeal—remains.

The CSC's complaint processing scheme was not created in a vacuum. Rather, the CSC developed its procedures based on those established in a series of Executive Orders issued by Presidents Roosevelt through Nixon. The first administrative system for resolving Federal sector EEO complaints was created in Executive Order (''E.O.'') 8802 (June 25, 1941). Among other things, U.S. agencies involved in ''defense production'' were ordered to administer their programs ''without discrimination because of race, creed, color, or national origin.'' The Order, as amended by E.O. 9346 (May 27, 1943), established a Committee on Fair Employment Practice whose function was to formulate policy, promulgate rules and regulations, investigate EEO complaints and make findings of fact, conduct hearings, and provide relief when appropriate. As can be seen, many of the element's in today's Federal sector EEO complaint process were created more than 70 years ago.

E.O. 9980 (July 26, 1948) expanded the reach of the Federal Government's EEO policy to include ''all departments and agencies of the executive branch . . .'' The Order created within each agency the position of ''Fair Employment Officer'' (''FEO''), the precursor to today's Director of Equal Employment Opportunity (''EEO Director''). The E.O. also introduced an appeal stage, wherein a complainant could appeal the decision of the agency head to the Fair Employment Board (''Board'') of the CSC. The Board was empowered to ''make recommendations'' to the agency head. The Board also was given the authority to promulgate ''necessary'' rules and regulations and coordinate EEO policies and procedures among the agencies.

Over the next 20 years, the CSC's authority over the Federal sector EEO process was modified by subsequent Presidents. E.O. 10590 (January 18, 1955), as amended, explicitly superseded E.O. 9980, abolished the CSC's Board, and replaced it with a ''President's Committee.'' The position of FEO was replaced with an ''Employment Policy Officer,'' who, like a current EEO Director, is ''outside of the division handling the personnel matters of the . . . agency'' and ''under the immediate supervision of the head of his department or agency.'' A complainant could appeal an agency final decision to the President's Committee, which could issue an

advisory opinion. The CSC retained the authority to issue ''necessary'' regulations.

E.O. 11246 (September 24, 1965), as amended, explicitly superseded all previous E.O.'s regarding the Federal sector EEO process and returned oversight authority to the CSC. In addition, the CSC was directed to establish a complaint processing procedure that included ''at least one impartial review with the executive department or agency and [an] appeal to the Civil Service Commission.'' [1] In response, and as noted above, the CSC issued its first formal complaint processing regulations in 1966. Selectively adopting procedures from the various E.O.'s, CSC's regulations required that a complaint be filed with and investigated by the agency alleged to have engaged in discrimination, that an agency offer the complainant a hearing, and that the agency issue a final decision on the complaint. A complainant could appeal an agency's final decision to the CSC. E.O. 11478 (August 8, 1969) directed agencies to ''provide access to counseling for employees who feel aggrieved and shall encourage the resolution of employee problems on an informal basis.'' [2] Thus, CSC revised its regulations to include counseling and informal resolution.

In 1972, the Equal Opportunity Act of 1972 was enacted, amending Title VII of the Civil Rights Act of 1964. New section 717(a) provided that ''all personnel actions affecting employees or applicants for employment'' in the executive branch (with some exclusions and additions) ''shall be free from any discrimination based on race, color, religion, sex, or national origin.'' Importantly, section 717(c) gave Federal employees the right to file *de novo* suit in Federal court once administrative remedies had been exhausted. While the Act was being debated, some members of Congress criticized the CSC's administrative EEO complaint process, noting the conflict of interest inherent in an agency investigating itself and determining whether it had engaged in prohibited discrimination, and the lack of confidence Federal employees had in its effectiveness. *See* S. Rpt. 92–416 at 14, H. Rpt. 92–238 at 23–24. The Senate Report stated that ''[o]ne feature of the present equal employment opportunity program which deserves special scrutiny by the Civil Service Commission is the complaint process.'' Furthermore, one version of section 717(b) transferred administrative oversight of the Federal sector EEO complaint process from the CSC to EEOC. The final bill, however, retained oversight authority in the CSC. In October 1972, the CSC revised its regulations at 5 CFR part 713, adding provisions to reflect that a Federal complainant who had filed an administrative EEO complaint had the right to file a civil action in an appropriate United States District Court.

The Civil Service Reform Act of 1978 abolished the CSC and created in its place the Office of Personnel Management. The Act also created the Merit Systems Protection Board (''MSPB''), the Federal Labor Relations Authority, and the Office of Special Counsel. Pursuant to the Reform Act, Reorganization Plan No. 1 of 1978, and E.O. 12106 (December 28, 1978), the CSC's functions under section 717 of Title VII were transferred to EEOC effective January 1, 1979. At the same time, EEOC was given enforcement responsibility regarding the provisions applicable to Federal employees contained in the Equal Pay Act of 1963, the Age Discrimination in Employment Act of 1967, and the Rehabilitation Act of 1973.

Pursuant to E.O. 12106, EEOC was made ''responsible for directing and furthering the implementation of the Policy of the Government of the United States to provide equal employment opportunity in Federal employment for all employees and applicants for employment * * * and to prohibit discrimination in employment because of race, color, religion, sex, national origin, handicap, or age.'' The Order directed EEOC, ''after consultation with all affected departments and agencies,'' to ''issue such rules, regulations, orders, and instructions and request such information from the affected departments and agencies as it deems necessary and appropriate to carry out [E.O. 12106].''

At the time of the transfer of functions from the CSC to EEOC, EEOC adopted CSC's complaint processing procedures, only making changes to reflect EEOC's oversight authority. Thus, for example, an administrative hearing was held before an EEOC ''Complaints Examiner'' (now referred to as an Administrative Judge (''AJ'')), and a complainant could appeal an agency final decision to EEOC's ''Office of Review and Appeals'' (now called the Office of Federal Operations). Thus, CSC's basic complaint processing structure—counseling, filing of complaint with the agency accused of discrimination, investigation of the complaint by that agency, a hearing at complainant's request, an agency final decision, and an optional appeal—remained intact.[3]

EEOC's regulations were codified at 29 CFR part 1613. EEOC amended part 1613 in 1980 to authorize agencies to award attorney's fees and costs to prevailing complainants. In 1983, EEOC and the MSPB added mixed case complaint procedures to their respective regulations, at 29 CFR part 1613 and 5 CFR part 1201, respectively.

In 1987, EEOC enacted additional, minor revisions to part 1613. Among other things, a provision was added requiring an agency to notify an aggrieved person of the election of remedies pertaining to filing an EEO complaint, an appeal with MSPB, or a grievance under a collective bargaining agreement. Official time for complainants to prepare and pursue complaints was addressed. The EEOC's then private sector policy statement on remedies and relief was incorporated into the Federal sector process.

In 1992, EEOC issued a final rule abolishing 29 CFR part 1613 (except with respect to complaints filed before a certain date), and replaced it with 29 CFR part 1614. While EEOC made significant changes to many parts of the complaint process, the basic structure inherited from the CSC remained.

In 1995, EEOC established a Federal Sector Workgroup which evaluated the complaint process and made numerous recommendations for reform. The Commission published a Notice of Proposed Rulemaking in 1998, proposing many of the Workgroup recommendations, including requiring alternative dispute resolution (hereinafter ''ADR'') during the counseling and investigative stages, and making an AJ decision final. In their comments, agencies contended that EEOC could not make an AJ decision final because section 717 of Title VII gives an agency the right to take final action on an administrative EEO complaint. Consequently, the Final Rule, published in 1999, while retaining the ADR requirements, provided an agency with the opportunity to issue a notice of final action after receiving an AJ decision. That final action was not termed a decision, but it allowed an agency to indicate whether it would fully implement the decision of the AJ. If not, the agency was required to file an appeal with EEOC.

[1] E.O. 11375 (October 13, 1967) added sex as a prohibited basis.

[2] In subsequent Executive Orders, additional bases of discrimination were added to E.O. 11478: handicap and age (E.O. 12106 (December 28, 1978)); sexual orientation (E.O. 13087 (May 28, 1998)); status as a parent (E.O. 13152 (May 2, 2000)); and, gender identity (E.O. 13672 (July 21, 2014)).

[3] Although E.O. 12106 revised E.O. 11478 to eliminate the counseling and informal resolution language of E.O. 11478, EEOC chose not to drop these components when it adopted the CSC regulations.

EEOC established another Federal Sector Workgroup in 2004, again to consider ways in which to improve the Federal sector EEO complaint process. The Workgroup failed to reach internal consensus for large scale revisions, but did reach agreement on several discrete changes that clarified and built upon the improvements made by the last major revisions in 1999. The resulting final rule was published on July 25, 2012. *See* 77 FR 43498. One revision authorizes EEOC, after it reviews an agency program for compliance with EEOC rules and directives, to issue a notice to an agency when non-compliance is found and not corrected. Another revision allows an agency to seek approval from EEOC to conduct a complaint processing pilot project. An AJ's decision on the merits of a class complaint was made final in the revised regulation, which meant that an agency could implement it or appeal. Additionally, there is now a provision which requires an agency that has not completed its investigation of a complaint in a timely manner to notify the complainant that the investigative period has expired and that, as a result, the complainant has an immediate right to request a hearing or file a civil action.

As previously noted, although the Federal sector EEO complaint process has undergone various permutations over the last seven decades, certain procedures, once introduced, have remained. The Truman administration, for example, introduced agency self-investigation and the opportunity to appeal an agency decision to an outside entity. The Eisenhower administration created the hearing and required an agency to appoint an EEO Officer who worked outside the personnel office and was under the immediate supervision of the agency head. Under President Nixon, pre-complaint counseling was established. Thus, when the CSC issued its last regulations in 1972, the Federal sector complaint process consisted of a combination of requirements first introduced in the various Executive Orders and certain rights provided by section 717 of Title VII.

In this regard, when most of the Executive Orders discussed above were issued, EEOC either did not exist or did not have oversight authority for the Federal sector. Questions that the Commission wishes the public to explore and answer in response to this ANPRM are as follows:

1. If EEOC were to create a new Federal sector EEOC complaint process, what current elements would you retain or remove, and what new elements would you introduce?

a. With respect to a current element you believe should be retained, in what way does that element provide value, efficiency, or fairness?

b. With respect to a current element you believe should be removed, how will its removal improve the process for the complainant, the agency, or both?

c. With respect to a new element, why should it be included, and how will it improve the process for the complainant, the agency, or both?

2. Should the process include an investigative stage?

a. Should agency personnel investigate complaints filed against the agency?

b. Should agencies pick from a pool of investigators made up of in-house personnel from various agencies so that no agency is investigated by one of its own investigators?

c. Should investigators employed by EEOC conduct all investigations, similar to the process EEOC uses when an aggrieved individual from the private sector files a charge of employment discrimination with EEOC?

3. Should the hearing stage be retained?

a. If the hearing stage is retained as a matter of right, should the administrative hearing take place after an investigation?

b. If there is a hearing, should the hearing be a continuation of the investigative process, as it is now, or should the hearing be adversarial in nature, such as those conducted by the MSPB?

c. Should there be a hearing as of right only as an alternative to an investigation?

d. Should a hearing always be discretionary, and if so, at whose discretion?

4. What time limits should be imposed at various stages of the process?

a. How many days should a complainant have to contact a counselor from the date of the alleged discriminatory matter?

b. How many days should a complainant have to file a complaint following the conclusion of counseling?

c. If there is an investigative stage, within how many days should the investigation be completed?

d. How many days should a complainant and agency have to file an appeal from an agency final action?

5. What standard of review should apply when EEOC considers an appeal?

a. What standard of review should apply when there is a hearing decision?

b. What standard of review should apply when there is only an agency decision?

6. How can the Commission continue to enhance its ability to ensure agencies' compliance with Federal sector equal employment opportunity requirements and the Federal sector EEO complaint process?

a. For example, pursuant to 29 CFR 1614.102(e), should the EEOC conduct Commission meetings from time to time to review agencies' compliance efforts?

b. Also, for example, as part of the complaint process, should the Commissioners from time to time hear arguments on appeals from final agency actions?

c. What value would these and any other related ideas bring to the Federal sector complaint process?

7. When discrimination is found, what enforcement mechanisms can EEOC use to ensure agency compliance?

The above questions are not meant to be exhaustive and, in fact, only touch upon the many issues and stages of the current complaint process. Therefore, EEOC is interested in any ideas and comments regarding all aspects of the process. In this regard, EEOC will consider comments that advocate abolition of all or part of the current system coupled with ideas for a replacement system, as well as comments from those who believe that only a few changes are necessary in order to improve the Federal sector complaint process.

In drafting comments, stakeholders and other members of the public should keep in mind the requirements imposed by section 717 of Title VII, which cannot be altered or discarded. This means for example, that any administrative process must include agency final action on a complaint and the opportunity for a complainant to appeal the agency's final action to EEOC. Additionally, a complainant's right to file a civil action and the time limits applicable to that right cannot be changed. Comments advocating that EEOC retain any non-mandated feature of the current process should be based on a fresh assessment of the extent to which that element has served to advance the policy goals and purposes of the EEO statutes.

For the Commission,

Dated: January 30, 2015.

Jenny R. Yang,

Chair.

[FR Doc. 2015–02330 Filed 2–5–15; 8:45 am]

BILLING CODE 6570–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2014–0910; FRL–9922–43–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Infrastructure Requirements for the 2008 Ozone, 2010 Nitrogen Dioxide, 2010 Sulfur Dioxide, and 2012 Fine Particulate Matter National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve portions of four State Implementation Plan (SIP) revision submittals from the Commonwealth of Pennsylvania pursuant to the Clean Air Act (CAA). Whenever new or revised national ambient air quality standards (NAAQS) are promulgated, the CAA requires states to submit a plan for the implementation, maintenance, and enforcement of such NAAQS. The plan is required to address basic program elements, including, but not limited to, regulatory structure, monitoring, modeling, legal authority, and adequate resources necessary to assure attainment and maintenance of the standards. These elements are referred to as infrastructure requirements. Pennsylvania has made four separate submittals addressing the infrastructure requirements for the 2008 ozone, the 2010 nitrogen dioxide (NO_2), the 2010 sulfur dioxide (SO_2), and the 2012 fine particulate matter ($PM_{2.5}$) NAAQS. In this rulemaking action, EPA is proposing to approve, in accordance with the requirements of the CAA, the four infrastructure SIP submissions with the exception of some portions of the submittals addressing visibility protection.

DATES: Written comments must be received on or before March 9, 2015.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2014–0910 by one of the following methods:

A. *www.regulations.gov.* Follow the on-line instructions for submitting comments.

B. *Email: fernandez.cristina@epa.gov.*

C. *Mail:* EPA–R03–OAR–2014–0910, Cristina Fernandez, Associate Director, Office of Air Program Planning, Mailcode 3AP30, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R03–OAR–2014–0910. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittals are available at the Pennsylvania Department of Environmental Protection, Bureau of Air Quality Control, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105.

FOR FURTHER INFORMATION CONTACT: Ruth Knapp (215) 814–2191, or by email at *knapp.ruth@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On March 27, 2008 (73 FR 16436), EPA promulgated a revised NAAQS for ozone based on 8-hour average concentrations. EPA revised the level of the 8-hour ozone NAAQS from 0.08 parts per million (ppm) to 0.075 ppm. On February 9, 2010 (75 FR 6474), EPA established a new 1-hour primary NAAQS for NO_2 at a level of 100 parts per billion (ppb), based on a 3-year average of the 98th percentile of the yearly distribution of 1-hour daily maximum concentrations. On June 22, 2010 (75 FR 35520), EPA promulgated a revised NAAQS for SO_2 at a level of 75 ppb, based on a 3-year average of the annual 99th percentile of 1-hour daily maximum concentrations. On December 14, 2012, EPA promulgated a revised primary NAAQS for $PM_{2.5}$ for the annual standard. The revised standard was set at the level of 12 micrograms per cubic meter (ug/m^3) calculated as the annual average which is averaged over a three year period. This specific NAAQS will be referred to as the 2012 $PM_{2.5}$ NAAQS.

Pursuant to section 110(a)(1) of the CAA, states are required to submit SIPs meeting the applicable requirements of section 110(a)(2) within three years after promulgation of a new or revised NAAQS or within such shorter period as EPA may prescribe. Section 110(a)(2) requires states to address basic SIP elements such as requirements for monitoring, basic program requirements, and legal authority that are designed to assure attainment and maintenance of the NAAQS. Section 110(a) imposes the obligation upon states to make a SIP submission to EPA for a new or revised NAAQS, but the contents of that submission may vary depending upon the facts and circumstances. In particular, the data and analytical tools available at the time the state develops and submits the SIP for a new or revised NAAQS affects the content of the submission. The content of such SIP submission may also vary depending upon what provisions the state's existing SIP already contains.

More specifically, section 110(a)(1) provides the procedural and timing requirements for SIPs. Section 110(a)(2) lists specific elements that states must meet for ''infrastructure'' SIP requirements related to a newly

established or revised NAAQS. As mentioned earlier, these requirements include basic SIP elements such as requirements for monitoring, basic program requirements, and legal authority that are designed to assure attainment and maintenance of the NAAQS.

II. Summary of State Submittals

The Commonwealth of Pennsylvania through the Pennsylvania Department of Environmental Protection (PADEP) submitted four separate revisions to its SIP to satisfy the requirements of section 110(a)(2) of the CAA for the different NAAQS. On July 15, 2014, PADEP submitted SIP revisions addressing the infrastructure requirements for the 2008 ozone, 2010 NO_2, 2010 SO_2 as well as the 2012 $PM_{2.5}$ NAAQS. Each of the infrastructure SIP revisions addressed the following infrastructure elements for the applicable NAAQS which EPA is proposing to approve: Section 110(a)(2)(A), (B), (C), (D)(i)(II) (prevention of significant deterioration(PSD)), (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M). The four infrastructure SIP submittals do not address section 110(a)(2)(D)(i)(I), which pertains to interstate transport of emissions, nor section 110(a)(2)(I), which pertains to the nonattainment requirements of part D, Title I of the CAA, because this element, section 110(a)(2)(I), is not required to be submitted by the 3 year submission deadline of CAA section 110(a)(1) and will be addressed in a separate process, if necessary for the respective NAAQS. The Pennsylvania infrastructure SIP submittals included provisions addressing section 110(a)(2)(D)(i)(II) (visibility protection). However, EPA is not taking action on the portion of the SIP submittals addressing 110(a)(2)(D)(i)(II) (visibility protection) at this time and will take later separate action on the portion of the infrastructure SIP submittals addressing this element for the four NAAQS.

III. EPA's Approach To Review Infrastructure SIPs

EPA is acting upon the Commonwealth's SIP submissions that address the infrastructure requirements of section 110(a)(1) and (2) of the CAA for the 2008 ozone, the 2010 NO_2, the 2010 SO_2, and the 2012 $PM_{2.5}$ NAAQS. The requirement for states to make a SIP submission of this type arises out of section 110(a)(1). Pursuant to section 110(a)(1), states must make SIP submissions ''within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national primary ambient air quality standard (or any revision thereof),'' and these SIP submissions are to provide for the ''implementation, maintenance, and enforcement'' of such NAAQS. The statute directly imposes on states the duty to make these SIP submissions, and the requirement to make the submissions is not conditioned upon EPA's taking any action other than promulgating a new or revised NAAQS. Section 110(a)(2) includes a list of specific elements that ''[e]ach such plan'' submission must address.

EPA has historically referred to these SIP submissions made for the purpose of satisfying the requirements of section 110(a)(1) and (2) as ''infrastructure SIP'' submissions. Although the term ''infrastructure SIP'' does not appear in the CAA, EPA uses the term to distinguish this particular type of SIP submission from submissions that are intended to satisfy other SIP requirements under the CAA, such as ''nonattainment SIP'' or ''attainment plan SIP'' submissions to address the nonattainment planning requirements of part D of Title I of the CAA, ''regional haze SIP'' submissions required by EPA rule to address the visibility protection requirements of section 169A of the CAA, and nonattainment new source review permit program submissions to address the permit requirements of CAA, Title I, part D.

Section 110(a)(1) addresses the timing and general requirements for infrastructure SIP submissions and section 110(a)(2) provides more details concerning the required contents of these submissions. The list of required elements provided in section 110(a)(2) contains a wide variety of disparate provisions, some of which pertain to required legal authority, some of which pertain to required substantive program provisions, and some of which pertain to requirements for both authority and substantive program provisions.[1] EPA therefore believes that while the timing requirement in section 110(a)(1) is unambiguous, some of the other statutory provisions are ambiguous. In particular, EPA believes that the list of required elements for infrastructure SIP submissions provided in section 110(a)(2) contains ambiguities concerning what is required for inclusion in an infrastructure SIP submission.

The following examples of ambiguities illustrate the need for EPA to interpret some section 110(a)(1) and section 110(a)(2) requirements with respect to infrastructure SIP submissions for a given new or revised NAAQS. One example of ambiguity is that section 110(a)(2) requires that ''each'' SIP submission must meet the list of requirements therein, while EPA has long noted that this literal reading of the statute is internally inconsistent and would create a conflict with the nonattainment provisions in part D of Title I of the CAA, which specifically address nonattainment SIP requirements.[2] Section 110(a)(2)(I) pertains to nonattainment SIP requirements and part D addresses when attainment plan SIP submissions to address nonattainment area requirements are due. For example, section 172(b) requires EPA to establish a schedule for submission of such plans for certain pollutants when the Administrator promulgates the designation of an area as nonattainment, and section 107(d)(1)(B) allows up to two years or in some cases three years, for such designations to be promulgated.[3] This ambiguity illustrates that rather than apply all the stated requirements of section 110(a)(2) in a strict literal sense, EPA must determine which provisions of section 110(a)(2) are applicable for a particular infrastructure SIP submission.

Another example of ambiguity within section 110(a)(1) and (2) with respect to infrastructure SIPs pertains to whether states must meet all of the infrastructure SIP requirements in a single SIP submission, and whether EPA must act upon such SIP submission in a single action. Although section 110(a)(1) directs states to submit ''a plan'' to meet these requirements, EPA interprets the CAA to allow states to make multiple SIP submissions separately addressing infrastructure SIP elements for the same NAAQS. If states elect to make such multiple SIP submissions to meet the

[1] For example: Section 110(a)(2)(E)(i) provides that states must provide assurances that they have adequate legal authority under state and local law to carry out the SIP; Section 110(a)(2)(C) provides that states must have a SIP-approved program to address certain sources as required by part C of Title I of the CAA; and section 110(a)(2)(G) provides that states must have legal authority to address emergencies as well as contingency plans that are triggered in the event of such emergencies.

[2] *See, e.g.,* ''Rule To Reduce Interstate Transport of Fine Particulate Matter and Ozone (Clean Air Interstate Rule); Revisions to Acid Rain Program; Revisions to the NO_X SIP Call; Final Rule,'' 70 FR 25162, at 25163–65 (May 12, 2005) (explaining relationship between timing requirement of section 110(a)(2)(D) versus section 110(a)(2)(I)).

[3] EPA notes that this ambiguity within section 110(a)(2) is heightened by the fact that various subparts of part D set specific dates for submission of certain types of SIP submissions in designated nonattainment areas for various pollutants. Note, *e.g.,* that section 182(a)(1) provides specific dates for submission of emissions inventories for the ozone NAAQS. Some of these specific dates are necessarily later than three years after promulgation of the new or revised NAAQS.

infrastructure SIP requirements, EPA can elect to act on such submissions either individually or in a larger combined action.[4] Similarly, EPA interprets the CAA to allow it to take action on the individual parts of one larger, comprehensive infrastructure SIP submission for a given NAAQS without concurrent action on the entire submission. For example, EPA has sometimes elected to act at different times on various elements and sub-elements of the same infrastructure SIP submission.[5]

Ambiguities within section 110(a)(1) and (2) may also arise with respect to infrastructure SIP submission requirements for different NAAQS. Thus, EPA notes that not every element of section 110(a)(2) would be relevant, or as relevant, or relevant in the same way, for each new or revised NAAQS. The states' attendant infrastructure SIP submissions for each NAAQS therefore could be different. For example, the monitoring requirements that a state might need to meet in its infrastructure SIP submission for purposes of section 110(a)(2)(B) could be very different for different pollutants, because the content and scope of a state's infrastructure SIP submission to meet this element might be very different for an entirely new NAAQS than for a minor revision to an existing NAAQS.[6]

EPA notes that interpretation of section 110(a)(2) is also necessary when EPA reviews other types of SIP submissions required under the CAA. Therefore, as with infrastructure SIP submissions, EPA also has to identify and interpret the relevant elements of section 110(a)(2) that logically apply to these other types of SIP submissions. For example, section 172(c)(7) requires attainment plan SIP submissions required by part D to meet the ''applicable requirements'' of section 110(a)(2); thus, attainment plan SIP submissions must meet the requirements of section 110(a)(2)(A) regarding enforceable emission limits and control measures and section 110(a)(2)(E)(i) regarding air agency resources and authority. By contrast, it is clear that attainment plan SIP submissions required by part D would not need to meet the portion of section 110(a)(2)(C) that pertains to the PSD program required in part C of Title I of the CAA, because PSD does not apply to a pollutant for which an area is designated nonattainment and thus subject to part D planning requirements. As this example illustrates, each type of SIP submission may implicate some elements of section 110(a)(2) but not others.

Given the potential for ambiguity in some of the statutory language of section 110(a)(1) and section 110(a)(2), EPA believes that it is appropriate to interpret the ambiguous portions of section 110(a)(1) and section 110(a)(2) in the context of acting on a particular SIP submission. In other words, EPA assumes that Congress could not have intended that each and every SIP submission, regardless of the NAAQS in question or the history of SIP development for the relevant pollutant, would meet each of the requirements, or meet each of them in the same way. Therefore, EPA has adopted an approach under which it reviews infrastructure SIP submissions against the list of elements in section 110(a)(2), but only to the extent each element applies for that particular NAAQS.

Historically, EPA has elected to use guidance documents to make recommendations to states for infrastructure SIPs, in some cases conveying needed interpretations on newly arising issues and in some cases conveying interpretations that have already been developed and applied to individual SIP submissions for particular elements.[7] EPA most recently issued guidance for infrastructure SIPs on September 13, 2013 (2013 Guidance).[8] EPA developed this document to provide states with up-to-date guidance for infrastructure SIPs for any new or revised NAAQS. Within this guidance, EPA describes the duty of states to make infrastructure SIP submissions to meet basic structural SIP requirements within three years of promulgation of a new or revised NAAQS. EPA also made recommendations about many specific subsections of section 110(a)(2) that are relevant in the context of infrastructure SIP submissions.[9] The guidance also discusses the substantively important issues that are germane to certain subsections of section 110(a)(2). EPA interprets section 110(a)(1) and (2) such that infrastructure SIP submissions need to address certain issues and need not address others. Accordingly, EPA reviews each infrastructure SIP submission for compliance with the applicable statutory provisions of section 110(a)(2), as appropriate.

As an example, section 110(a)(2)(E)(ii) is a required element of section 110(a)(2) for infrastructure SIP submissions. Under this element, a state must meet the substantive requirements of section 128, which pertain to state boards that approve permits or enforcement orders and heads of executive agencies with similar powers. Thus, EPA reviews infrastructure SIP submissions to ensure that the state's SIP appropriately addresses the requirements of section 110(a)(2)(E)(ii) and section 128. The 2013 Guidance explains EPA's interpretation that there may be a variety of ways by which states can appropriately address these substantive statutory requirements, depending on the structure of an individual state's permitting or enforcement program (*e.g.,* whether permits and enforcement orders are approved by a multi-member board or by a head of an executive agency). However, they are addressed by the state, the substantive requirements of

[4] *See, e.g.,* ''Approval and Promulgation of Implementation Plans; New Mexico; Revisions to the New Source Review (NSR) State Implementation Plan (SIP); Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NNSR) Permitting,'' 78 FR 4339 (January 22, 2013) (EPA's final action approving the structural PSD elements of the New Mexico SIP submitted by the State separately to meet the requirements of EPA's 2008 $PM_{2.5}$ NSR rule), and ''Approval and Promulgation of Air Quality Implementation Plans; New Mexico; Infrastructure and Interstate Transport Requirements for the 2006 $PM_{2.5}$ NAAQS,'' 78 FR 4337 (January 22, 2013) (EPA's final action on the infrastructure SIP for the 2006 $PM_{2.5}$ NAAQS).

[5] On December 14, 2007, the State of Tennessee, through the Tennessee Department of Environment and Conservation, made a SIP revision to EPA demonstrating that the State meets the requirements of sections 110(a)(1) and (2). EPA proposed action for infrastructure SIP elements (C) and (J) on January 23, 2012 (77 FR 3213) and took final action on March 14, 2012 (77 FR 14976). On April 16, 2012 (77 FR 22533) and July 23, 2012 (77 FR 42997), EPA took separate proposed and final actions on all other section 110(a)(2) infrastructure SIP elements of Tennessee's December 14, 2007 submittal.

[6] For example, implementation of the 1997 $PM_{2.5}$ NAAQS required the deployment of a system of new monitors to measure ambient levels of that new indicator species for the new NAAQS.

[7] EPA notes, however, that nothing in the CAA requires EPA to provide guidance or to promulgate regulations for infrastructure SIP submissions. The CAA directly applies to states and requires the submission of infrastructure SIP submissions, regardless of whether or not EPA provides guidance or regulations pertaining to such submissions. EPA elects to issue such guidance in order to assist states, as appropriate.

[8] ''Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and 110(a)(2),'' Memorandum from Stephen D. Page, September 13, 2013.

[9] EPA's September 13, 2013, guidance did not make recommendations with respect to infrastructure SIP submissions to address Section 110(a)(2)(D)(i)(I). EPA issued the guidance shortly after the U.S. Supreme Court agreed to review the DC Circuit decision in *EME Homer City,* 696 F.3d 7 (D.C. Cir. 2012) which had interpreted the requirements of section 110(a)(2)(D)(i)(I). In light of the uncertainty created by ongoing litigation, EPA elected not to provide additional guidance on the requirements of section 110(a)(2)(D)(i)(I) at that time. As the guidance is neither binding nor required by statute, whether EPA elects to provide guidance on a particular section has no impact on a state's CAA obligations.

Section 128 are necessarily included in EPA's evaluation of infrastructure SIP submissions because section 110(a)(2)(E)(ii) explicitly requires that the state satisfy the provisions of section 128.

As another example, EPA's review of infrastructure SIP submissions with respect to the PSD program requirements in section 110(a)(2)(C), (D)(i)(II), and (J) focuses upon the structural PSD program requirements contained in part C and EPA's PSD regulations. Structural PSD program requirements include provisions necessary for the PSD program to address all regulated sources and NSR pollutants, including Green House Gases (GHGs). By contrast, structural PSD program requirements do not include provisions that are not required under EPA's regulations at 40 CFR 51.166 but are merely available as an option for the state, such as the option to provide grandfathering of complete permit applications with respect to the $PM_{2.5}$ NAAQS. Accordingly, the latter optional provisions are types of provisions EPA considers irrelevant in the context of an infrastructure SIP action.

For other section 110(a)(2) elements, however, EPA's review of a state's infrastructure SIP submission focuses on assuring that the state's SIP meets basic structural requirements. For example, section 110(a)(2)(C) includes, *inter alia,* the requirement that states have a program to regulate minor new sources. Thus, EPA evaluates whether the state has an EPA-approved minor new source review program and whether the program addresses the pollutants relevant to that NAAQS. In the context of acting on an infrastructure SIP submission, however, EPA does not think it is necessary to conduct a review of each and every provision of a state's existing minor source program (*i.e.,* already in the existing SIP) for compliance with the requirements of the CAA and EPA's regulations that pertain to such programs.

With respect to certain other issues, EPA does not believe that an action on a state's infrastructure SIP submission is necessarily the appropriate type of action in which to address possible deficiencies in a state's existing SIP. These issues include: (i) Existing provisions related to excess emissions from sources during periods of startup, shutdown, or malfunction (SSM) that may be contrary to the CAA and EPA's policies addressing such excess emissions; (ii) existing provisions related to ''director's variance'' or ''director's discretion'' that may be contrary to the CAA because they purport to allow revisions to SIP-approved emissions limits while limiting public process or not requiring further approval by EPA; and (iii) existing provisions for PSD programs that may be inconsistent with current requirements of EPA's ''Final NSR Improvement Rule,'' 67 FR 80186 (December 31, 2002), as amended by 72 FR 32526 (June 13, 2007) (NSR Reform). Thus, EPA believes it may approve an infrastructure SIP submission without scrutinizing the totality of the existing SIP for such potentially deficient provisions and may approve the submission even if it is aware of such existing provisions.[10] It is important to note that EPA's approval of a state's infrastructure SIP submission should not be construed as explicit or implicit re-approval of any existing potentially deficient provisions that relate to the three specific issues just described.

EPA's approach to review of infrastructure SIP submissions is to identify the CAA requirements that are logically applicable to that submission. EPA believes that this approach to the review of a particular infrastructure SIP submission is appropriate, because it would not be reasonable to read the general requirements of section 110(a)(1) and the list of elements in section 110(a)(2) as requiring review of each and every provision of a state's existing SIP against all requirements in the CAA and EPA regulations merely for purposes of assuring that the state in question has the basic structural elements for a functioning SIP for a new or revised NAAQS. Because SIPs have grown by accretion over the decades as statutory and regulatory requirements under the CAA have evolved, they may include some outmoded provisions and historical artifacts. These provisions, while not fully up to date, nevertheless may not pose a significant problem for the purposes of ''implementation, maintenance, and enforcement'' of a new or revised NAAQS when EPA evaluates adequacy of the infrastructure SIP submission. EPA believes that a better approach is for states and EPA to focus attention on those elements of section 110(a)(2) of the CAA most likely to warrant a specific SIP revision due to the promulgation of a new or revised NAAQS or other factors.

For example, EPA's 2013 Guidance gives simpler recommendations with respect to carbon monoxide than other NAAQS pollutants to meet the visibility requirements of section 110(a)(2)(D)(i)(II), because carbon monoxide does not affect visibility. As a result, an infrastructure SIP submission for any future new or revised NAAQS for carbon monoxide need only state this fact in order to address the visibility prong of section 110(a)(2)(D)(i)(II).

Finally, EPA believes that its approach with respect to infrastructure SIP requirements is based on a reasonable reading of section 110(a)(1) and (2) because the CAA provides other avenues and mechanisms to address specific substantive deficiencies in existing SIPs. These other statutory tools allow EPA to take appropriately tailored action, depending upon the nature and severity of the alleged SIP deficiency. Section 110(k)(5) authorizes EPA to issue a ''SIP call'' whenever the Agency determines that a state's SIP is substantially inadequate to attain or maintain the NAAQS, to mitigate interstate transport, or to otherwise comply with the CAA.[11] Section 110(k)(6) authorizes EPA to correct errors in past actions, such as past approvals of SIP submissions.[12] Significantly, EPA's determination that an action on a state's infrastructure SIP submission is not the appropriate time and place to address all potential existing SIP deficiencies does not preclude EPA's subsequent reliance on provisions in section 110(a)(2) as part of the basis for action to correct those deficiencies at a later time. For example, although it may not be appropriate to require a state to eliminate all existing inappropriate director's discretion provisions in the course of acting on an infrastructure SIP submission, EPA believes that section 110(a)(2)(A) may be

[10] By contrast, EPA notes that if a state were to include a new provision in an infrastructure SIP submission that contained a legal deficiency, such as a new exemption for excess emissions during SSM events, then EPA would need to evaluate that provision for compliance against the rubric of applicable CAA requirements in the context of the action on the infrastructure SIP.

[11] For example, EPA issued a SIP call to Utah to address specific existing SIP deficiencies related to the treatment of excess emissions during SSM events. *See* ''Finding of Substantial Inadequacy of Implementation Plan; Call for Utah State Implementation Plan Revisions,'' 74 FR 21639 (April 18, 2011).

[12] EPA has used this authority to correct errors in past actions on SIP submissions related to PSD programs. *See* ''Limitation of Approval of Prevention of Significant Deterioration Provisions Concerning Greenhouse Gas Emitting-Sources in State Implementation Plans; Final Rule,'' 75 FR 82536 (December 30, 2010). EPA has previously used its authority under section 110(k)(6) of the CAA to remove numerous other SIP provisions that the Agency determined it had approved in error. *See, e.g.,* 61 FR 38664 (July 25, 1996) and 62 FR 34641 (June 27, 1997) (corrections to American Samoa, Arizona, California, Hawaii, and Nevada SIPs); 69 FR 67062, November 16, 2004 (corrections to California SIP); and 74 FR 57051 (November 3, 2009) (corrections to Arizona and Nevada SIPs).

among the statutory bases that EPA relies upon in the course of addressing such deficiency in a subsequent action.[13]

IV. Summary of EPA's Rationale for Proposing Approval

In this rulemaking action, EPA is proposing approval of the Commonwealth's four infrastructure SIP submittals for the 2008 ozone, 2010 NO_2, 2010 SO_2, and 2012 $PM_{2.5}$ NAAQS as addressing requirements in section 110(a)(2)(A), (B), (C), (D)(i)(II) (prevention of significant deterioration), (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M) of the CAA. A detailed analysis of EPA's review and rationale for proposing to approve the four infrastructure SIP submittals as addressing these CAA requirements may be found in the Technical Support Document (TSD) for this proposed rulemaking action which is available on line at *www.regulations.gov,* Docket ID Number EPA–R03–OAR–2014–0910. EPA is not taking rulemaking action at this time on the portion of the infrastructure SIP submittals which address section 110(a)(2)(D)(i)(II) (visibility protection) for the four NAAQS. EPA will take later rulemaking action on these submittals regarding section 110(a)(2)(D)(i)(II) (visibility protection).

EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

V. Proposed Action

EPA is proposing to approve the Commonwealth's infrastructure submittals dated July 15, 2014 for the 2008 ozone, the 2010 NO_2, the 2010 SO_2, and the 2012 $PM_{2.5}$ NAAQS respectively, as meeting the requirements of section 110(a)(2) of the CAA, including specifically section 110(a)(2)(A), (B), (C), (D)(i)(II) (prevention of significant deterioration), (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M) for the four NAAQS with the exception of the requirements related to section 110(a)(2)(D)(i)(II) (visibility protection). The Commonwealth's infrastructure SIP submissions for the four NAAQS did not include provisions addressing CAA 110(a)(2)(D)(i)(I) and therefore EPA is not taking any action on section 110(a)(2)(D)(i)(I) for any of the four NAAQS. The Commonwealth's infrastructure SIP submissions for the four NAAQS also did not include provisions addressing section 110(a)(2)(I) for any nonattainment requirements of part D, Title I of the CAA, because this element is not required to be submitted by the 3 year submission deadline of CAA section 110(a)(1). EPA is also not taking action at this time on the portions of the four infrastructure SIP submittals intended to address section 110(a)(2)(D)(i)(II) (visibility protection). EPA will take later separate action on the portion of the infrastructure SIP submittals addressing CAA section 110(a)(2)(D)(i)(II) (visibility protection) for the four NAAQS.

VI. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

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

In addition, this proposed rulemaking action, pertaining to Pennsylvania's section 110(a)(2) infrastructure requirements for the 2008 ozone, the 2010 NO_2, the 2010 SO_2, and 2012 $PM_{2.5}$ NAAQS does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

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

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

Dated: January 13, 2015.

William C. Early,

Acting Regional Administrator, Region III.

[FR Doc. 2015–02482 Filed 2–5–15; 8:45 am]

BILLING CODE 6560–50–P

[13] *See, e.g.,* EPA's disapproval of a SIP submission from Colorado on the grounds that it would have included a director's discretion provision inconsistent with CAA requirements, including section 110(a)(2)(A). *See, e.g.,* 75 FR 42342 at 42344 (July 21, 2010) (proposed disapproval of director's discretion provisions); 76 FR 4540 (January 26, 2011) (final disapproval of such provisions).

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2014–0471 [FRL–9922–13–OAR]

RIN 2060–AS26

Petition To Add n-Propyl Bromide to the List of Hazardous Air Pollutants

AGENCY: Environmental Protection Agency.

ACTION: Receipt of a complete petition.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is announcing the receipt of a complete petition requesting that the EPA add the chemical n-Propyl Bromide (nPB) (Chemical Abstract Service No. 106–94–5) to the list of hazardous air pollutants (HAP) contained in section 112(b)(1) of the Clean Air Act (CAA). On October 28, 2010 and November 28, 2012, the Halogenated Solvent Industry Alliance (HSIA) submitted a petition to list nPB as a HAP and a supplement to the petition, respectively. In addition, on

November 24, 2011, the New York State Department of Environmental Conservation (NYSDEC) submitted a petition to add nPB to the HAP list. We have determined that these petitions are complete for purposes of this process, which means they provide sufficient information to assess the human health impacts on people living in the vicinity of facilities emitting nPB. Today's document initiates our comprehensive technical review phase of the petition process. The EPA invites the public to comment on these petitions and to provide additional data, beyond what are in these petitions, on sources, emissions, exposure, health effects and environmental impacts associated with nPB that may be relevant to our technical review. These petitions and supporting information are available through Docket ID EPA–HQ–OAR–2014–0471. Following completion of the technical review phase that is initiated by today's notice and runs through the EPA's evaluation of all the comments received, the EPA will decide whether to grant or deny the petitions.

DATES: *Comments.* Comments must be received on or before March 9, 2015.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2014–0471, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Email: a-and-r-docket@epa.gov,* include Docket ID No. EPA–HQ–OAR–2014–0471 in the subject line of the message.
- *Fax:* (202) 566–9744, Attention Docket ID No. EPA–HQ–OAR–2014–0471.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center (EPA/DC), Mail Code 28221T, Attention Docket ID No. EPA–HQ–OAR–2014–0471, 1200 Pennsylvania Avenue NW., Washington, DC 20460. Please include a total of two copies. In addition, please mail a copy of your comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attn: Desk Officer for EPA, 725 17th Street NW., Washington, DC 20503.
- *Hand/Courier Delivery:* EPA Docket Center, Room 3334, EPA WJC West Building, 1301 Constitution Avenue NW., Washington, DC 20004, Attention Docket ID No. EPA–HQ–OAR–2014–0471. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: All submissions must include agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. Direct your comments to Docket ID No. EPA–HQ–OAR–2014–0471. The EPA's policy is that all comments received will be included in the public docket and may be made available online at: *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be confidential business information (CBI), or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI, or otherwise protected through *http://www.regulations.gov* or email. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *http://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment, and with any disk or CD–ROM you submit. If the EPA cannot read your comment due to technical difficulties, and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at *http://www.regulations.gov.*

Docket: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2014–0471. All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy form. Publicly available docket materials are available either electronically at: *http://www.regulations.gov,* or in hard copy at the EPA Docket Center, EPA WJC West Building, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Mr. John Schaefer, U.S. EPA, Office of Air Quality Planning and Standards, Sector Policies and Programs Division, Policies and Strategies Group (D205–02), Research Triangle Park, North Carolina 27711; telephone number: (919) 541–0296; fax number: (919) 541–5600; email address: *schaefer.john@epa.gov.*

SUPPLEMENTARY INFORMATION:

Organization of This Document. The following outline is provided to aid in locating information in this preamble.

I. General Information
A. What should I consider as I prepare my comments for EPA?
B. Where can I get a copy of this document?
II. Background Information for Petitions Received by the EPA
A. What is the list of hazardous air pollutants?
B. What is a listing petition?
C. How does the EPA review a petition to list a HAP?
D. How is the decision to list a HAP made?
III. Completeness Determination and Request for Public Comment
IV. Description of the Petitions

I. General Information

A. What should I consider as I prepare my comments for EPA?

Submitting CBI. Do not submit information that you consider to be CBI electronically through *http://www.regulations.gov* or email. Send or deliver information identified as CBI to only the following address: OAQPS Document Control Officer (Room C404–02), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Attn: Docket ID No. EPA–HQ–OAR–2014–0471.

Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to the EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. If you submit a CD–ROM or disk that does not contain CBI, mark the outside of the disk or CD–ROM clearly that it does not contain CBI. Information marked as CBI will not be disclosed except in

accordance with procedures set forth in 40 CFR part 2.

If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

B. Where can I get a copy of this document?

In addition to being available in the docket, electronic copies of this notice will be available on the World Wide Web through the Technology Transfer Network (TTN). Following signature, a copy of this proposed rule will be posted on the TTN's Air Toxics Web site at the following address: *http://www.epa.gov/ttn/atw/pollutants/atwsmod.html.*

II. Background Information for Petitions Received by the EPA

A. What is the list of hazardous air pollutants?

The HAPs, which can be found in CAA section 112(b)(1), is a list of a wide variety of organic and inorganic substances released from large and small industrial operations, fossil fuel combustion, gasoline and diesel-powered vehicles, and many other sources. These HAPs have been associated with a wide variety of adverse health effects, including cancer, neurological effects, reproductive effects and developmental effects. The health effects associated with various HAPs may differ depending upon the toxicity of the individual HAP and the particular circumstances of exposure, such as the amount of chemical present, the length of time a person is exposed, and the stage in life of the person when the exposure occurs.

B. What is a listing petition?

CAA section 112(b)(3)(A) specifies that any person may petition the Administrator to modify, by addition or deletion, the list of HAPs contained in CAA section 112(b)(1). The EPA Administrator is required under CAA section 112(b)(3)(A) to either grant or deny a petition to list a specific HAP within 18 months of the receipt of a petition to add a substance to the HAP list. CAA section 112(b)(3)(B) says the, ''Administrator shall add a substance to the list upon a showing by the petitioner or on the Administrator's own determination that the substance is an air pollutant and that emissions, ambient concentrations, bioaccumulation or deposition of the substance are known to cause or may reasonably be anticipated to cause adverse effects to human health or adverse environmental effects.'' The addition of a HAP to the list in CAA section 112(b)(1) brings sources emitting HAP into consideration in the EPA's program to promulgate national technology-based emissions control standards. This technology-based standards program is commonly referred to as the maximum achievable control technology (MACT) program.

C. How does the EPA review a petition to list a HAP?

The petition review process consists of two phases: A completeness determination and a technical review. During the completeness determination, the EPA conducts a broad review of the petition to determine whether all of the necessary subject areas are addressed. In addition, the EPA determines if adequate data, analyses, and evaluation are included for each subject area. Once the petition is determined to be complete, the EPA places a notice of receipt of a complete petition in the **Federal Register**. That notice announces a public comment period on the petition and starts the technical review phase of our decision-making process. The technical review determines whether the petition has satisfied the necessary requirements and can support a decision to list the HAP. All comments and data submitted during the public comment period are considered during the technical review.

D. How is the decision to list a HAP made?

The decision to either grant or deny a petition is made after a comprehensive technical review of both the petition and the information received from the public to determine whether the petition satisfies the requirements of CAA section 112(b)(3)(B). If the Administrator decides to grant a petition, a proposal will be published in the **Federal Register** announcing that decision and the opportunity for public comment. That notice would propose a modification of the HAP list and present the reasoning for doing so. However, if the Administrator decides to deny a petition, a notice setting forth an explanation of the reasons for denial will be published in the **Federal Register** instead. A notice of denial constitutes final agency action of nationwide scope and applicability and is subject to judicial review as provided in CAA section 307(b).

III. Completeness Determination and Request for Public Comment

The EPA Administrator is required under CAA section 112(b)(3)(A) to either grant or deny a petition to list a specific HAP within 18 months of the receipt of a petition. On October 28, 2010, we received a petition from the HSIA to add nPB to the HAP list. Because of incomplete emissions estimates, modeling procedures and a lack of sufficient citations supporting adverse human health effects, the EPA determined that the petition was incomplete and requested that the petitioner provide additional information. On November 30, 2012, the petitioner submitted supplemental information and data addressing the EPA's concerns regarding the completeness of the petition. Additionally, on November 24, 2011, the NYSDEC submitted a petition to add nPB to the HAP list.

After reviewing these petitions and supplemental information, we have determined that all of the necessary subject areas for a human health and environmental risk assessment have been addressed and, therefore, the petitions are ready for technical review. Today's notice initiates our comprehensive technical review of the petition and invites public comment on the substance of the petitions as described above.

IV. Description of the Petitions

These petitions contain the following information:

- Background data on nPB including chemical properties, physical properties, production data, and use data;
- Toxicological data describing the human health and environmental effects of nPB;
- Atmospheric dispersion modeling that provides estimates of nPB concentrations adjacent to facilities that emit it; and
- Characterization of risks to human health due to emissions of nPB.

Based on the chemical and physical properties of nPB, petitioners claim that nPB is carcinogenic, has toxic reproductive effects, and is a neurotoxin. HSIA's petition estimated cancer incidence by estimating emissions from five facilities that use nPB. HSIA also used the site-specific data as input for air dispersion modeling to develop anticipated lifetime cancer risk that would occur beyond facility boundaries. Neither HSIA nor NYSDEC provided estimates of anticipated chronic or acute adverse health impacts in people living near nPB-emitting facilities, although such effects were identified in the scientific literature referenced by both petitioners.

We invite the public to comment on the technical merits of these petitions and to submit any information that may

impact the EPA's ultimate decision to grant or deny these requests to list nPB as a HAP.

Dated: January 21, 2015.

Janet G. McCabe,

Acting Assistant Administrator for Air and Radiation.

[FR Doc. 2015–01705 Filed 2–5–15; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 140, 143, and 146

46 CFR Parts 61 and 62

[USCG–2014–0063]

RIN 1625–AC16

Requirements for MODUs and Other Vessels Conducting Outer Continental Shelf Activities With Dynamic Positioning Systems—Comment Period Extension

AGENCY: Coast Guard, DHS.

ACTION: Notice.

SUMMARY: The Coast Guard is extending for 90 days the comment period for the notice of proposed rulemaking (NPRM) entitled ''Requirements for MODUs and Other Vessels Conducting Outer Continental Shelf Activities With Dynamic Positioning Systems'' published on November 28, 2014. This extension is necessary to allow sufficient time for the Coast Guard to hold a public meeting and receive any subsequent public comments on the NPRM.

DATES: Comments and related material must either be submitted to our online docket via *http://www.regulations.gov* on or before May 27, 2015 or reach the Docket Management Facility by that date.

ADDRESSES: You may submit comments identified by docket number USCG–2014–0481 using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* 202–493–2251.

(3) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email LT Stephanie Waller, Human Element and Ship Design Division, Commandant (CG–ENG–1), Coast Guard; telephone 202–372–1374, email *Stephanie.E.Waller@uscg.mil,* or fax 202–372–8380. If you have questions on viewing or submitting material to the docket, call Ms. Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

A. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2014–0063), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. We recommend that you include your name and a mailing address, an email address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov* and insert ''USCG–2014–0063'' in the ''Search'' box. Click on ''Submit a Comment'' in the ''Actions'' column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope.

We will consider all comments and material received during the comment period and may change this notice of proposed rulemaking (NPRM) based on your comments.

B. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov* and insert ''USCG–2014–0063'' in the ''Search'' box. Click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

C. Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008 issue of the **Federal Register** (73 FR 3316).

II. Background and Purpose

The Coast Guard published a notice of proposed rulemaking (NPRM) in the **Federal Register** on November 28, 2014 entitled, ''Requirements for MODUs and Other Vessels Conducting Outer Continental Shelf Activities With Dynamic Positioning Systems'' (79 FR 70943). The proposed rule would establish minimum design, operation, training, and manning standards for mobile offshore drilling units (MODUs) and other vessels using dynamic positioning systems to engage in Outer Continental Shelf activities. Establishing these minimum standards is necessary to improve the safety of people and property involved in such operations, and the protection of the environment in which they operate. The rule would decrease the risk of a loss of position by a dynamically-positioned MODU or other vessel that could result in a fire, explosion, or subsea spill, and support the Coast Guard's strategic goals of maritime safety and protection of natural resources.

In the NPRM, we stated our intention to hold a public meeting, and to publish a notice to announce the location and date of that meeting (79 FR 70944). In order to allow sufficient time for the Coast Guard to hold such a meeting and receive any subsequent public comments on the NPRM, we are

extending the end of the public comment period from February 26, 2015 to May 27, 2015.

III. Authority

This notice is issued under the authority of 5 U.S.C. 552(a).

Dated: February 3, 2015.

J.G. Lantz,

Director of Commercial Regulations and Standards, U.S. Coast Guard.

[FR Doc. 2015–02415 Filed 2–5–15; 8:45 am]

BILLING CODE 9110–04–P

Notices

Federal Register

Vol. 80, No. 25

Friday, February 6, 2015

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

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2014–0100]

Notice of Availability of Proposed Changes to the National Poultry Improvement Plan Program Standards

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: We are advising the public that proposed changes to the National Poultry Improvement Plan Program Standards are available for review and comment.

DATES: We will consider all comments that we receive on or before March 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-2014-0100.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2014–0100, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

The proposed standards and any comments we receive may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0100* 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: Dr. Denise Brinson, DVM, Director, National Poultry Improvement Plan, VS, APHIS, USDA, 1506 Klondike Road, Suite 101, Conyers, GA 30094–5104; (770) 922–3496.

SUPPLEMENTARY INFORMATION: The National Poultry Improvement Plan (NPIP, also referred to below as ''the Plan'') is a cooperative Federal-State-Industry mechanism for controlling certain poultry diseases. The Plan consists of a variety of programs intended to prevent and control poultry diseases. Participation in all Plan programs is voluntary, but breeding flocks, hatcheries, and dealers must first qualify as ''U.S. Pullorum-Typhoid Clean'' as a condition for participating in the other Plan programs.

The Plan identifies States, flocks, hatcheries, dealers, and slaughter plants that meet certain disease control standards specified in the Plan's various programs. As a result, customers can buy poultry that has tested clean of certain diseases or that has been produced under disease-prevention conditions.

The regulations in 9 CFR parts 145, 146, and 147 (referred to below as the regulations) contain the provisions of the Plan. The Animal and Plant Health Inspection Service (APHIS, also referred to as ''the Service'') of the U.S. Department of Agriculture (USDA, also referred to as ''the Department'') amends these provisions from time to time to incorporate new scientific information and technologies within the Plan.

In the past, APHIS has updated the regulations once every 2 years, following the Biennial Plan Conference. However, with the continual changes in diagnostic science and testing technology and in best practices for maintaining sanitation, the biennial update schedule has occasionally resulted in the regulations becoming out of date between updates. In some instances, tests have also been difficult to render properly in the regulations due to the need to describe flow charts or diagrams in a narrative format.

On July 9, 2014, we published in the **Federal Register** (79 FR 38752–38768, Docket No. APHIS–2011–0101) a final rule [1] that, among other things, amended the regulations by removing tests and detailed testing procedures, as well as sanitation procedures, from part 147, and making these available in an NPIP Program Standards document.[2] The rule also amended the regulations to provide for the Program Standards document to be updated through the issuance of a notice in the **Federal Register** followed by a period of public comment. This action was intended to make the NPIP program more effective by streamlining the provisions of the Plan, keeping those provisions current with changes in the poultry industry, and providing for the use of new approved sampling and testing procedures without the need for rulemaking.

We are advising the public that we have prepared updates to the NPIP Program Standards document. The proposed updates include changes to blood testing procedures for mycoplasma, bacteriological examination procedure changes for *Salmonella,* and the addition of new approved diagnostic test kits. After reviewing any comments we receive on the proposed updates, we will publish a second notice in the **Federal Register** announcing our decision regarding the proposed changes.

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 2nd day of February 2015.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2015–02406 Filed 2–5–15; 8:45 am]

BILLING CODE 3410–34–P

[1] To view the final rule and related documents, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0101.*

[2] This document may be viewed on the NPIP Web site at *http://www.poultryimprovement.org/documents/ProgramStandardsAugust2014.pdf,* or by writing to the Service at National Poultry Improvement Plan, APHIS, USDA, 1506 Klondike Road, Suite 101, Conyers, GA 30094.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2008–0119]

Implementation of Revised Lacey Act Provisions

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The Food, Conservation, and Energy Act of 2008 amended the Lacey Act to provide, among other things, that importers submit a declaration at the

time of importation for certain plants and plant products. Enforcement of the declaration requirement began on April 1, 2009, and products requiring a declaration are being phased-in. The purpose of this notice is to inform the public of another phase of the Federal Government's enforcement schedule.

DATES: We will consider all comments that we receive on or before April 7, 2015.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0119.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2008–0119, 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-2008-0119* 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. Parul Patel, Senior Agriculturalist, Regulations, Permits, and Manuals, PPQ, APHIS, 4700 River Road, Unit 60, Riverdale, MD 20737–1231; (301) 851–2351.

SUPPLEMENTARY INFORMATION:

Background

The Lacey Act (16 U.S.C. 3371 *et seq.*), first enacted in 1900 and significantly amended in 1981, is the United States' oldest wildlife protection statute. The Act combats trafficking in illegally taken wildlife, fish, and plants. The Food, Conservation, and Energy Act of 2008 amended the Lacey Act by expanding its protection to a broader range of plants and plant products (Section 8204, Prevention of Illegal Logging Practices). As amended, the Lacey Act makes it unlawful to import, export, transport, sell, receive, acquire, or purchase in interstate or foreign commerce any plant, with some limited exceptions, taken in violation of the laws of a U.S. State or any foreign law that protects plants. The Lacey Act also makes it unlawful to make or submit any false record, account, or label for, or any false identification of, any plant.

In addition, Section 3 of the Lacey Act, as amended (16 U.S.C. 3372), makes it unlawful to import certain plants and plant products without an import declaration. The declaration must contain, among other things, the scientific name of the plant, value of the importation, quantity of the plant, and name of the country from where the plant was harvested. For paper and paperboard products containing recycled content, the declaration also must include the average percent of recycled content without regard for species or country of harvest. Currently, enforcement of the declaration requirement is being phased in, as described in two notices we published in the **Federal Register,**[1] the first on February 3, 2009 (74 FR 5911–5913, Docket No. APHIS–2008–0119) and the second on September 2, 2009 (74 FR 45415–45418, Docket No. APHIS–2008–0119).

In our February 2009 notice, we committed to providing affected individuals and industry with at least 6 months' notice for any products that would be added to the phase-in schedule. The phased-in enforcement schedule began April 1, 2009. The most recent phase (IV) began on April 1, 2010. The enforcement schedule is available on the Animal and Plant Health Inspection Service (APHIS) Web site at *http://www.aphis.usda.gov/plant_health/lacey_act/.* We continue to consider the applicability of the declaration requirement to products not included in the current phase-in schedule and we invite public comment on how the declaration requirement should be enforced as to these products.

Phase V of the enforcement schedule, which would begin on August 6, 2015, is described below. We invite public comment on the products covered under this phase of the plan, as well as on whether any additional Harmonized Tariff Schedule (HTS) chapters should be included in the current phase-in schedule. Should there be additions to phase V, we intend to provide at least 6 months' notice to persons and industries affected by those changes to facilitate compliance with the new requirements. Changes will be announced in the **Federal Register**.

Ch. 44 Headings (Wood & Articles of Wood)

- 4416003010—new casks, barrels, and parts of wood
- 4416003020—used assembled casks of wood
- 4416003030—used unassembled casks of wood
- 4416006010—new barrel staves of wood
- 4416006020—new barrel hoops of softwood
- 4416006030—new tight barrelheads of wood
- 4416006040—used barrels staves of softwood
- 4416006050—used hoops, tight barrelheads of softwood
- 4416009020—new other casks, barrels, wood
- 4416009040—used other cooper goods, wood

Ch. 82 Headings (Tools, Implements, Cutlery, Spoons and Forks, of Base Metal; Parts Thereof of Base Metal)

- 8211926000—hunting knives with wood handles
- 8215992400—table barbeque forks with wood handles

Ch. 94 Headings (Furniture, etc.)

- 9401612010—upholstered teak chair, household
- 9401612030—upholstered teak chairs, other
- 9401901500—parts of bent-wood seats
- 9403304000—bent-wood office furniture
- 9403404000—bent-wood kitchen furniture
- 9403504000—bent-wood bedroom furniture
- 9403604000—other bent-wood furniture

Ch. 96 Headings (Miscellaneous Manufactured Articles)

- 9614002100—rough wood blocks for smoking pipe manufacture

Additional Information

Several commenters on our earlier notices contended that identifying composite and recycled or reused materials (*e.g.,* medium density fiberboard, particleboard, and scrap wood) to the genus and/or species level would be difficult and in some cases impossible. These commenters asked that we consider describing a level at which the declaration requirement does not apply for minimal amounts of unidentifiable plant materials in such products. The commenters also asked that we describe a level at which the declaration requirement does not apply for minimal amounts of non-listed (*i.e.,* not of conservation concern) plant materials contained in an otherwise non-plant product, such as wooden buttons on a shirt. Some commenters referred to this as a de minimis exception from the declaration requirement. We are in the process of

[1] To view these notices and the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0119.*

developing a proposal to establish exceptions from the declaration requirement for composite materials and products that contain a minimal amount of plant material. Upon completion of the proposal, we will publish it in the **Federal Register** for public comment.

APHIS will continue to provide the latest information regarding the Lacey Act on our Web site, *http://www.aphis.usda.gov/plant_health/lacey_act/*. The Web site currently contains the Lacey Act, as amended; a slideshow covering background and context, requirements, commodities and products covered, information on prohibitions, and the current status of implementation of the declaration requirement of the Lacey Act; frequently asked questions; the phase-in implementation plan; a link to the Lacey Act Web Governance System (LAWGS); and the paper declaration form. The Web site will be updated as new materials become available. We encourage persons interested in receiving timely updates on APHIS' Lacey Act efforts to register for our stakeholder registry at *https://public.govdelivery.com/accounts/USDAAPHIS/subscriber/new/* and select ''Lacey Act Declaration'' as a topic of interest.

Done in Washington, DC, this 2nd day of February 2015.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2015–02403 Filed 2–5–15; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Forest Service

RIN 0596–AD06

National Forest System, Land Management Planning Directives

AGENCY: Forest Service, USDA.

ACTION: Notice of final directives.

SUMMARY: On February 29, 2013, the Forest Service (Agency) proposed to revise the Forest Service Handbook (FSH 1909.12) and Manual (FSM 1920) establishing procedures and responsibilities for implementing the National Forest System (NFS) land management planning regulation (collectively ''planning directives''). The final issuance of planning directives, effective today, will provide consistent overall guidance to Forest Service Line Officers and Agency employees in developing, amending, or revising land management plans for units of the NFS. Public comment was accepted until May 24, 2013. The Agency considered all public comment, including recommendations from an advisory committee formed pursuant to the Federal Advisory Committee Act (FACA), in developing final planning directives.

DATES: These directives are effective January 30, 2015.

ADDRESSES: The Forest Service Manual and Handbook, including the planning directives, are available electronically via the World Wide Web/Internet at *http://www.fs.fed.us/im/directives.* Single paper copies are available by contacting Annie Eberhart Goode, Forest Service, USDA, Ecosystem Management Coordination Staff (Mail Stop 1104), 1400 Independence Avenue SW., Washington, DC 20250–1104. Additional information and analysis, including a description of how the Agency considered public comment, can be found at *http://www.fs.usda.gov/main/planningrule/home.*

FOR FURTHER INFORMATION CONTACT: Annie Eberhart Goode, Planning Specialist, Ecosystem Management Coordination staff, (202) 205–1056.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at (800) 877–8339 between 8:00 a.m. and 8:00 p.m. Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Background

On April 9, 2012, the U.S. Department of Agriculture (Department or USDA) adopted final planning regulations for the NFS at 36 CFR part 219 (77 FR 21161). These regulations, known collectively as the 2012 Planning Rule, provide broad programmatic direction in developing and implementing land management plans. The rule explicitly directs the Chief of the Forest Service to establish planning procedures in the Forest Service Directives System (36 CFR 219.2(b)(5)(i). Those Responsible Officials that are implementing the 2012 Planning Rule shall follow the regulations at 36 CFR part 219 and the revised planning directives.

The Forest Service Directives System consists of the Forest Service Manual (FSM) and the Forest Service Handbook (FSH), which contain the Agency's policies, practices, and procedures, and serves as the primary basis for the internal management and control of programs and administrative direction to Forest Service employees. The directives are set out on the World Wide Web/Internet at *http://www.fs.fed.us/im/directives.* Specifically, the FSM contains legal authorities, objectives, policies, responsibilities, instructions, and guidance needed on a continuing basis by Forest Service Line Officers and primary staff to plan and execute programs and activities. The FSH is the principal source of specialized guidance and instruction for carrying out the policies, objectives, and responsibilities contained in the FSM.

FSM 1920 and FSH 1909.12 (planning directives) provide policy direction, objectives, instructions, and guidance for Forest Service Line Officers and primary staff to plan and execute the process of developing, revising, amending, and making administrative changes to land management plans to provide for the sustainability of ecosystems and resources; meet the need for forest restoration and conservation, watershed protection, and species diversity and conservation; and assist the Agency in providing a sustainable flow of benefits, including economic benefits, services, and uses of NFS lands. The 2012 Planning Rule and the FSM 1920 and FSH 19092.12 together provide requirements and guidance for the Agency in land management planning pursuant to the National Forest Management Act.

On February 29, 2013, the Forest Service proposed to revise the planning directives (FSM 1920 and FSH 1909.12) to ensure that the Agency's planning directives are consistent with the 2012 Planning Rule. Issuance of planning directives will provide consistent overall guidance to Forest Service Line Officers and Agency employees in developing, amending, or revising land management plans pursuant to the 2012 Planning Rule. Public comment was accepted until May 24, 2013. The Agency considered all public comment in developing final planning directives.

In addition to seeking public comment on the proposed directives, the Agency considered recommendations from the Planning Rule Implementation Federal Advisory Committee (FACA Committee), established in June 2012 to advise the Secretary of Agriculture and the Chief of the Forest Service regarding implementation of the 2012 Planning Rule. The FACA Committee is comprised of 21 members who provide balanced and broad representation of public interests including industry and user groups; environmental organizations; conservation organizations; recreation interests; members of the scientific community; State, County, or local elected officials (or designee); Tribal representatives; and other public interests. The initial FACA Committee provided its recommendations regarding the

proposed Planning Directives in November, 2013. The previous committee's membership expired in June 2014. The Secretary announced August 12, 2014, the selection of 21 new members to the FACA committee. The charter, background information, and other information for the Planning Rule Advisory Committee can be found *www.fs.usda.gov/main/planningrule/committee.* The committee was rechartered in June, 2014 to continue in an advisory capacity for an additional 2 years. The text of the initial FACA Committee's recommendations can be found at *http://www.fs.usda.gov/detail/planningrule/home/?cid=stelprdb5346267.*

Content of Final Directives

The following is an overview of the content of the directives.

FSM 1920—Land Management Planning Manual. This Forest Service Manual describes the responsibilities of Agency Line Officers and staff regarding the process for developing, revising, amending, and making administrative changes to land management plans for the National Forest System (NFS). It includes authorities and responsibilities. It should be used in conjunction with the FSH.

FSH 1909.12—Land Management Planning Handbook. This FSH provides policy direction, objectives, instructions and guidance for the process of developing, revising, amending, and making administrative changes to plans for the NFS. It includes authorities and responsibilities.

Zero Code. The chapter known as the zero code contains authorities, responsibilities, and select definitions applicable to subsequent chapters, along with definitions and guidance applicable to all sections of FSH 1909.12, such as direction on best available scientific information (BASI) and adaptive management. The zero code also includes exhibits or references not easily found electronically.

Chapter 10—The Assessment. This chapter provides direction regarding the procedures for writing an assessment for development, amendment, or revision of land management plans.

Chapter 20—Land Management Plan. This chapter describes the land management plan under the 2012 Planning Rule and provides guidance for developing, amending, and revising land management plans.

Chapter 30—Monitoring. This chapter provides direction regarding the plan monitoring program, broader-scale monitoring strategy, and biennial evaluation of information obtained from implementation of the plan monitoring program.

Chapter 40—Public Participation. This chapter sets out direction regarding provision of public participation opportunities and for collaboration, intergovernmental participation, and Tribal consultation relating to land management planning.

Chapter 50—Objection Process. This chapter sets out direction regarding administration of the objection process that provides for administrative review of plans, plan revisions, and plan amendments before their approval.

Chapter 60—Forest Vegetation Resource Planning. This chapter provides procedures for developing plan components and other plan content to guide management of timber resources, including identification of lands that are not suitable for timber production, limitations on timber harvest, display of the planned timber sale program, and components related to timber harvest for timber production or other purposes.

Chapter 70—Wilderness Evaluation. This chapter provides direction for identifying and evaluating lands that may be suitable for inclusion in the National Wilderness Preservation System and determining whether to recommend any such lands for wilderness designation.

Chapter 80—Wild and Scenic River Evaluation. This chapter provides direction for identifying and evaluating potential additions to the National Wild and Scenic Rivers System. This chapter also includes provisions on interim management of river segments determined to be eligible and suitable, documentation of study results, as well as the process for notifying Congress of Agency wild and scenic river recommendations.

Chapter 90—Reserved.

Public Comments

The availability of proposed directives for public review and comment was published in the **Federal Register** on February 27, 2013 (77 FR 35323). The public comment period closed on April 29, but the Agency reopened the comment period for an additional 15 days to provide an opportunity to gather additional public input to inform the Agency's development of final planning directives. The Forest Service received 17,449 responses to the proposed directives, consisting of letters, emails, Web-based submissions, and facsimiles. Of those, 370 were unique letters, and the remaining 17,079 responses were form letters. The responses were received from a wide variety of respondents from more than 40 states, and came from the public and non-governmental organizations as well as local governments and other State and Federal agencies.

Public comment on the proposed planning directives addressed a wide range of topics. Many people supported the proposed planning directives or favored stronger guidance in particular areas, while others opposed the proposed directives or recommended limitations or alternate approaches to Agency policies related to land management planning. The Forest Service considered all the comments in finalizing the directives. This section provides a summary of revisions, by chapter, made in response to public comment. A more detailed description of public comments and the Agency's responses can be found at *http://www.fs.usda.gov/planningrule.*

The following is a chapter-by-chapter overview of the comments provided about the directives and the Forest Service's response to those comments.

Zero Code

Many comments were received regarding the use of best available scientific information (BASI) and adaptive management. Some commenters felt there was a lack of clear direction on how to implement adaptive management, while other questions centered on the use of BASI. Questions about BASI included objections to the detailed process for its integration, questions about sources of scientific information, and questions about how the Responsible Official will determine BASI.

After considering these comments, the Forest Service clarified and modified the direction on BASI and adaptive management. The final directive simplifies the direction on considering the accuracy and reliability of information when making BASI determinations and clarifying sections on BASI documentation attributes. In addition, the direction on BASI and adaptive management was moved from Chapter 40 to the chapter on zero code since they are relevant to all chapters.

Chapter 10. Assessment. Some comments about the assessment chapter concerned recommendations for clarifying the purpose and scale of the assessment and minimizing problems with data gaps. Other comments concerned specific assessment topics, such as socio-economic conditions, ecosystem services, and multiple uses. After considering comments, the Agency revised Chapter 10 so that the guidance for assessments more clearly defined terms and scale, reduced redundancy within the directives, and

added sources of information. For example, the Agency clarified how to identify species of conservation concern and the use of natural range of variation in the assessment. In addition, the Agency clarified the guidance for assessing the major contributions of the plan area to social, cultural, and economic conditions from multiple uses, ecosystem services, infrastructure, and administrative operations of the plan area.

The Agency added a requirement for the Responsible Official to publish a notice in the **Federal Register** to announce the beginning of the assessment.

Chapter 20—Land Management Plan. Chapter 20 sets out the procedures for developing, amending, and revising land management plans under the 2012 Planning Rule. Comments on developing plans were extensive, and ranged from general observations about the process to specific comments about a variety of plan components and procedures. Comments covered topics such as direction on water resources management, fire management, and the role of recreation. For example, some of the recreational concerns were that recreation was not clearly addressed in the section that set out the matters to be considered during plan revision. Commenters also had concerns about requiring the inclusion of specific direction in plans, such as requiring plans to include project consistency guidelines.

After considering these comments, the Forest Service made many edits and clarifications. For example, the Agency clarified the direction on the need to change the plan, and the requirements for integrating plan components, such as desired conditions, standards, guidelines, and objectives. The Agency added the direction that the Responsible Official should complete the plan development or plan revision, from the public notice of the assessment to final plan approval, within 4 years. Other parts of Chapter 20 were rewritten or replaced; for example, the section on recreation guidance was revised to require application of the Recreation Opportunity Spectrum tool in parts of the plan and to more clearly define sustainable recreation.

The Agency also enhanced guidance on how to coordinate required National Environmental Policy Act (NEPA) procedures with the required planning procedures. The Agency expanded sections for species of conservation concern to give guidance on the responsibilities of the Regional Forester, including guidance on managing new information. The Agency clarified how the Responsible Official should design plan components for ecological integrity and the influence of climate change. The Agency also added a section to clarify how land management plans give direction for designated areas.

Chapter 30—Monitoring. In general, comments on Chapter 30 emphasized the need to acknowledge and use consistent monitoring data generated throughout the plan's lifecycle. Questions were also raised about ensuring adequate funding to help ensure the success of monitoring programs. Some commenters suggested specific changes to information considered when identifying monitoring indicators. In response to these comments, edits were made throughout the chapter to improve clarity. The Agency added direction about questions and indicators for social, cultural, and economic sustainability to the guidance for monitoring progress toward meeting desired conditions and objectives

Chapter 40—Public Participation. Comments on Chapter 40 regarding adaptive management and best available science were reflected in revisions to the zero code.

With regard to public participation, some commenters sought an expanded discussion of how the Forest Service is to provide opportunities for public involvement in the planning process. After considering these comments, and to improve clarity, the content of Chapter 40 was revised to focus on public participation only. Changes to Chapter 40 included providing guidance on working with other public agencies and tribes during the land management planning process. This guidance includes a section on the participation of and consultation with federally recognized Indian tribes, Alaska Native Corporations, other Federal agencies, and State and local governments. Also, Chapter 40 provides guidance on coordinating the public engagement processes required by both the 2012 Planning Rule and NEPA. The additional guidance identifies the requirements for formal notices and other forms of outreach to the public.

Chapter 50—Objection Process. There were few comments on the objection process, and the majority of these asked for clarifications regarding various parts of the objection process. In response, the Agency added definitions and clarifications throughout the chapter, including clarification of who is eligible to object or participate as an interested person. Some commenters wanted to see the entire objection process eliminated. The Agency responded that the objection process could not be eliminated, as the 2012 Planning Rule mandates it. Revisions to Chapter 50 were also made to clarify the Reviewing Officer's discretion in managing resolution meetings.

Chapter 60—Forest Vegetation Resource Planning. Comments focused on various aspects of the guidance on National Forest Management Act (NFMA) requirements and 2012 Planning Rule requirements. This included aspects related to identifying lands suitable for timber production, and plan components needed to comply with NFMA requirements for timber harvest. The Forest Service was also asked to clarify various terms and definitions in the chapter, including the calculation of long-term sustained yield capacity and other measures of timber volume. After considering comments, the Forest Service made changes to the chapter to improve clarity by revising narratives, adding displays, and adopting a new set of terminology and definitions for measures of timber volume.

Chapter 70—Wilderness Planning. A significant percentage of the comments received concerned Chapter 70, which describes the process during land management planning of inventorying, evaluating, and analyzing National Forest System lands for possible inclusion in the National Wilderness Preservation System. Many respondents sent a form letter which was generally supportive of the broadly inclusive nature of the procedure outlined for inventorying and evaluating potential wilderness lands. The letter also urged the Forest Service to go further in the preservation of potential wilderness areas by prohibiting all motorized uses from potential wilderness areas, pending designation decisions. Other respondents sent a form letter expressing views highly critical of the new inventory and evaluation process, and objecting to what was perceived as the creation of de facto wilderness without Congressional approval. Respondents also commented that identifying broad areas of Forest lands as potential wilderness and managing them for wilderness qualities would effectively eliminate motorized recreation uses across large sections of Forests.

Additional concerns focused on the inventory process, seeking clarification on how inventories would be conducted, whether existing inventory data could be included, and the criteria to be used for wilderness inventories. Concerns also focused on the management of recommended wilderness areas, including whether or not recommended areas should be managed as wilderness.

After considering comments, the Forest Service edited Chapter 70 to clarify the inventory process including the use of existing information, previous decisions, travel management, travel analysis, public engagement, and government to government engagement. In addition, the Agency retained the approach included in the proposed directives to keep the inventory process broad, inclusive, and transparent to the public, but the final directives eliminate from the inventory areas that contain certain types of roads. Finally, the chapter was edited to clarify the range of management actions available to the Responsible Official once a decision is made to recommend an area for inclusion in the Wilderness Preservation System.

Chapter 80—Wild and Scenic River Planning. Some commenters were concerned about the process for identifying and evaluating potential Wild and Scenic Rivers during plan revisions. Most of these concerns focused on the inventory process, and commenters sought clarification on elements such as river segment eligibility. After considering comments, the Agency reorganized the chapter and made several clarifications, including clarifying the process for identifying river eligibility. Chapter 80 was also revised to clarify interim management of study rivers.

FACA Committee Recommendations

The FACA Committee provided recommendations regarding the proposed directives to the Agency for consideration. The Agency substantially incorporated the FACA Committee's recommendations into the final directives. A detailed description of the Agency's response to each recommendation from the FACA Committee can be found at *http://www.fs.usda.gov/planningrule.*

The following is a chapter-by-chapter overview of the FACA Committee recommendations provided about the directives and the Agency's response.

Forest Service Manual—The final directives reflect the FACA Committee's recommendation to clarify intent for timing, objectives, policies, and Responsible Official obligations regarding planning.

Zero code—The FACA Committee recommended revision of definitions and inclusion of several new definitions, and the Agency both revised the definitions section and included additional language in other sections of the directives that support the definitions.

Chapter 10—Changes to the assessment's approach to social, cultural, and economic conditions were incorporated into the final directives, along with revisions recommended by the FACA Committee on ecological concepts, transparency, adaptive management, climate change, natural range of variation, recreation, and designation areas.

Chapter 20—Revisions related to the description of plan components and the integration of multiple planning needs into land management plans were incorporated into the final directives, along with revisions recommended by the FACA Committee on social and economic sustainability, ecosystem integrity, natural range of variation, and water resources.

Chapter 30—FACA Committee recommendations related to the monitoring program, including partnerships, were incorporated into the final directives.

Chapter 40—Revisions recommended by the FACA Committee related to notifications, outreach to underserved communities, and interaction with Tribes, States, and local governments were incorporated into the final directives.

Chapter 50—Revisions related to participation of interested persons in the objection process and provisions related to transparency were recommended by the FACA Committee and incorporated into the final directives.

Chapter 60—Revisions related to monitoring timber management were incorporated into the final directives, based on recommendations by the FACA Committee.

Chapter 70—The FACA Committee recommended provisions to clarify public participation opportunities, overall transparency in the wilderness evaluation process, the inventory process and evaluation; these approaches were included in the final directives.

Regulatory Certifications

Regulatory Impact

This notice has been reviewed under USDA procedures and Executive Order (E.O.) 12866, Regulatory Planning and Review. The Office of Management and Budget (OMB) has reviewed this notice and has determined that it is a significant action because of the high level of public interest in the Forest Service's land management planning activities, which will be guided by the directives.

The final directives would not have an annual effect of $100 million or more on the economy nor adversely affect productivity, competition, jobs, the environment, public health or safety, nor State or local governments. The final directives would not interfere with an action taken or planned by another agency nor raise new legal or policy issues. Finally, the final directives would not alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients of such programs. Moreover, the final directives have been considered in light of E.O. 13272 regarding proper consideration of small entities and the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), which amended the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). No direct or indirect financial impact on small businesses or other entities has been identified. Therefore, it is hereby certified that these final directives will not have a significant economic impact on a substantial number of small entities as defined by the act.

Environmental Impact

These final directives provide the detailed direction to Agency employees necessary to carry out the final 2012 Planning Rule codified at 36 CFR part 219 governing land management planning. Forest Service NEPA procedures exclude from documentation in an environmental assessment or impact statement ''rules, regulations, or policies to establish servicewide administrative procedures, program processes, or instructions.'' 36 CFR 220.6(d)(2). The Agency's conclusion is that these final directives fall within this category of actions and that no extraordinary circumstances exist as currently defined that require preparation of an environmental assessment or an environmental impact statement.

No Takings Implications

These final directives have been analyzed in accordance with the principles and criteria contained in E.O. 12360, Governmental Actions and Protected Property Rights, and it has been determined that they would not pose the risk of a taking of private property as they are limited to the establishment of administrative procedures.

Energy Effects

These final directives have been analyzed under E.O. 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. It has been determined that they do not constitute a significant energy action as defined in the Executive Order.

Civil Justice Reform

These proposed directives have been reviewed under E.O. 12988, Civil Justice Reform. These final directives will guide the work of Forest Service employees and are not intended to preempt any State and local laws and regulations that might be in conflict or that would impede full implementation of these directives. The directives would not retroactively affect existing permits, contracts, or other instruments authorizing the occupancy and use of NFS lands and would not require the institution of administrative proceedings before parties may file suit in court challenging their provisions

Unfunded Mandates

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), which the President signed into law on March 22, 1995, the effects of these final directives on State, local, and Tribal governments, and on the private sector have been assessed and do not compel the expenditure of $100 million or more by any State, local, or Tribal government, or anyone in the private sector. Therefore, a statement under section 202 of the act is not required.

Federalism

The Agency has considered these final directives under the requirements of E.O. 13132, Federalism. The Agency has made an assessment that they conform with the federalism principles set out in this Executive Order; would not impose any significant compliance costs on the States; and would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Moreover, these final directives address the land management planning process on National Forests, Grasslands or other units of the NFS, and provide direction regarding the Agency's interaction with State, local and Tribal governments, to ensure consideration of concerns, impacts and opportunities.

Consultation and Coordination With Indian Tribal Governments

The Forest Service conducted government-to-government consultation on the planning directives. The Forest Service considers Tribal consultation as an ongoing, iterative process that encompasses development of the proposed directives through the issuance of final directives. The Agency contacted all federally recognized Tribes and Alaska Native Corporations by mail to formally initiate consultation on the proposed directives and asked for comments within 120 days. Hopi Nation Tribal leaders requested consultation and met with the Deputy Regional Forester of Region 3 on June 6, 2013, to discuss the planning directives. Written comments were received from tribes in California and Oregon, the California Indian Water Commission and an Alaska native corporation. Comments were focused on coordination and consultation with tribes and Alaska native corporations.

Controlling Paperwork Burdens on the Public

These final directives do not contain any record keeping or reporting requirements or other information collection requirements as defined in 5 CFR part 1320 and, therefore, impose no paperwork burden on the public. While most land management planning activities do not involve information collection as defined in 5 CFR part 1320, the Agency recognizes that a wide variety of strategies may be used pursuant to the 2012 Planning Rule to engage the public in the planning process. To ensure compliance with the review provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and implementing regulations at 5 CFR part 1320 in a timely manner to support land management planning, the Agency has developed a generic information collection which is currently under review by OMB and has been assigned control number 0596–0234. In addition, Chapter 50 of these final directives contains information collection requirements as defined in 5 CFR part 1320. The information collection requirements for the objection process to the land management plans has been approved by OMB and assigned control number 0596–0158.

Dated: January 30, 2015.

Robert Bonnie,

Under Secretary, NRE.

[FR Doc. 2015–02369 Filed 2–5–15; 8:45 am]

BILLING CODE 3411–15–P

ARCTIC RESEARCH COMMISSION

103rd Commission Meeting

January 29, 2015.

Notice is hereby given that the U.S. Arctic Research Commission will hold its 103rd meeting in Washington, District of Columbia, on March 4–5, 2015. The business sessions, open to the public, will convene at 9:00 a.m.

The Agenda items include:

(1) Call to order and approval of the agenda

(2) Approval of the minutes from the 102nd meeting

(3) Commissioners and staff reports

(4) Discussion and presentations concerning Arctic research activities.

The focus of the meeting will be on Arctic policy issues, and on programs and research projects affecting the Arctic.

If you plan to attend this meeting, please notify us via the contact information below. Any person planning to attend who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission of those needs in advance of the meeting.

Contact person for further information: John Farrell, Executive Director, U.S. Arctic Research Commission, 703–525–0111 or TDD 703–306–0090.

Kathy Farrow,

Communications Specialist.

[FR Doc. 2015–02346 Filed 2–5–15; 8:45 am]

BILLING CODE 7555–01–P

ARCTIC RESEARCH COMMISSION

103rd Commission Meeting

January 29, 2015.

Notice is hereby given that the U.S. Arctic Research Commission will hold its 103rd meeting in Washington, District of Columbia, on March 4–5, 2015. The business sessions, open to the public, will convene at 9:00 a.m.

The Agenda items include:

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Contact person for further information: John Farrell, Executive Director, U.S. Arctic Research

Commission, 703–525–0111 or TDD 703–306–0090.

Kathy Farrow,

Communications Specialist.

[FR Doc. 2015–02347 Filed 2–5–15; 8:45 am]

BILLING CODE 7555–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Missouri Advisory Committee for a Meeting To Hear Testimony Regarding Police and Community Interaction in Missouri

AGENCY: U.S. Commission on Civil Rights.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Missouri Advisory Committee (Committee) will hold a meeting on Monday, February 23, 2015, for the purpose of hearing presenters testify about the civil rights issues regarding police and community interactions in Missouri.

Members of the public are invited and welcomed to make statements into the record during two open forum periods. The first open forum will be held from 12:00 p.m. until 12:30 p.m. The second open forum will be held from 4:15 p.m. until 5:15 p.m. Members of the public are also entitled to submit written comments; the comments must be received in the regional office by March 27, 2015. Written comments may be mailed to the Midwestern Regional Office, U.S. Commission on Civil Rights, 55 W. Monroe St., Suite 410, Chicago, IL 60615. They may also be faxed to the Commission at (312) 353–8311, or emailed to Melissa Wojnaroski, Civil Rights Analyst, at *mwojnaroski@usccr.gov.* Persons who desire additional information may contact the Midwestern Regional Office at (312) 353–8311.

Closed-captioning of the meeting will be provided. If other persons who will attend the meeting require other accommodations, please contact Carolyn Allen at *callen@usccr.gov* at the Midwestern Regional Office at least ten (10) working days before the scheduled date of the meeting.

Records generated from this meeting may be inspected and reproduced at the Midwestern Regional Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Missouri Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's Web site, *http://www.usccr.gov*, or may contact the Midwestern Regional Office at the above email or street address.

Agenda

8:00–8:15 a.m. Introduction and Opening Remarks
S. David Mitchell, Missouri Advisory Committee Chairman
Martin Castro, U.S. Commission on Civil Rights Chairman

8:15–9:30 a.m. *Panel 1: Academic Experts*
- Dr. Richard Rosenfeld, UMSL
- Dr. Justin Hansford, St. Louis University
- Dr. Stefan Bradley, St. Louis University
- Dr. Marva Robinson, Association of Black Psychologists

9:35–10:30 a.m. *Panel 2: Community Representatives I*
- Ms. Pamela Meanes, National Bar Association
- Mr. Adolphus Pruitt, NAACP St. Louis
- Mr. Marius Johnson-Malone, Better Together

10:30–10:40 a.m. Break

10:40–11:55 a.m. *Panel 3: Community Representatives II*
- Rev. Traci Blackmon, Christ the King Church
- Mr. James Clark, Better Family Life
- Ms. Charli Cooksey, Young Citizens Council of St. Louis
- Ms. Leticia Seitz, Latinos en Axion St. Louis
- Mr. David Nehrt-Flores, MO Immigrant and Refugee Advocates

12:00–12:30 p.m. Open Forum I

12:30–1:30 p.m. Lunch Break

1:30–2:45 p.m. *Panel 5: Law Enforcement Representatives*
- Chief Jon Belmar, St. Louis County
- Chief Frank McCall, Berkeley Police
- Chief Thomas Jackson, Ferguson Police
- Representative from the MO Highway Patrol
- Representative from St. Louis Metropolitan Police

2:50–4:05 p.m. *Panel 4: Government Representatives*
- Dr. Daniel Isom, MO Department of Public Safety
- Ms. Tishaura Jones, St. Louis City Treasurer and Young Citizen's Council of St. Louis
- Dr. Ellen Scrivner, The Police Foundation
- Representative from U.S. Department of Justice COPS program (tentative)
- Representative from the Office of the Governor of Missouri (tentative)

4:05–4:15 p.m. Break

4:15–5:15 p.m. Open Forum II

5:15–5:30 p.m. Closing Remarks
S. David Mitchell, Missouri Advisory Committee Chair

5:30 p.m. Adjournment

DATES: The meeting will be held on Monday, February 23, 2015, at 8:00 a.m.

ADDRESSES: The meeting will be held at the University of Missouri—St. Louis, J.C. Penney Conference Center, One University Boulevard, St. Louis, MO 63121.

Dated: February 3, 2015.

David Mussatt,

Chief, Regional Programs Unit.

[FR Doc. 2015–02400 Filed 2–5–15; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Office of the Secretary

Estimates of the Voting Age Population for 2014

AGENCY: Office of the Secretary, Commerce.

ACTION: General notice announcing population estimates.

SUMMARY: This notice announces the voting age population estimates as of July 1, 2014, for each state and the District of Columbia. We are providing this notice in accordance with the 1976 amendment to the Federal Election Campaign Act, Title 2, United States Code, Section 441a(e).

FOR FURTHER INFORMATION CONTACT: Karen Humes, Chief, Population Division, U.S. Census Bureau, Room HQ–5H174, Washington, DC 20233, at 301–763–2071.

SUPPLEMENTARY INFORMATION: Under the requirements of the 1976 amendment to the Federal Election Campaign Act, Title 2, United States Code, Section 441a(e), I hereby give notice that the estimates of the voting age population for July 1, 2014, for each state and the District of Columbia are as shown in the following table.

ESTIMATES OF THE POPULATION OF VOTING AGE FOR EACH STATE AND THE DISTRICT OF COLUMBIA: JULY 1, 2014

Area	Population 18 and over
United States	245,273,438
Alabama	3,741,806
Alaska	550,189

ESTIMATES OF THE POPULATION OF VOTING AGE FOR EACH STATE AND THE DISTRICT OF COLUMBIA: JULY 1, 2014—Continued

Area	Population 18 and over
Arizona	5,109,792
Arkansas	2,259,350
California	29,649,348
Colorado	4,109,494
Connecticut	2,821,247
Delaware	731,367
District of Columbia	543,588
Florida	15,839,713
Georgia	7,604,061
Hawaii	1,111,117
Idaho	1,203,384
Illinois	9,892,106
Indiana	5,014,928
Iowa	2,381,172
Kansas	2,181,355
Kentucky	3,400,843
Louisiana	3,536,183
Maine	1,071,112
Maryland	4,625,863
Massachusetts	5,354,940
Michigan	7,686,087
Minnesota	4,175,347
Mississippi	2,262,810
Missouri	4,670,966
Montana	798,555
Nebraska	1,414,894
Nevada	2,175,874
New Hampshire	1,059,672
New Jersey	6,926,094
New Mexico	1,583,623
New York	15,517,321
North Carolina	7,656,415
North Dakota	570,955
Ohio	8,955,859
Oklahoma	2,925,352
Oregon	3,112,217
Pennsylvania	10,086,316
Rhode Island	842,321
South Carolina	3,747,734
South Dakota	642,768
Tennessee	5,054,826
Texas	19,841,344
Utah	2,038,787
Vermont	504,976
Virginia	6,457,174
Washington	5,458,809
West Virginia	1,470,179
Wisconsin	4,457,375
Wyoming	445,830

Source: U.S. Census Bureau, Population Division, Vintage 2014 Population Estimates.

I have certified these estimates for the Federal Election Commission.

Dated: January 29, 2015.

Penny Pritzker,

Secretary of Commerce.

[FR Doc. 2015–02473 Filed 2–5–15; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–351–841, A–520–803, A–570–924]

Polyethylene Terephthalate Film, Sheet, and Strip From Brazil, the People's Republic of China, and the United Arab Emirates: Continuation and Revocation of Antidumping Duty Orders

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

SUMMARY: As a result of the determinations by the Department of Commerce (the Department) and the International Trade Commission (the ITC) in their five year (sunset) reviews that revocation of the antidumping duty (AD) order on polyethylene terephthalate film, sheet, and strip (PET Film) from the People's Republic of China (PRC) and the United Arab Emirates (UAE) would likely lead to a continuation or recurrence of dumping and material injury to an industry in the United States, the Department is publishing a notice of continuation for these antidumping duty orders. As a result of the ITC's determination that revocation of the AD order on PET Film from Brazil is not likely to lead to the continuation or recurrence of material injury to an industry in the United States, the Department is revoking this AD order.

DATES: *Effective Date:* AD Brazil Revocation: November 10, 2013; AD PRC and UAE Continuation: February 6, 2015.

FOR FURTHER INFORMATION CONTACT: Jacqueline Arrowsmith, Office VII, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–5255.

SUPPLEMENTARY INFORMATION:

Background

On October 1, 2013, the Department initiated the sunset reviews on the AD orders on PET film from Brazil, the PRC, and the UAE pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[1] As a result of the reviews, the Department found that revocation of the AD orders on PET Film from Brazil, the PRC, and the UAE would likely to lead to continuation or recurrence of dumping, and notified the ITC of the margins of dumping likely to prevail should the order be revoked.[2]

On January 23, 2015, the ITC published its determination, pursuant to section 751(c)(1) and section 752(a) of the Act, that revocation of the AD order on PET Film the PRC and the UAE would be likely to lead to the continuation or recurrence of material injury within a reasonably foreseeable time, but that revocation of the AD order on PET Film from Brazil would not be likely to do so.[3]

Scope of the Order

The products covered by this order are all gauges of raw, pre-treated, or primed PET film, whether extruded or co-extruded. Excluded are metallized films and other finished films that have had at least one of their surfaces modified by the application of a performance-enhancing resinous or inorganic layer more than 0.00001 inches thick. Also excluded is roller transport cleaning film which has at least one of its surfaces modified by application of 0.5 micrometers of SBR latex. Tracing and drafting film is also excluded. PET film is classifiable under subheading 3920.62.0090 of the Harmonized Tariff Schedule of the United States (HTSUS). While HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of the order is dispositive.

Scope Determinations on PET Film From the PRC

Since these orders were published, there was one scope determination for PET film from the PRC, with notice of the decision published on July 1, 2010. In this determination, requested by Coated Fabrics Company, the Department determined that Amorphous PET (''APET''), Glycol-modified PET (''PETG''), and coextruded APET with PETG on its outer surfaces (''GAG Sheet''), are within the scope of the antidumping duty order of PET Film from the PRC.[4]

[1] *See Initiation of Five year (''Sunset'') Review,* 78 FR 60253 (October 1, 2013).

[2] *See Polyethylene Terephthalate Film, Sheet and Strip From Brazil, the People's Republic of China, and the United Arab Emirates: Final Results of the Expedited Sunset Reviews of the Antidumping Duty Orders,* 79 FR 10095, (February 24, 2014).

[3] *See Polyethylene Terephthalate Film, Sheet, and Strip from Brazil, China, and the United Arab Emirates,* 80 FR 3623 (January 23, 2015). On the same day, the ITC also determined that revocation of the antidumping orders of PET Film from the PRC and the UAE would lead to a continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

[4] *See* Notice of Scope Rulings, 75 FR 38081 (July 1, 2010).

Continuation of the Order on PET Film From the PRC and the UAE

As a result of the determinations by the Department and the ITC that revocation of these antidumping duty orders would likely lead to a continuation or recurrence of dumping and material injury to an industry in the United States, pursuant to sections 751(c) and 751(d)(2) of the Act, the Department hereby orders the continuation of the AD order on PET Film from the PRC and the UAE. U.S. Customs and Border Protection (CBP) will continue to collect antidumping duty cash deposits at the rates in effect at the time of entry for all imports of subject merchandise.

The effective date of the continuation of this order will be the date of publication in the **Federal Register** of this notice of continuation. Pursuant to section 751(c)(2) of the Act, the Department intends to initiate the next five-year review of this order not later than 30 days prior to the fifth anniversary of the effective date of continuation.

Revocation of the Order on PET Film From Brazil

As a result of the determination by the ITC that revocation of this AD order is not likely to lead to the continuation or recurrence of material injury to an industry in the United States, the Department is revoking the AD order on PET Film from Brazil. Pursuant to section 751(d)(2) of the Act and 19 CFR 351.222(i)(2)(i), the effective date of revocation is November 10, 2013 (*i.e.,* the fifth anniversary of the date of publication in the **Federal Register** of the order [5]).

Cash Deposit and Assessment of Duties on PET Film From Brazil

The Department will notify U.S. Customs and Border Protection (CBP), 15 days after the publication of this notice, to terminate the suspension of liquidation and to discontinue the collection of cash deposits on entries of PET Film from Brazil, entered or withdrawn from warehouse, on or after November 10, 2013. The Department will further instruct CBP to refund with interest all cash deposits on entries made on or after November 10, 2013. Entries of subject merchandise prior to the effective date of revocation will continue to be subject to suspension of liquidation and AD deposit requirements and assessments. The Department will complete any pending or requested administrative reviews of the order on PET Film from Brazil covering entries prior to November 10, 2013.

Administrative Protective Order

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return/destruction or conversion to judicial protective order of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Failure to comply is a violation of the APO which, may be subject to sanctions.

This five-year (sunset) review and notice are in accordance with sections 751(c) and 751(d)(2), and 777(i) of the Act, and 19 CFR 351.218(f)(4).

Dated: January 30, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2015–02456 Filed 2–5–15; 8:45 am]

BILLING CODE 3510–DS–P

[5] *See Polyethylene Terephthalate Film, Sheet, and Strip From Brazil, the People's Republic of China and the United Arab Emirates: Antidumping Duty Orders and Amended Final Determination of Sales at Less Than Fair Value for United Arab Emirates,* 73 FR 66595 (November 10, 2008).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–890]

Wooden Bedroom Furniture From the People's Republic of China: Preliminary Results of Changed Circumstances Review, and Intent To Revoke Antidumping Duty Order in Part

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

SUMMARY: On June 2, 2014, the Department of Commerce (the ''Department'') received a request for revocation, in part, of the antidumping duty (''AD'') order on wooden bedroom furniture from the People's Republic of China (''PRC'') [1] with respect to certain shoe cabinets. We preliminarily determine that the producers accounting for substantially all of the production of the domestic like product to which the *Order* pertains lack interest in the relief provided by the *Order* with respect to certain shoe cabinets described below. Accordingly, we intend to revoke, in part, the *Order* as to imports of certain shoe cabinets. The Department invites interested parties to comment on these preliminary results.

DATES: Effective Date: February 6, 2015.

FOR FURTHER INFORMATION CONTACT: Thomas Martin or Howard Smith, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–3936 or (202) 482–5193, respectively.

Background

On January 4, 2005, the Department published the *Order* in the **Federal Register**. On June 2, 2014, the Department received a request on behalf of Elements International Group LLC (''Elements'') for a changed circumstances review to revoke, in part, the *Order* with respect to certain shoe cabinets.[2] In its request, Elements stated that the American Furniture Manufacturing Committee for Legal Trade and Vaughan-Basset Furniture Company, Inc. (''Petitioners'') discussed the scope exclusion described below and are in agreement with the revocation, in part. On June 3, 2014, the Department received a letter from the Petitioners in which they stated they were in agreement with the proposed scope exclusion language in Elements' June 2, 2014, changed circumstances review request.[3]

On July 15, 2014, we published the *Initiation Notice* in the **Federal Register**.[4] Because the statement submitted by Petitioners in support of Elements' Request did not indicate whether Petitioners account for substantially all of the domestic wooden bedroom furniture production, in the *Initiation Notice,* we invited interested parties to submit comments concerning industry support, as well as comments and/or factual information regarding the changed circumstances review.[5] We received no comments concerning industry support.

Scope of the Order

The product covered by the order is wooden bedroom furniture. Wooden

[1] See Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Wooden Bedroom Furniture From the People's Republic of China, 70 FR 329 (January 4, 2005) (''Order'').

[2] *See* Submission from Elements, ''Wooden Bedroom Furniture From the People's Republic of China: Request for a Changed Circumstance Review Regarding Shoe Cabinets,'' dated June 2, 2014 (''Elements' Request'').

[3] *See* Submission from Petitioners, ''Wooden Bedroom Furniture From The People's Republic of China/Petitioners' Response to Elements' Letter of June 2, 2014,'' dated June 3, 2014.

[4] *See* Wooden Bedroom Furniture From the People's Republic of China: Notice of Initiation of Changed Circumstances Review, and Consideration of Revocation of the Antidumping Duty Order in Part, 79 FR 41260 (July 15, 2014) (''*Initiation Notice''*)

[5] *Id.* at 41262.

bedroom furniture is generally, but not exclusively, designed, manufactured, and offered for sale in coordinated groups, or bedrooms, in which all of the individual pieces are of approximately the same style and approximately the same material and/or finish. The subject merchandise is made substantially of wood products, including both solid wood and also engineered wood products made from wood particles, fibers, or other wooden materials such as plywood, strand board, particle board, and fiberboard, with or without wood veneers, wood overlays, or laminates, with or without non-wood components or trim such as metal, marble, leather, glass, plastic, or other resins, and whether or not assembled, completed, or finished.

The subject merchandise includes the following items: (1) Wooden beds such as loft beds, bunk beds, and other beds; (2) wooden headboards for beds (whether stand-alone or attached to side rails), wooden footboards for beds, wooden side rails for beds, and wooden canopies for beds; (3) night tables, night stands, dressers, commodes, bureaus, mule chests, gentlemen's chests, bachelor's chests, lingerie chests, wardrobes, vanities, chessers, chifforobes, and wardrobe-type cabinets; (4) dressers with framed glass mirrors that are attached to, incorporated in, sit on, or hang over the dresser; (5) chests-on-chests,[6] highboys,[7] lowboys,[8] chests of drawers,[9] chests,[10] door chests,[11] chiffoniers,[12] hutches,[13] and armoires;[14] (6) desks, computer stands, filing cabinets, book cases, or writing tables that are attached to or incorporated in the subject merchandise; and (7) other bedroom furniture consistent with the above list.

The scope of the order excludes the following items: (1) Seats, chairs, benches, couches, sofas, sofa beds, stools, and other seating furniture; (2) mattresses, mattress supports (including box springs), infant cribs, water beds, and futon frames; (3) office furniture, such as desks, stand-up desks, computer cabinets, filing cabinets, credenzas, and bookcases; (4) dining room or kitchen furniture such as dining tables, chairs, servers, sideboards, buffets, corner cabinets, china cabinets, and china hutches; (5) other non-bedroom furniture, such as television cabinets, cocktail tables, end tables, occasional tables, wall systems, book cases, and entertainment systems; (6) bedroom furniture made primarily of wicker, cane, osier, bamboo or rattan; (7) side rails for beds made of metal if sold separately from the headboard and footboard; (8) bedroom furniture in which bentwood parts predominate;[15] (9) jewelry armories;[16] (10) cheval mirrors;[17] (11) certain metal parts;[18] (12) mirrors that do not attach to, incorporate in, sit on, or hang over a dresser if they are not designed and marketed to be sold in conjunction with a dresser as part of a dresser-mirror set; (13) upholstered beds[19]; and (14) toy boxes.[20]

Imports of subject merchandise are classified under subheadings 9403.50.9042 and 9403.50.9045 of the

[6] A chest-on-chest is typically a tall chest-of-drawers in two or more sections (or appearing to be in two or more sections), with one or two sections mounted (or appearing to be mounted) on a slightly larger chest; also known as a tallboy.

[7] A highboy is typically a tall chest of drawers usually composed of a base and a top section with drawers, and supported on four legs or a small chest (often 15 inches or more in height).

[8] A lowboy is typically a short chest of drawers, not more than four feet high, normally set on short legs.

[9] A chest of drawers is typically a case containing drawers for storing clothing.

[10] A chest is typically a case piece taller than it is wide featuring a series of drawers and with or without one or more doors for storing clothing. The piece can either include drawers or be designed as a large box incorporating a lid.

[11] A door chest is typically a chest with hinged doors to store clothing, whether or not containing drawers. The piece may also include shelves for televisions and other entertainment electronics.

[12] A chiffonier is typically a tall and narrow chest of drawers normally used for storing undergarments and lingerie, often with mirror(s) attached.

[13] A hutch is typically an open case of furniture with shelves that typically sits on another piece of furniture and provides storage for clothes.

[14] An armoire is typically a tall cabinet or wardrobe (typically 50 inches or taller), with doors, and with one or more drawers (either exterior below or above the doors or interior behind the doors), shelves, and/or garment rods or other apparatus for storing clothes. Bedroom armoires may also be used to hold television receivers and/or other audio-visual entertainment systems.

[15] As used herein, bentwood means solid wood made pliable. Bentwood is wood that is brought to a curved shape by bending it while made pliable with moist heat or other agency and then set by cooling or drying. *See* CBP's Headquarters Ruling Letter 043859, dated May 17, 1976.

[16] Any armoire, cabinet or other accent item for the purpose of storing jewelry, not to exceed 24 inches in width, 18 inches in depth, and 49 inches in height, including a minimum of 5 lined drawers lined with felt or felt-like material, at least one side door (whether or not the door is lined with felt or felt-like material), with necklace hangers, and a flip-top lid with inset mirror. *See* Issues and Decision Memorandum from Laurel LaCivita to Laurie Parkhill, Office Director, concerning ''Jewelry Armoires and Cheval Mirrors in the Antidumping Duty Investigation of Wooden Bedroom Furniture from the People's Republic of China,'' dated August 31, 2004. *See also Wooden Bedroom Furniture From the People's Republic of China: Final Changed Circumstances Review, and Determination To Revoke Order in Part,* 71 FR 38621 (July 7, 2006).

[17] Cheval mirrors are any framed, tiltable mirror with a height in excess of 50 inches that is mounted on a floor-standing, hinged base. Additionally, the scope of the order excludes combination cheval mirror/jewelry cabinets. The excluded merchandise is an integrated piece consisting of a cheval mirror, *i.e.,* a framed tiltable mirror with a height in excess of 50 inches, mounted on a floor-standing, hinged base, the cheval mirror serving as a door to a cabinet back that is integral to the structure of the mirror and which constitutes a jewelry cabinet line with fabric, having necklace and bracelet hooks, mountings for rings and shelves, with or without a working lock and key to secure the contents of the jewelry cabinet back to the cheval mirror, and no drawers anywhere on the integrated piece. The fully assembled piece must be at least 50 inches in height, 14.5 inches in width, and 3 inches in depth. *See Wooden Bedroom Furniture From the People's Republic of China: Final Changed Circumstances Review and Determination To Revoke Order in Part,* 72 FR 948 (January 9, 2007).

[18] Metal furniture parts and unfinished furniture parts made of wood products (as defined above) that are not otherwise specifically named in this scope (*i.e.,* wooden headboards for beds, wooden footboards for beds, wooden side rails for beds, and wooden canopies for beds) and that do not possess the essential character of wooden bedroom furniture in an unassembled, incomplete, or unfinished form. Such parts are usually classified under HTSUS subheadings 9403.90.7005, 9403.90.7010, or 9403.90.7080.

[19] Upholstered beds that are completely upholstered, *i.e.,* containing filling material and completely covered in sewn genuine leather, synthetic leather, or natural or synthetic decorative fabric. To be excluded, the entire bed (headboards, footboards, and side rails) must be upholstered except for bed feet, which may be of wood, metal, or any other material and which are no more than nine inches in height from the floor. *See Wooden Bedroom Furniture From the People's Republic of China: Final Results of Changed Circumstances Review and Determination to Revoke Order in Part,* 72 FR 7013 (February 14, 2007).

[20] To be excluded the toy box must: (1) Be wider than it is tall; (2) have dimensions within 16 inches to 27 inches in height, 15 inches to 18 inches in depth, and 21 inches to 30 inches in width; (3) have a hinged lid that encompasses the entire top of the box; (4) not incorporate any doors or drawers; (5) have slow-closing safety hinges; (6) have air vents; (7) have no locking mechanism; and (8) comply with American Society for Testing and Materials (''ASTM'') standard F963–03. Toy boxes are boxes generally designed for the purpose of storing children's items such as toys, books, and playthings. *See Wooden Bedroom Furniture From the People's Republic of China: Final Results of Changed Circumstances Review and Determination to Revoke Order in Part,* 74 FR 8506 (February 25, 2009). Further, as determined in the scope ruling memorandum ''Wooden Bedroom Furniture from the People's Republic of China: Scope Ruling on a White Toy Box,'' dated July 6, 2009, the dimensional ranges used to identify the toy boxes that are excluded from the wooden bedroom furniture order apply to the box itself rather than the lid.

HTSUS as ''wooden . . . beds'' and under subheading 9403.50.9080 of the HTSUS as ''other . . . wooden furniture of a kind used in the bedroom.'' In addition, wooden headboards for beds, wooden footboards for beds, wooden side rails for beds, and wooden canopies for beds may also be entered under subheading 9403.50.9042 or 9403.50.9045 of the HTSUS as ''parts of wood.'' Subject merchandise may also be entered under subheadings 9403.50.9041, 9403.60.8081, or 9403.20.0018. Further, framed glass mirrors may be entered under subheading 7009.92.1000 or 7009.92.5000 of the HTSUS as ''glass mirrors . . . framed.'' The order covers all wooden bedroom furniture meeting the above description, regardless of tariff classification. Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

Scope of Changed Circumstances Review

The products covered by this changed circumstances review are shoe cabinets 31.5–33.5 inches wide by 15.5–17.5 inches deep by 34.5–36.5 inches high. They are designed strictly to store shoes, which are intended to be aligned in rows perpendicular to the wall along which the cabinet is positioned. Shoe cabinets do not have drawers, rods, or other indicia for the storage of clothing other than shoes. The cabinets are not designed, manufactured, or offered for sale in coordinated groups or sets and are made substantially of wood, have two to four shelves inside them, and are covered by doors. The doors often have blinds that are designed to allow air circulation and release of bad odors. The doors themselves may be made of wood or glass. The depth of the shelves does not exceed 14''. Each shoe cabinet has doors, adjustable shelving, and ventilation holes.

Preliminary Results of Changed Circumstances Review, and Intent To Revoke the Order, in Part

Pursuant to section 751(d)(1) of the Tariff Act of 1930, as amended (the ''Act''), and 19 CFR 351.222(g), the Department may revoke an AD order, in whole or in part, based on a review under section 751(b) of the Act (*i.e.,* a changed circumstances review). Section 751(b)(1) of the Act requires a changed circumstances review to be conducted upon receipt of a request which shows changed circumstances sufficient to warrant a review. Section 782(h)(2) of the Act gives the Department the authority to revoke an order if producers accounting for substantially all of the production of the domestic like product have expressed a lack of interest in the order. 19 CFR 351.222(g) provides that the Department will conduct a changed circumstances review under 19 CFR 351.216, and may revoke an order (in whole or in part), if it concludes that (i) producers accounting for substantially all of the production of the domestic like product to which the order pertains have expressed a lack of interest in the relief provided by the order, in whole or in part, or (ii) if other changed circumstances sufficient to warrant revocation exist. Both the Act and the Department's regulations require that ''substantially all'' domestic producers express a lack of interest in the order for the Department to revoke the order, in whole or in part.[21] The Department has interpreted ''substantially all'' to represent producers accounting for at least 85 percent of U.S. production of the domestic like product.[22]

On June 2, 2014, Elements requested that the Department expedite the changed circumstances review.[23] The Department's regulations do not specify a deadline for the issuance of preliminary results of a changed circumstances review, but provide that the Department will issue the final results of review within 270 days after the date on which the changed circumstances review is initiated, or within 45 days if all parties to the proceeding agree to the outcome of the review.[24] The Department did not issue a combined notice of initiation and preliminary results because, as discussed above, the statement provided by Petitioners and offered in support of Elements' Request does not indicate whether Petitioners account for substantially all domestic wooden bedroom furniture production.[25] Thus, the Department did not determine in the *Initiation Notice* that producers accounting for substantially all of the production of the domestic like product lacked interest in the continued application of the *Order* as to certain shoe cabinets. Further, the Department requested interested party comments on the issue of domestic industry support of a partial revocation.[26] Because the Department received no comments concerning a lack of industry support or opposing initiation of the changed circumstances review of the *Order,* the Department now preliminarily finds that producers accounting for substantially all of the production of the domestic like product lack interest in the relief afforded by the *Order* with respect to the certain shoe cabinets described in Elements' Request. We request comment from interested parties on that preliminary finding before issuing the final results of this review.[27]

As noted in the *Initiation Notice,* Elements requested the revocation of the *Order,* in part, and supported its request. In light of Elements' Request and the interested party comments received during the comment period, we preliminarily conclude that changed circumstances warrant revocation of the *Order,* in part, because the producers accounting for substantially all of the production of the domestic like product to which the *Order* pertains lack interest in the relief provided by the *Order* with respect to the certain shoe cabinets that are the subject of Elements' Request.

Accordingly, we are notifying the public of our intent to revoke the *Order,* in part, with respect to certain shoe cabinets. We intend to revoke the *Order* as to certain shoe cabinets by including the following language in the scope of the *Order:*

Also excluded from the scope are certain shoe cabinets 31.5–33.5 inches wide by 15.5–17.5 inches deep by 34.5–36.5 inches high. They are designed strictly to store shoes, which are intended to be aligned in rows perpendicular to the wall along which the cabinet is positioned. Shoe cabinets do not have drawers, rods, or other indicia for the storage of clothing other than shoes. The cabinets are not designed, manufactured, or offered for

[21] *See* Section 782(h) of the Act and 19 CFR 351.222(g).

[22] *See Honey From Argentina; Antidumping and Countervailing Duty Changed Circumstances Reviews; Preliminary Intent to Revoke Antidumping and Countervailing Duty Orders,* 77 FR 67790, 67791 (November 14, 2012), unchanged in *Honey From Argentina; Final Results of Antidumping and Countervailing Duty Changed Circumstances Reviews; Revocation of Antidumping and Countervailing Duty Orders,* 77 FR 77029 (December 31, 2012) (''*Honey from Argentina''*).

[23] *See* Elements' Request.

[24] 19 CFR 351.216(e).

[25] *See Initiation Notice.*

[26] *Id.*

[27] *See, e.g., Honey From Argentina; Aluminum Extrusions From the People's Republic of China: Preliminary Results of Changed Circumstances Reviews, and Intent To Revoke Antidumping and Countervailing Duty Orders in Part,* 78 FR 66895, 66897 (November 7, 2013), unchanged in *Aluminum Extrusions From the People's Republic of China: Final Results of Changed Circumstances Reviews; Partial Revocation of Antidumping and Countervailing Duty Orders,* 79 FR 634 (January 6, 2014); *Wooden Bedroom Furniture From the People's Republic of China: Preliminary Results of Changed Circumstances Review, and Intent To Revoke Antidumping Duty Order in Part,* 79 FR 48727, 48729 (August 18, 2014)), unchanged in *Wooden Bedroom Furniture From the People's Republic of China: Final Results of Changed Circumstances Review, and Revocation of Antidumping Duty Order, in Part,* 79 FR 64569 (October 30, 2014); *see also* 19 CFR 351.222(g)(1)(v).

sale in coordinated groups or sets and are made substantially of wood, have two to four shelves inside them, and are covered by doors. The doors often have blinds that are designed to allow air circulation and release of bad odors. The doors themselves may be made of wood or glass. The depth of the shelves does not exceed 14 inches. Each shoe cabinet has doors, adjustable shelving, and ventilation holes.

Public Comment

Interested parties are invited to comment on these preliminary results in accordance with 19 CFR 351.309(c)(1)(ii). If an interested party is of the view that certain arguments continue to be relevant to the Department's final results of this review, that interested party is required to file a case brief containing all such arguments, including any such arguments presented to the Department before the date of publication of the preliminary results, pursuant to 19 CFR 351.309(c)(2). Written comments may be submitted no later than 10 days after the date of publication of these preliminary results. Rebuttals to written comments, limited to issues raised in such comments, may be filed no later than seven days after the due date for comments. All comments are to be filed electronically using Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (''ACCESS'') which is available to registered users at *http://access.trade.gov* and in the Central Records Unit, Room 7046 of the main Department of Commerce building. Comments must also be served on interested parties.[28] An electronically filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Standard Time on the day it is due.[29]

The Department will issue the final results of this changed circumstances review, which will include its analysis of any written comments, no later than 270 days after the date on which this review was initiated.

If, in the final results of this review, the Department continues to determine that changed circumstances warrant the revocation of the *Order,* in part, we will instruct U.S. Customs and Border Protection (''CBP'') to liquidate without regard to antidumping duties, and to refund any estimated antidumping duties, on all unliquidated entries of the merchandise covered by the revocation that are not covered by the final results of an administrative review or automatic liquidation.

The current requirement for cash deposits of estimated antidumping duties on all entries of subject merchandise will continue unless until they are modified pursuant to the final results of this changed circumstances review.

These preliminary results of review and notice are in accordance with sections 751(b) and 777(i) of the Act and 19 CFR 351.221 and 19 CFR 351.222.

Dated: January 30, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2015–02448 Filed 2–5–15; 8:45 am]

BILLING CODE 3510–DS–P

[28] *See* 19 CFR 351.303(f).

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

DEPARTMENT OF COMMERCE

International Trade Administration

[A–520–804]

Certain Steel Nails From the United Arab Emirates: Preliminary Results of Antidumping Duty Administrative Review; 2013–2014

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 certain steel nails (nails) from the United Arab Emirates (UAE). The period of review (POR) is May 1, 2013, through April 30, 2014. The review covers two producers/exporters of the subject merchandise, Dubai Wire FZE (Dubai Wire) and Precision Fasteners, L.L.C. (Precision). We preliminarily find that Dubai Wire and Precision sold subject merchandise at less than normal value in the United States during the POR. Interested parties are invited to comment on these preliminary results.

DATES: *Effective Date:* February 6, 2015.

FOR FURTHER INFORMATION CONTACT: Dmitry Vladimirov 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) 482–0665, and (202) 482–0198, respectively.

SUPPLEMENTARY INFORMATION:

Scope of the Order

The merchandise subject to the *Order*[1] is nails from the UAE. The products are currently classifiable under the Harmonized Tariff Schedule of the United States (HTSUS) subheadings 7317.00.55, 7317.00.65, and 7317.00.75. Although the HTSUS numbers are provided for convenience and customs purposes, the written product description remains dispositive.[2]

Methodology

The Department has determined the weighted-average dumping margins for Dubai Wire and Precision based on facts otherwise available pursuant to section 776(a) of the Tariff Act of 1930, as amended (the Act). For a full description of the methodology underlying our conclusions, *see* 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).[3] 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. 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.* A list of the topics discussed in the Preliminary Decision Memorandum is attached as an Appendix to this notice.

Preliminary Results of Review

As a result of this review, we preliminarily determine that the following weighted-average dumping margins on steel nails from the UAE exist for the period May 1, 2013,

[1] *See Certain Steel Nails from the United Arab Emirates: Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order,* 77 FR 27421 (May 10, 2012) (*Order*).

[2] A full description of the scope of the *Order* is contained in the memorandum to Paul Piquado, Assistant Secretary for Enforcement and Compliance, from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, ''Certain Steel Nails from the United Arab Emirates: Decision Memorandum for Preliminary Results of Antidumping Duty Administrative Review; 2013–2014,'' dated concurrently with and hereby adopted by this notice (Preliminary Decision Memorandum).

[3] On November 24, 2014, Enforcement and Compliance changed the name of Enforcement and Compliance's AD and CVD Centralized Electronic Service System (IA ACCESS) to AD and CVD Centralized Electronic Service System (ACCESS). The Web site location was changed from *http://iaaccess.trade.gov* to *http://access.trade.gov.* The Final Rule changing the references to the Regulations can be found at 79 FR 69046 (November 20, 2014).

through April 30, 2014, at the following rates:

Company	Weighted-average dumping margin (percent)
Dubai Wire FZE	18.13
Precision Fasteners, L.L.C.	184.41

Public Comment

Pursuant to 19 CFR 351.309(c), interested parties may submit cases briefs not later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[4] 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.[5]

Pursuant to 19 CFR 351.310(c), 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, filed electronically *via* ACCESS. An electronically filed hearing request must be received successfully in its entirety by the Department's electronic records system, ACCESS, by 5 p.m. Eastern Time within 30 days after the date of publication of this notice. 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 and rebuttal briefs. The Department intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, unless extended, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

Assessment Rates

Upon issuance of the final results, the Department shall determine and U.S. Customs and Border Protection (CBP) shall assess antidumping duties on all appropriate entries covered by this review. If we continue to rely on facts available to establish Dubai Wire's and Precision's weighted-average dumping margins, we will instruct CBP to apply an *ad valorem* assessment rates of 18.13 percent and 184.41 percent, respectively, to all entries of subject merchandise during the POR which were produced and/or exported by Dubai Wire and Precision, respectively, in accordance with 19 CFR 351.212(b)(1).

We intend to issue instructions to CBP 15 days after publication of the final results of this review.

Cash Deposit Requirements

The following deposit requirements will be effective upon publication of the notice of final results of administrative review for all shipments of nails from the UAE entered, or withdrawn from warehouse, for consumption on or after the date of publication as provided by section 751(a)(2) of the Act: (1) The cash deposit rates for Dubai Wire and Precision will be the rates established in the final results of this administrative review; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation but the manufacturer is, the cash deposit rate will be the rate established for the manufacturer of the merchandise for the most recently completed segment of this proceeding; (4) the cash deposit rate for all other manufacturers or exporters will continue to be 4.30 percent.[6] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

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(h)(1).

Dated: February 2, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

Summary
Background
Scope of the Order
Facts Available
  Dubai Wire
  Precision
  Corroboration of Information Used as Facts Available
  (a) Dubai Wire
  (b) Precision
Duty Absorption
Recommendation

[FR Doc. 2015–02453 Filed 2–5–15; 8:45 am]

BILLING CODE 3510–DS–P

[4] *See* 19 CFR 351.309(d).

[5] *Id.; see also* 19 CFR 351.303 (for general filing requirements).

[6] The all-others rate established in the *Order.*

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Proposed Information Collection; Comment Request; Survey of the Need for the Improvement of the Infrared Reflectance Measurements Standards

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before April 7, 2015.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Leonard Hanssen, Sensor Science Division, NIST, 100 Bureau Dr., Stop 8442, Gaithersburg, MD 20899–8442, telephone: 301–975–2344, *hanssen@nist.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

NIST plans to survey members of the infrared optical properties measurement

community concerning their needs for standard reference materials, calibration services, workshops, courses, and other means for improvement of the quality of their measurement data and traceability to national standards.

II. Method of Collection

The survey will be delivered in electronic format as a WORD Form document. It will be sent as an email attachment to the survey participants. The participants will return the filled out forms to NIST, similarly via email.

III. Data

OMB Control Number: 0693–0065.

Form Number(s): None.

Type of Review: Extension without change of a Regular submission.

Affected Public: Businesses, academic institutions, and Federal government.

Estimated Number of Respondents: 30.

Estimated Time Per Response: 30 minutes.

Estimated Total Annual Burden Hours: 15.

Estimated Total Annual Cost to Public: $1,500.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, 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 OMB approval of this information collection; they also will become a matter of public record.

Dated: February 2, 2015.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2015–02340 Filed 2–5–15; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD756

Endangered and Threatened Species; Initiation of 5-Year Reviews for 32 Listed Species of Pacific Salmon and Steelhead, Puget Sound Rockfishes, and Eulachon

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

ACTION: Notice of initiation of 5-year reviews; request for information.

SUMMARY: We, NMFS, announce 5-year reviews of 32 species listed under the Endangered Species Act of 1973, as amended (ESA): 17 evolutionarily significant units (ESUs) of Pacific salmon (*Oncorhynchus spp.*); 11 distinct population segments (DPSs) of steelhead (*Oncorhynchus mykiss*); the Puget Sound/Georgia Basin DPSs of yelloweye rockfish (*Sebastes ruberrimus*), canary rockfish (*S. pinniger*), and bocaccio rockfish (*S. paucispinis*); and the southern DPS of eulachon (*Thaleichthys pacificus*). The purpose of these reviews is to ensure the accuracy of the listing classifications of these threatened and endangered species. The 5-year reviews will be based on the best scientific and commercial data available at the time of the reviews; therefore, we request submission of any such information on these ESUs and DPSs that has become available since the original listing determinations, or since the species' status was last updated. Based on the results of these 5-year reviews, we will make the requisite determinations under the ESA.

DATES: To allow us adequate time to conduct these reviews, we must receive your information no later than May 7, 2015. However, we will continue to accept new information about any listed species at any time.

ADDRESSES: You may submit information on this document, identified by NOAA–NMFS–2015–0021, by any of the following methods:

- Electronic Submissions: Submit all electronic public comments via the Federal e-Rulemaking Portal *www.regulations.gov.* To submit comments via the e-Rulemaking Portal, first click the ''submit a comment'' icon, then enter NOAA–NMFS–2015–0021 in the keyword search. Locate the document you wish to comment on from the resulting list and click on the ''Submit a Comment'' icon on the right of that line.
- Mail or hand-delivery: Dr. Scott Rumsey, NMFS, West Coast Region, 1201 NE Lloyd Blvd., Suite 1100, Portland, OR 97232.

Instructions: Comments must be submitted by one of the above methods to ensure that the comments are received, documented, and considered by NMFS. Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.) submitted voluntarily by the sender will be publicly accessible. Do not submit confidential business information, or otherwise sensitive or protected information. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Dr. Scott Rumsey at the above address, by phone at (503) 872–2791, or by email at *scott.rumsey@noaa.gov.*

SUPPLEMENTARY INFORMATION: Section 4(c)(2)(A) of the ESA requires that we conduct a review of listed species at least once every five years. On the basis of such reviews, we determine under section 4(c)(2)(B) whether a species should be delisted, or reclassified from endangered to threatened or from threatened to endangered.

We will undertake reviews for the following 17 Pacific salmon ESUs: (1) Sacramento River winter-run Chinook salmon, (2) Upper Columbia River spring-run Chinook salmon, (3) Snake River spring/summer-run Chinook salmon; (4) Central Valley spring-run Chinook salmon: (5) California Coastal Chinook salmon; (6) Puget Sound Chinook salmon; (7) Lower Columbia River Chinook salmon; (8) Upper Willamette River Chinook salmon; (9) Snake River fall-run Chinook salmon; (10) Hood Canal summer-run chum salmon; (11) Columbia River chum salmon; (12) Central California Coast coho salmon; (13) Southern Oregon/Northern California Coast coho salmon; (14) Lower Columbia River coho salmon; (15) Oregon Coast coho salmon; (16) Snake River sockeye salmon; and (17) Ozette Lake sockeye salmon. We will undertake reviews for the following 11 steelhead DPSs: (1) Southern California; (2) Upper Columbia River; (3) Middle Columbia River; (4) Snake River Basin; (5) Lower Columbia River; (6) Upper Willamette; (7) South-Central California Coast; (8) Central California

Coast; (9) Northern California; (10) California Central Valley; and (11) Puget Sound. We will also conduct reviews for 4 non-salmonid DPSs: the three Puget Sound/Georgia Basin rockfish DPSs of yelloweye rockfish, canary rockfish, and bocaccio rockfish; and the southern DPS of eulachon. Information about these 32 ESUs and DPSs can be found at our West Coast regional Web site: *http://www.westcoast.fisheries.noaa.gov.*

Our regulations for periodic reviews at 50 CFR 424.21 require that we publish a notice in the **Federal Register** announcing those species currently under active review. This notice announces our active reviews of the ESUs and DPSs listed above. Any change in listing classification would require a separate rulemaking process.

Determining if a Species Is Threatened or Endangered

Section 4(a)(1) of the ESA requires that we determine whether a species is endangered or threatened based on one or more of the five following factors: (1) The present or threatened destruction, modification, or curtailment of its habitat or range; (2) overutilization for commercial, recreational, scientific, or educational purposes; (3) disease or predation; (4) the inadequacy of existing regulatory mechanisms; or (5) other natural or manmade factors affecting its continued existence. Section 4(b) also requires that our determination be made on the basis of the best scientific and commercial data available after taking into account those efforts, if any, being made to protect such species.

Application of the ESU and DPS Policies

NMFS is responsible for determining whether species, subspecies, or DPSs of marine and anadromous species are threatened or endangered under the ESA. For Pacific salmon, we use our *Policy on Applying the Definition of Species under the ESA to Pacific Salmon* (ESU Policy) (56 FR 58612) in determining the appropriate taxonomic unit for listing consideration. Under this policy, populations of salmon that are substantially reproductively isolated from other conspecific populations and that represent an important component in the evolutionary legacy of the biological species are considered to be an ESU. In our listing determinations for Pacific salmon under the ESA, we have treated an ESU as constituting a DPS, and hence a ''species,'' under the ESA.

For non-salmon species, including steelhead, NMFS applies the joint U.S. Fish and Wildlife Service-NMFS DPS policy (61 FR 4722) in identifying the appropriate taxonomic unit for listing consideration. Under this policy, a DPS must be discrete from other conspecific populations, and it must be significant to its taxon. A group of organisms is discrete if it is ''markedly separated from other populations of the same taxon as a consequence of physical, physiological, ecological, and behavioral factors.'' Under the DPS Policy, if a population group is determined to be discrete, the agency must then consider whether it is significant to the taxon to which it belongs. Considerations in evaluating the significance of a discrete population include: (1) Persistence of the discrete population in an unusual or unique ecological setting for the taxon; (2) evidence that the loss of the discrete population segment would cause a significant gap in the taxon's range; (3) evidence that the discrete population segment represents the only surviving natural occurrence of a taxon that may be more abundant elsewhere outside its historical geographic range; or (4) evidence that the discrete population has marked genetic differences from other populations of the species.

On June 28, 2005, we announced a final policy addressing the role of artificially propagated (hatchery produced) Pacific salmon and steelhead in listing determinations under the ESA (70 FR 37204). Specifically, this policy: (1) Establishes criteria for including hatchery stocks in ESUs and DPSs; (2) provides direction for considering hatchery fish in extinction risk assessments of ESUs and DPSs; (3) requires that hatchery fish determined to be part of an ESU will be included in any listing of the ESU; (4) affirms NMFS' commitment to conserving natural salmon and steelhead populations and the ecosystems upon which they depend; and (5) affirms NMFS' commitment to fulfilling trust and treaty obligations with regard to the harvest of some Pacific salmon and steelhead populations, consistent with the conservation and recovery of listed salmon and steelhead ESUs.

Public Solicitation of New Information

The 5-year reviews will consider the best scientific and commercial data available, particularly new information that has become available since the species' previous status review. Our Northwest and Southwest Fisheries Science Centers will assist the West Coast Region in gathering and analyzing this information. To ensure that the 5-year reviews are complete and based on the best available information, we are soliciting new information from the public, concerned governmental agencies, tribes, the scientific community, industry, environmental entities, and any other interested parties concerning the status of the salmon ESUs as well as the steelhead, rockfish, and eulachon DPSs listed above.

Specifically, we request new information that has become available since the respective species' previous status review on: (1) Population abundance; (2) population productivity; (3) changes in species distribution or population spatial structure; (4) genetics or other indicators of diversity; (5) changes in habitat conditions and associated limiting factors and threats; (6) conservation measures that have been implemented that benefit the species, including monitoring data demonstrating the effectiveness of such measures in addressing identified limiting factors or threats; (7) data concerning the status and trends of identified limiting factors or threats; (8) information that may affect determinations regarding the composition of an ESU or DPS; (9) for Pacific salmon and steelhead, information on changes to hatchery programs that may affect determinations regarding their ESU or DPS membership; (10) information on targeted harvest (commercial, tribal, and recreational) and bycatch of the species; and (11) other new information, data, or corrections including, but not limited to, taxonomic or nomenclatural changes, identification of erroneous information in the previous listing determination, and improved analytical methods for evaluating extinction risk. Previous status reviews and supporting information are available on the internet at: *http://www.westcoast.fisheries.noaa.gov/publications/status_reviews/salmon_steelhead/2011_status_reviews_of_listed_salmon_steelhead.html.*

With respect to Puget Sound/Strait of Georgia DPSs of yelloweye, canary, and bocaccio rockfish we also request any new information concerning: Species' spatial distribution and habitat associations of larval, young of the year, and adult fish in the nearshore and deep waters; the effectiveness of regulations to protect and restore rockfish habitats; genetics; effects of contaminants on species productivity, growth, or survival; effects of climate change and ocean acidification on these rockfish species; catch or bycatch of these species in specific fisheries, including information on the ability of anglers to properly identify rockfish by species; the effectiveness of fisheries management in reducing impacts on these rockfish species; efforts to remove and prevent derelict fishing gear; enumeration of bycatch by derelict

fishing gear; and the use and effectiveness of devices designed to reduce the effects of barotrauma in rockfish bycatch.

With respect to the southern DPS of eulachon, we also request any new information concerning: Species' spatial distribution and abundance in freshwater and marine environments; genetics; the effects of natural climate variability and anthropogenically forced climate change on eulachon and their freshwater and marine habitat; the effects of ocean acidification on eulachon; eulachon bycatch in the ocean shrimp fisheries; predation on eulachon; and the effects of dams and large-scale water control structures on estuary-plume environments and eulachon.

If you wish to provide information for these 5-year reviews, see **ADDRESSES** for instructions. We request that all information be accompanied by: (1) Supporting documentation such as maps, bibliographic references, or reprints of pertinent publications. We also would appreciate the submitter's name, address, and any association, institution, or business that the person represents; however, anonymous submissions will also be accepted.

Authority: 16 U.S.C. 1531 *et seq.*

Dated: February 2, 2015.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2015–02337 Filed 2–5–15; 8:45 am]

BILLING CODE 3510–22–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

Consumer Advisory Board Meeting

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice of public meeting.

SUMMARY: This notice sets forth the announcement of a public meeting of the Consumer Advisory Board (CAB or Board) of the Consumer Financial Protection Bureau (Bureau). The notice also describes the functions of the Board. Notice of the meeting is permitted by section 6 of the CAB Charter and is intended to notify the public of this meeting. Specifically, Section X of the CAB Charter states:

(1) Each meeting of the Board shall be open to public observation, to the extent that a facility is available to accommodate the public, unless the Bureau, in accordance with paragraph (4) of this section, determines that the meeting shall be closed. The Bureau also will make reasonable efforts to make the meetings available to the public through live web streaming. (2) Notice of the time, place and purpose of each meeting, as well as a summary of the proposed agenda, shall be published in the **Federal Register** not more than 45 or less than 15 days prior to the scheduled meeting date. Shorter notice may be given when the Bureau determines that the Board's business so requires; in such event, the public will be given notice at the earliest practicable time. (3) Minutes of meetings, records, reports, studies, and agenda of the Board shall be posted on the Bureau's Web site (*www.consumerfinance.gov*). (4) The Bureau may close to the public a portion of any meeting, for confidential discussion. If the Bureau closes a meeting or any portion of a meeting, the Bureau will issue, at least annually, a summary of the Board's activities during such closed meetings or portions of meetings.

DATES: The meeting date is Thursday, February 19, 2015, 10:00 a.m. to 4:00 p.m. Eastern Standard Time.

ADDRESSES: The meeting location is Consumer Financial Protection Bureau, Auditorium, 1275 First Street NE., Washington, DC 20002.

FOR FURTHER INFORMATION CONTACT: Jennifer Draper, Consumer Advisory Board & Councils, External Affairs, 1700 G Street NW., Washington, DC 20552; telephone: 202–435–7176; *CFPB_CABandCouncilsEvents@cfpb.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 1014(a) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (*http://www.sec.gov/about/laws/wallstreetreform-cpa.pdf*) (Dodd-Frank Act) provides: ''The Director shall establish a Consumer Advisory Board to advise and consult with the Bureau in the exercise of its functions under the Federal consumer financial laws, and to provide information on emerging practices in the consumer financial products or services industry, including regional trends, concerns, and other relevant information.'' 12 U.S.C. 5494.

(a) The purpose of the Board is outlined in Section 1014(a) of the Dodd-Frank Act (*http://www.sec.gov/about/laws/wallstreetreform-cpa.pdf*), which states that the Board shall ''advise and consult with the Bureau in the exercise of its functions under the Federal consumer financial laws'' and ''provide information on emerging practices in the consumer financial products or services industry, including regional trends, concerns, and other relevant information.'' (b) To carry out the Board's purpose, the scope of its activities shall include providing information, analysis, and recommendations to the Bureau. The Board will generally serve as a vehicle for market intelligence and expertise for the Bureau. Its objectives will include identifying and assessing the impact on consumers and other market participants of new, emerging, and changing products, practices, or services. (c) The Board will also be available to advise and consult with the Director and the Bureau on other matters related to the Bureau's functions under the Dodd-Frank Act.

II. Agenda

The Consumer Advisory Board will discuss trends and themes related to consumer financial marketplace.

Persons who need a reasonable accommodation to participate should contact *CFPB_504Request@cfpb.gov,* 202–435–9EEO, 1–855–233–0362, or 202–435–9742 (TTY) at least ten business days prior to the meeting or event to request assistance. The request must identify the date, time, location, and title of the meeting or event, the nature of the assistance requested, and contact information for the requester. CFPB will strive to provide, but cannot guarantee that accommodation will be provided for late requests.

Individuals who wish to attend the Consumer Advisory Board meeting must RSVP to *cfpb_cabandcouncilsevents@cfpb.gov* by noon, 17, February, 2015. Members of the public must RSVP by the due date and must include ''CAB'' in the subject line of the RSVP.

III. Availability

The Board's agenda will be made available to the public on February 3, 2015, via *consumerfinance.gov.* Individuals should express in their RSVP if they require a paper copy of the agenda.

A recording and transcript of this meeting will be available after the meeting on the CFPB's Web site *consumerfinance.gov.*

Dated: January 30, 2015.

Christopher D'Angelo,

Chief of Staff, Bureau of Consumer Financial Protection.

[FR Doc. 2015–02445 Filed 2–5–15; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Vietnam War Commemoration Advisory Committee; Notice of Federal Advisory Committee Meeting

AGENCY: DoD.

ACTION: Meeting notice.

SUMMARY: The Department of Defense is publishing this notice to announce the following Federal advisory committee meeting of the Vietnam War Commemoration Advisory Committee. This meeting is open to the public.

DATES: The public meeting of the Vietnam War Commemoration Advisory Committee (hereafter referred to as ''the Committee'') will be held on Friday, February 20, 2015. The meeting will begin at 1:00 p.m. and end at 3:30 p.m.

ADDRESSES: 214 McNair Rd, Spates Club & Conference Center, Bldg #407, Joint Base Myer-Henderson Hall, Ft Myer VA 22211.

FOR FURTHER INFORMATION CONTACT: Committee's Designated Federal Officer: The committee's Designated Federal Officer is Mark Franklin, Vietnam War Commemoration Advisory Committee, 1101 Wilson Blvd., Suite 810, Arlington VA 22209, *mark.r.franklin.civ@mail.mil,* 703–697–4849. For meeting information please contact Mr. Mark Franklin, *mark.r.franklin.civ@mail.mil,* 703–697–4849 or Ms. Scherry Chewning, *scherry.l.chewning.civ@mail.mil,* 703–697–4908.

SUPPLEMENTARY INFORMATION: Due to circumstances beyond the control of the Department of Defense, the Vietnam War Commemoration Advisory Committee was unable to provide public notification of its meeting of February 20, 2015, as required by 41 CFR 102–3.150(a). Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.

This meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

Purpose of the Meeting: At this meeting, the Committee will convene and receive a series of updates on the Vietnam War Commemoration. The mission of the Committee is to provide the Secretary of Defense, through the Director of Administration and Management (DA&M), independent advice and recommendations regarding major events and priority of efforts during the commemorative program for the 50th Anniversary of the Vietnam War, in order to achieve the objectives for the Commemorative Program.

Availability of Materials for the Meeting: A copy of the agenda for the Committee may be obtained from the Commemoration's Web site at *http://vietnamwar50th.com.* Copies will also be available at the meeting.

Meeting Agenda

1:00 p.m.–1:10 p.m. Convene with Committee Chairman Remarks

1:10 p.m.–3:30 p.m. Committee Meeting/Agenda items

- Strategy and Engagement Initiatives
- Congressional Ceremony Update
- History and Legacy Update
- Advisory Committee Deliberation and Discussion
- Closing remarks

3:30 p.m. Adjourn

Public's Accessibility to the Meeting: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, and the availability of space, this meeting is open to the public. All members of the public who wish to attend the public meeting must contact Mark Franklin or Ms. Scherry Chewning at the number listed in the **FOR FURTHER INFORMATION CONTACT** section. Please come prepared to present one form of photo identification to gain access to Ft Myer.

Special Accommodations: Individuals requiring special accommodations to access the public meeting should contact Mr. Mark Franklin or Ms. Scherry Chewning at least five (5) business days prior to the meeting so that appropriate arrangements can be made.

Procedures for Providing Public Comments

Pursuant to 41 CFR 102–3.105(j) and 102–3.140, and section 10(a)(3) of the Federal Advisory Committee Act of 1972, the public or interested organizations may submit written comments to the Commemoration about its mission and topics pertaining to this public meeting.

Written comments should be received by the DFO at least five (5) business days prior to the meeting date so that the comments may be made available to the Commemoration for their consideration prior to the meeting. Written comments should be submitted via email to the address for the DFO given in the **FOR FURTHER INFORMATION CONTACT** section in either Adobe Acrobat or Microsoft Word format. Please note that since the Commemoration operates under the provisions of the Federal Advisory Committee Act, as amended, all submitted comments and public presentations will be treated as public documents and will be made available for public inspection, including, but not limited to, being posted on the Commemoration's Web site.

Dated: February 3, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2015–02383 Filed 2–5–15; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Independent Review Panel on Military Medical Construction Standards; Notice of Federal Advisory Committee Meeting

AGENCY: Department of Defense (DoD).

ACTION: Notice of meeting.

SUMMARY: The Department of Defense is publishing this notice to announce the following Federal Advisory Committee meeting of the Independent Review Panel on Military Medical Construction Standards (''the Panel''). This meeting will be open to the public.

DATES:

Tuesday, February 24, 2015

8:00 a.m.–1:00 p.m. EST (Preparatory Session)

1:00 p.m.–5:00 p.m. EST (Open Session)

ADDRESSES: Defense Health Headquarters (DHHQ), Conference Room 3M505, 7700 Arlington Blvd., Falls Church, Virginia 22042 (escort required; see guidance in **SUPPLEMENTARY INFORMATION**, ''Public's Accessibility to the Meeting'').

FOR FURTHER INFORMATION CONTACT: The Executive Director is Ms. Christine Bader, 7700 Arlington Boulevard, Suite 5101, Falls Church, Virginia 22042, *Christine.e.bader.civ@mail.mil,* (703) 681–6653, Fax: (703) 681–9539. For meeting information, please contact Ms. Kendal Brown, 7700 Arlington Boulevard, Suite 5101, Falls Church, Virginia 22042, *Kendal.l.brown2.ctr@mail.mil,* (703) 681–6670, Fax: (703) 681–9539.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

Purpose of the Meeting

At this meeting, the Panel will address the Ike Skelton National Defense Authorization Act (NDAA) for Fiscal Year 2011 (Pub. L. 111–383), Section 2852(b) requirement to provide the Secretary of Defense independent advice and recommendations regarding a construction standard for military medical centers to provide a single standard of care, as set forth below:

a. Reviewing the unified military medical construction standards to determine the standards consistency with industry practices and benchmarks for world class medical construction;

b. Reviewing ongoing construction programs within the DoD to ensure medical construction standards are uniformly applied across applicable military centers;

c. Assessing the DoD approach to planning and programming facility improvements with specific emphasis on facility selection criteria and proportional assessment system; and facility programming responsibilities between the Assistant Secretary of Defense for Health Affairs and the Secretaries of the Military Departments;

d. Assessing whether the Comprehensive Master Plan for the National Capital Region Medical (''the Master Plan''), dated April 2010, is adequate to fulfill statutory requirements, as required by section 2714 of the Military Construction Authorization Act for Fiscal Year 2010 (division B of Pub. L. 111–84; 123 Stat. 2656), to ensure that the facilities and organizational structure described in the Master Plan result in world class military medical centers in the National Capital Region; and

e. Making recommendations regarding any adjustments of the Master Plan that are needed to ensure the provision of world class military medical centers and delivery system in the National Capital Region.

Agenda:

Pursuant to 5 U.S.C. 552b, as amended, and 41 CFR 102–3.140 through 102–3.165 and subject to availability of space, the Panel meeting is open to the public from 1:00 p.m. to 5:00 p.m. on February 24, 2015, as the Panel will meet in an open forum to receive briefings on military medical construction, sustainment, restoration, and modernization standards.

Availability of Materials for the Meeting

A copy of the agenda or any updates to the agenda for the February 24, 2015, meeting, as well as any other materials presented, may be obtained at the meeting.

Public's Accessibility to the Meeting

Pursuant to 5 U.S.C. 552b, as amended, and 41 CFR 102–3.140 through 102–3.165 and subject to availability of space, this meeting is open to the public. Seating is limited and is on a first-come basis. All members of the public who wish to attend the public meeting must contact Ms. Kendal Brown at the number listed in the section **FOR FURTHER INFORMATION CONTACT** no later than 12:00 p.m. on Tuesday, February 17, 2015, to register and make arrangements for an escort, if necessary. Public attendees requiring escort should arrive with sufficient time to complete security screening no later than 30 minutes prior to the start of the meeting. To complete security screening, please come prepared to present two forms of identification and one must be a picture identification card.

Special Accommodations

Individuals requiring special accommodations to access the public meeting should contact Ms. Kendal Brown at least five (5) business days prior to the meeting so that appropriate arrangements can be made.

Written Statements

Any member of the public wishing to provide comments to the Panel may do so in accordance with 41 CFR 102–3.105(j) and 102–3.140 and section 10(a)(3) of the Federal Advisory Committee Act, and the procedures described in this notice.

Individuals desiring to provide comments to the Panel may do so by submitting a written statement to the Executive Director (see **FOR FURTHER INFORMATION CONTACT**). Written statements should address the following details: The issue, discussion, and a recommended course of action. Supporting documentation may also be included, as needed, to establish the appropriate historical context and to provide any necessary background information.

If the written statement is not received at least five (5) business days prior to the meeting, the Executive Director may choose to postpone consideration of the statement until the next open meeting.

The Executive Director will review all timely submissions with the Panel Chairperson and ensure they are provided to members of the Panel before the meeting that is subject to this notice. After reviewing the written comments, the Panel Chairperson and the Executive Director may choose to invite the submitter to orally present their issue during an open portion of this meeting or at a future meeting. The Executive Director, in consultation with the Panel Chairperson, may allot time for members of the public to present their issues for review and discussion by the Panel.

Dated: February 2, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2015–02344 Filed 2–5–15; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2015–ICCD–0012]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Application Package for Graduate Assistance in Areas of National Need (GAANN) Program (1890–0001)

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a reinstatement of a previously approved information collection.

DATES: Interested persons are invited to submit comments on or before March 9, 2015.

ADDRESSES: Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ED–2015–ICCD–0012 or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted; ED will ONLY accept comments during the comment period in this mailbox when the regulations.gov site is not available.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Mailstop L–OM–2–2E319, Room 2E103, Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Rebecca Green, (202) 502–7779.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Application package for Graduate Assistance in Areas of National Need (GAANN) Program (1890–0001).

OMB Control Number: 1840–0604.

Type of Review: A reinstatement of a previously approved information collection.

Respondents/Affected Public: Private Sector, State, Local and Tribal Governments.

Total Estimated Number of Annual Responses: 325.

Total Estimated Number of Annual Burden Hours: 13,432.

Abstract: This information collection provides the U.S. Department of Education with information needed to evaluate, score and rank the quality of the projects proposed by institutions of higher education applying for a Graduate Assistance in Areas of National Need grant. Title VII, Part A, Subpart 2 of the Higher Education Act of 1965, as amended, requires the collection of specific data that are necessary for applicant institutions to receive an initial competitive grant and non-competing continuation grants for the second and third years.

Dated: February 3, 2015.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

[FR Doc. 2015–02394 Filed 2–5–15; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2014–ICCD–0155]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Student Assistance General Provision—Subpart I—Immigration Status Confirmation

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before March 9, 2015.

ADDRESSES: Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ED–2014–ICCD–0155 or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted; ED will ONLY accept comments during the comment period in this mailbox when the regulations.gov site is not available.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Mailstop L–OM–2–2E319, Room 2E103, Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Student Assistance General Provision—Subpart I—Immigration Status Confirmation.

OMB Control Number: 1845–0052.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: Individuals or Households, Private Sector, State, Local and Tribal Governments.

Total Estimated Number of Annual Responses: 175,897.

Total Estimated Number of Annual Burden Hours: 21,987.

Abstract: This request is for an extension of the reporting requirements currently in Student Assistance General Provisions, 34 CFR 668, Subpart I which governs the Immigration-Status Confirmation authorized by section 484(g) of the Higher Education Act of 1965, as amended. This collection updates the usage by individuals and schools. This is necessary to determine eligibility to receive program benefits and to prevent fraud and abuse of program funds.

Dated: February 3, 2015.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

[FR Doc. 2015–02393 Filed 2–5–15; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2014–ICCD–0153]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Campus Safety and Security Survey

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before March 9, 2015.

ADDRESSES: Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ED–2014–ICCD–0153 or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted; ED will ONLY accept comments during the comment period in this mailbox when the regulations.gov site is not available.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Mailstop L–OM–2–2E319, Room 2E103, Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Ashley Higgins, 202–219–7061.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Campus Safety and Security Survey.

OMB Control Number: 1840–NEW.

Type of Review: A new information collection.

Respondents/Affected Public: Private Sector, State, Local and Tribal Governments.

Total Estimated Number of Annual Responses: 7,135.

Total Estimated Number of Annual Burden Hours: 2,996.

Abstract: The collection of information through the Campus Safety and Security Survey is necessary under section 485 of the Higher Education Act of 1965, as amended, with the goal of increasing transparency surrounding college safety and security information for student, prospective students, parents, employees and the general public. The survey is a collection tool to compile the annual data on campus crime and fire safety. The data collected from the individual institutions by ED is made available to the public through the Campus Safety and Security Data Analysis and Cutting Tool as well as the College Navigator.

Dated: February 3, 2015.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

[FR Doc. 2015–02392 Filed 2–5–15; 8:45 am]

BILLING CODE 4000–01–P

ELECTION ASSISTANCE COMMISSION

Sunshine Act Meetings

AGENCY: Election Assistance Commission.

DATE AND TIME: Wednesday, February 18, 2015 at 10:00 a.m.

PLACE: 1335 East West Highway (First Floor Conference Room), Silver Spring, MD 20910.

STATUS: This meeting will be open to the public.

ITEMS TO BE DISCUSSED:

Selection of Chair and Vice-Chair

Accreditation Decision for Pro V&V

Briefing and Discussion of Voluntary Voting Systems Guidelines (VVSG 1.1)

Briefing and Discussion of Program Manuals

Discussion and Consideration of Roles and Responsibilities Document

AGENDA: Commissioners will meet to select a chair and vice-chair and to discuss the following items: Accreditation Decision for Pro V&V; Briefing and Discussion of Voluntary Voting Systems Guidelines (VVSG 1.1); Briefing and Discussion of Program Manuals; and Discussion and Consideration of Roles and Responsibilities Document.

PUBLIC COMMENTS: Members of the public who wish to speak at the meeting on proposed changes to the Voluntary Voting Systems Guidelines VVSG 1.1 may send a request to participate to the EAC no later than 5:00 p.m. EDT on Thursday, February 12, 2015. Due to time constraints, the EAC will select no more than 7 participants to speak. Each of those selected will be allotted 5 minutes. Participants will be selected on a first-come, first-served basis. However, to maximize diversity of input, only one participant per organization or entity will be chosen, if necessary. Participants will receive confirmation by 12:00 p.m. EDT on Thursday, February 13, 2015. Requests to speak may be sent to the EAC via email at *testimony@eac.gov,* via standard mail addressed to the U.S. Election Assistance Commission, 1335 East West Highway, Suite 4300, Silver Spring, MD 20910, or by fax at 301–734–3108. All requests must include a description of the topic to be discussed, contact information that will be used to notify the requestor with status of request (phone number or email); include on the subject/attention line or on the outside of the envelope if by standard mail: EAC Public Meeting.

PERSON TO CONTACT FOR INFORMATION: Bryan Whitener, Telephone: (301) 563–3961.

Submitted: February 4, 2015.

Signed: Bryan Whitener,

Director of Communications & Clearinghouse.

[FR Doc. 2015–02569 Filed 2–4–15; 4:15 pm]

BILLING CODE 6820–KF–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Staff Attendance at the Southwest Power Pool Market Working Group Meeting

The Federal Energy Regulatory Commission (Commission) hereby gives notice that members of its staff may attend the meeting of the Southwest Power Pool, Inc. (SPP) Market Working Group, as noted below. Their attendance is part of the Commission's ongoing outreach efforts.

The meeting will be held at the office of American Electric Power Company, 1201 Elm Street, Dallas, TX 72501. The meeting will be held on February 10, 2015 from 8:15 a.m. to 6:00 p.m. and on February 11, 2015 from 8:15 a.m. to 12:00 p.m.

The discussions may address matters at issue in the following proceedings:

Docket No. EL05–19, *Southwestern Public Service Company*
Docket No. ER05–168, *Southwestern Public Service Company*
Docket No. ER06–274, *Southwestern Public Service Company*
Docket No. ER07–1069, *American Electric Power*
Docket No. ER09–35, *Tallgrass Transmission, LLC*
Docket No. ER09–36, *Prairie Wind Transmission, LLC*
Docket No. ER09–548, *ITC Great Plains, LLC*
Docket No. EL11–34, *Midcontinent Independent System Operator, Inc.*
Docket No. ER11–4105, *Southwest Power Pool, Inc.*
Docket No. EL12–28, *Xcel Energy Services Inc., et al.*
Docket No. EL12–59, *Golden Spread Electric Cooperative, Inc.*
Docket No. EL12–60, *Southwest Power Pool, Inc., et al.*
Docket No. ER12–480, *Midcontinent Independent System Operator, Inc.*
Docket No. ER12–1586, *Southwest Power Pool, Inc.*
Docket No. ER13–366, *Southwest Power Pool, Inc.*
Docket No. ER13–367, *Southwest Power Pool, Inc.*
Docket No. ER13–1748, *Southwest Power Pool, Inc.*
Docket No. ER13–1864, *Southwest Power Pool, Inc.*
Docket No. EL14–21, *Southwest Power Pool, Inc.*
Docket No. EL14–30, *Midcontinent Independent System Operator, Inc.*
Docket No. EL14–49, *Southwest Power Pool, Inc.*
Docket No. EL14–65, *Southwest Power Pool, Inc.*
Docket No. ER14–67, *Southwest Power Pool, Inc.*
Docket No. ER14–781, *Southwest Power Pool, Inc.*
Docket No. ER14–1174, *Southwest Power Pool, Inc.*
Docket No. ER14–1993, *Southwest Power Pool, Inc.*
Docket No. ER14–2081, *Southwest Power Pool, Inc.*
Docket No. ER14–2363, *Southwestern Public Service Company*
Docket No. ER14–2399, *Southwest Power Pool, Inc.*
Docket No. ER14–2445, *Midcontinent Independent System Operator, Inc.*
Docket No. ER14–2553, *Southwest Power Pool, Inc.*
Docket No. ER14–2570, *Southwest Power Pool, Inc.*
Docket No. ER14–2739, *Southwest Power Pool, Inc.*
Docket No. ER14–2753, *Southwest Power Pool, Inc.*
Docket No. ER14–2850, *Southwest Power Pool, Inc.*
Docket No. ER14–2851, *Southwest Power Pool, Inc.*
Docket No. ER14–2887, *Southwest Power Pool, Inc.*
Docket No. ER14–2891, *Southwest Power Pool, Inc.*
Docket No. ER14–2910, *Southwest Power Pool, Inc.*
Docket No. ER15–45, *Southwest Power Pool, Inc.*
Docket No. ER15–329, *Golden Spread Electric Cooperative, Inc.*
Docket No. ER15–492, *Southwest Power Pool, Inc.*
Docket No. ER15–534, *Southwest Power Pool, Inc.*
Docket No. ER15–551, *Southwest Power Pool, Inc.*
Docket No. ER15–552, *Southwest Power Pool, Inc.*
Docket No. ER15–532, *Southwest Power Pool, Inc.*
Docket No. ER15–561, *Southwestern Public Service Company*
Docket No. ER15–562, *Southwestern Public Service Company*
Docket No. ER15–568, *Southwest Power Pool, Inc.*
Docket No. ER15–569, *Southwest Power Pool, Inc.*
Docket No. ER15–570, *Southwest Power Pool, Inc.*
Docket No. ER15–571, *Southwest Power Pool, Inc.*
Docket No. ER15–576, *Southwest Power Pool, Inc.*
Docket No. ER15–579, *Southwest Power Pool, Inc.*
Docket No. ER15–599, *Southwest Power Pool, Inc.*
Docket No. ER15–603, *Southwest Power Pool, Inc.*
Docket No. ER15–617, *Southwest Power Pool, Inc.*
Docket No. ER15–627, *Golden Spread Electric Cooperative, Inc.*
Docket No. ER15–630, *Southwest Power Pool, Inc.*
Docket No. ER15–633, *Southwest Power Pool, Inc.*
Docket No. ER15–673, *Southwest Power Pool, Inc.*
Docket No. ER15–692, *Southwest Power Pool, Inc.*
Docket No. ER15–752, *Southwestern Public Service Company*
Docket No. ER15–763, *Southwest Power Pool, Inc.*
Docket No. ER15–774, *Southwest Power Pool, Inc.*
Docket No. ER15–787, *Southwest Power Pool, Inc.*
Docket No. ER15–788, *Southwest Power Pool, Inc.*
Docket No. ER15–859, *Southwest Power Pool, Inc.*

The meeting is 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: February 2, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–02462 Filed 2–5–15; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OARM–2011–0997; FRL 9922–57–OARM]

Proposed Information Collection Request; Comment Request; Contractor Cumulative Claim and Reconciliation (Renewal)

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit an information collection request (ICR), ''Contractor Cumulative Claim and Reconciliation'' (EPA ICR No. 0246.12, OMB Control No. 2030–0016) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through May 31, 2015. 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.

DATES: Comments must be submitted on or before April 7, 2015.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OARM–2011–0997, online using *www.regulations.gov* (our preferred method), by email to *hubbell.holly@epa.gov* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Holly Hubbell, Policy Training and Oversight Division, Office of Acquisition Management (3802R), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: 202–564–1091; email address: *hubbell.holly@epa.gov*.

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets*.

Pursuant to section 3506(c)(2)(A) of the PRA, EPA specifically solicits comments and information to enable it to: (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: All contractors who have completed an EPA cost reimbursement type contract will be required to submit EPA Form 1900–10. EPA Form 1900–10 summarizes all costs incurred in performance of the contract and sets forth the final indirect rates. This form is reviewed by the contracting officer to determine the final costs reimbursable to the contractor. FAR 52.216–7 states that the Government will pay only the costs determined to be allowable by the contracting officer in accordance with FAR 31.2. Furthermore, FAR 52.216–7 states that indirect cost rates shall be established for each fiscal year at the close of a contractor's fiscal year. EPA Form 1900–10 summarizes this information for the entire contract period and provides a basis for cost review by contracting, finance, and audit personnel. As stated previously, FAR 4.804–5 mandates that the office administering the contract shall ensure that the costs and indirect cost rates are settled.

Form Numbers: EPA Form 1900–10.

Respondents/affected entities: All contractors who have completed an EPA cost reimbursement type contract. These contractors represent a wide range of industries which include, but are not limited to: North American Industry Classification System (NAICS) code 541511 Custom Computer Programming, 5416 management and Consulting Services, 6215 medical Laboratories, and 541380 Testing Laboratories.

Respondent's obligation to respond: Required to complete contract close out and final payment.

Estimated number of respondents: 20.

Frequency of response: Once, at the end of the contract.

Total estimated burden: 4 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $8,491.00(per year) to all respondents, includes an estimated burden cost of $412.55/respondent and an estimated cost of $12.00/respondent for maintenance and operational costs. Capital investment costs are not necessary for respondents to provide the requested information.

Changes in Estimates: EPA estimates that the hourly burden will remain the same as reported in the previous information collection because there has been no change in the information being collected and approximately the same number of contracts remain active.

Dated: January 28, 2015.

John R. Bashista,

Director, Office of Acquisition Management.

[FR Doc. 2015–02486 Filed 2–5–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OARM–2011–0748; FRL–9922–61–OARM]

Proposed Information Collection Request; Comment Request; Monthly Progress Reports (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency is planning to submit an information collection request (ICR), ''Monthly Progress Reports (Renewal)'' to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through May 31, 2015. 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.

DATES: Comments must be submitted on or before April 7, 2015.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OARM–2011–0748, online using *http://www.regulations.gov* (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Thomas Valentino, Policy Training and Oversight Division, Office of Acquisition Management, (3802R), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: 202–564–

4522; email address: *valentino.thomas@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *http://www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: This notice is a proposed extension of EPA ICR No. 1039.14, OMB Control No. 2030–0005, which is approved through May 31, 2015. Appropriate Government surveillance of contractor performance is required to give reasonable assurance that efficient methods and effective cost controls are being used for various cost-reimbursable and fixed-rate contracts. Per 48 CFR 1552.211 regulations, on a monthly basis, the Agency requires contractors to provide the Contracting Officer's Representative (COR) with a report detailing: (a) What was accomplished on the contract for that period, (b) expenditures for the same period of time, and (c) what is expected to be accomplished on the contract for the next month. Responses to the information collection are mandatory for contractors and are required for the contractors to receive monthly payments.

Form numbers: 1900–68.

Respondents/affected entities: Private sector.

Respondent's obligation to respond: Mandatory per 48 CFR 1552.211.

Estimated number of respondents: 203.

Frequency of response: Monthly.

Total estimated burden: 60,900 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $5,391,258 (per year), includes $0 annualized capital or operation & maintenance costs.

Changes in estimates: Please note: the revised estimates and burden numbers are included in the Supporting Statement that will be added to Docket ID No. EPA–HQ–OARM–2011–0748 for public review and comment. There may be a decrease in the number of hours in total estimated respondent burden down from 60,900 hours, as collection activities may decrease with improved tracking software and overall efficiency.

Dated: January 28, 2015.

John R. Bashista,

Director, Office of Acquisition Management.

[FR Doc. 2015–02459 Filed 2–5–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OARM–2014–0858; FRL–9922–63–OARM]

Proposed Information Collection Request; Comment Request; Drug Testing for Contract Employees (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit an information collection request (ICR), ''Drug Testing for Contract Employees (Renewal)'' (EPA ICR No. 2183.06, OMB Control No. 2030–0044) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through April 30, 2015. 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.

DATES: Comments must be submitted on or before April 7, 2015.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OARM–2014–0858 online using *http://www.regulations.gov* (our preferred method), by email to *oei.docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Dianne Lyles, Policy Training and Oversight Division, Office of Acquisition Management (3802R), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–2017; email address: *lyles.dianne@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *http://www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology,

e.g., permitting electronic submission of responses. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: The EPA uses contractors to perform services throughout the nation in response to environmental emergencies involving the release, or threatened release, of oil, radioactive materials or hazardous chemicals that may potentially affect communities and the surrounding environment. Contractors responding to any of these types of incidents may be responsible for testing their employees for the use of marijuana, cocaine, opiates, amphetamines, phencyclidine (PCP), and any other controlled substances. The testing for drugs must be completed prior to contract employee performance in accordance with Title 5 CFR Administrative Personnel 731.104 Appointments Subject to Investigation, 732.201 Sensitivity Level Designations and Investigative Requirements, and 736.102 Notice to Investigative Sources. The contractor shall maintain records associated with all drug tests.

Form numbers: None.

Respondents/affected entities: Private contractors.

Respondent's obligation to respond: Required to obtain a benefit per Title 5 CFR Administrative Personnel 731.104 Appointments Subject to Investigation, 732.201 Sensitivity Level Designations and Investigative Requirements and 736.102 Notice to Investigative Sources.

Estimated number of respondents: 450.

Frequency of response: Annual.

Total estimated burden: 1,013 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $102,870 (per year), includes $0 annualized capital or operation & maintenance costs.

Changes in estimates: There is no change in the hours in the total estimated respondent burden compared with the ICR currently approved by OMB.

Dated: January 28, 2015.

John R. Bashista,

Director, Office of Acquisition Management.

[FR Doc. 2015–02457 Filed 2–5–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

[EPA–HQ–OW–2013–0820; 9922–59–OW]

Notice of Withdrawal

AGENCIES: Environmental Protection Agency (EPA) and the Department of the Army, Department of Defense.

ACTION: Notice.

SUMMARY: The U.S. Environmental Protection Agency (EPA) and the U.S. Department of the Army (Army) are announcing the withdrawal of an interpretive document addressing the exemption from permitting provided under section 404(f)(1)(A) of the Clean Water Act (CWA).

DATES: The interpretive rule is withdrawn as of January 29, 2015.

FOR FURTHER INFORMATION CONTACT: Ms. Damaris Christensen, Office of Water (4502–T), Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number 202–564–2442; email address: *Wetlands-HQ@epa.gov* or Ms. Stacey Jensen, Regulatory Community of Practice (CECW–CO–R), U.S. Army Corps of Engineers, 441 G Street NW., Washington, DC 20314; telephone number 202–761–5856; email address: *USACE_CWA_RULE@usace.army.mil.*

SUPPLEMENTARY INFORMATION: On March 25, 2014, the Agencies signed an, ''Interpretive Rule Regarding Applicability of the Exemption from Permitting under Section 404(f)(1)(A) of the Clean Water Act to Certain Agricultural Conservation Practices,'' that addressed applicability of the permitting exemption provided under section 404(f)(1)(A) of the CWA to discharges of dredged or fill material associated with certain agricultural conservation practices. Congress subsequently directed the agencies to withdraw this interpretive rule. See, *Consolidated and Further Continuing Appropriation Act, 2015,* Division D, section 112, Public Law 113–235. On January 29, 2015, the agencies signed a memorandum withdrawing the interpretive rule and this action is effective immediately. The memorandum of understanding signed on March 25, 2014, by the U.S. EPA, the U.S. Department of the Army and the U.S. Department of Agriculture, concerning the interpretive rule is also withdrawn. The memorandum withdrawing the interpretive rule is available on the EPA Web site at *http://water.epa.gov/lawsregs/guidance/wetlands/agriculture.cfm* and in the docket for this notice.

Dated: January 29, 2015.

Kenneth J. Kopocis,

Deputy Assistant Administrator for Water, Environmental Protection Agency.

Dated: January 29, 2015.

Jo-Ellen Darcy,

Assistant Secretary of the Army (Civil Works), Department of the Army.

[FR Doc. 2015–02175 Filed 2–5–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9019–4]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7146 or *http://www.epa.gov/compliance/nepa/.*

Weekly receipt of Environmental Impact Statements

Filed 01/26/2015 Through 01/30/2015

Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *http://www.epa.gov/compliance/nepa/eisdata.html.*

EIS No. 20150027, Revised Final EIS, USFWS, AK, Arctic National Wildlife Refuge Revised Comprehensive Conservation Plan, Review Period Ends: 03/09/2015, Contact: Stephanie Brady 907–306–7448.

Amended Notices

EIS No. 20140311, Draft EIS, BLM, 00, Southeastern States Draft Resource Management Plan, Comment Period Ends: 03/16/2015, Contact: Gary Taylor 601–977–5413.

Revision to FR Notice Published 10/31/2014; Extending Comment Period from 1/29/2015 to 03/16/2015.

EIS No. 20140371, Draft EIS, USACE, CA, South San Francisco Bay Shoreline Phase I, Comment Period Ends: 02/23/2015, Contact: William DeJager 415–503–6866.

Revision to FR Notice Published 12/19/2014; Extending the Comment Period from 02/02/2015 to 02/23/2015.

Dated: February 3, 2015.

Cliff Rader,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2015–02472 Filed 2–5–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2014–0835; FRL–9921–96]

Pesticide Experimental Use Permit; Receipt of Application; Comment Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's receipt of an application 88232–EUP–R from Southern Garden Citrus requesting an experimental use permit (EUP) for the SoD2 and SoD7 defensin proteins derived from spinach and inserted into citrus. The Agency has determined that the permit may be of regional and national significance. Therefore, because of the potential significance, EPA is seeking comments on this application.

DATES: Comments must be received on or before March 9, 2015.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2014–0835, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *BPPDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. Although this action may be of particular interest to those persons who conduct or sponsor research on pesticides, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. What should I consider as I prepare my comments for EPA?

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

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide(s) discussed in this document, compared to the general population.

II. What action is the Agency taking?

Under section 5 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. 136c, EPA can allow manufacturers to field test pesticides under development. Manufacturers are required to obtain an EUP before testing new pesticides or new uses of pesticides if they conduct experimental field tests on 10 acres or more of land or one acre or more of water.

Pursuant to 40 CFR 172.11(a), the Agency has determined that the following EUP application may be of regional and national significance, and therefore is seeking public comment on the EUP application:

Submitter: Southern Garden Citrus, 1820 Country Rd. 833, Clewiston, FL 33440 (88232–EUP–R).

Pesticide Chemicals: SoD2 and SoD7 defensin proteins derived from spinach (*Spinacia oleracea* L.) inserted into citrus in order to confer disease resistance.

Summary of Request: Southern Garden Citrus is requesting an experimental use permit (EUP) for the SoD2 and SoD7 defensin proteins derived from spinach (*Spinacia oleracea* L.) inserted into citrus in order to confer disease resistance. The purpose is to gather and evaluate samples collected in the field that will be used in analytical studies to produce data. Southern Garden Citrus' proposed experimental program would begin on May 1, 2015, and would go until April 18, 2018; would take place on a total of 200 acres in Florida and Texas; and would use 18.75 Kilogram (kg) (in Florida) and 3.75 kg (in Texas) of active ingredient. The proposed testing will be conducted to generate agronomic, efficacy and regulatory data and information.

Following the review of the application and any comments and data received in response to this solicitation, EPA will decide whether to issue or deny the EUP request, and if issued, the conditions under which it is to be conducted. Any issuance of an EUP will be announced in the **Federal Register**.

Authority: 7 U.S.C. 136 *et seq.*

Dated: January 27, 2015.

Robert McNally,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 2015–02173 Filed 2–5–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2015–0025; FRL–9921–95]

Pesticide Experimental Use Permit; Receipt of Application; Comment Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's receipt of application 72500–EUP–G from Scimetrics Ltd. Corp. requesting an experimental use permit (EUP) for the chemical warfarin. The Agency has determined that the permit may be of regional and national significance. Therefore, because of the potential significance, EPA is seeking comments on this application.

DATES: Comments must be received on or before March 9, 2015.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2015–0025, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. Although this action may be of particular interest to those persons who conduct or sponsor research on pesticides, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. What should I consider as I prepare my comments for EPA?

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

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide(s) discussed in this document, compared to the general population.

II. What action is the agency taking?

Under section 5 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S. C. 136c, EPA can allow manufacturers to field test pesticides under development. Manufacturers are required to obtain an EUP before testing new pesticides or new uses of pesticides if they conduct experimental field tests on 10 acres or more of land or one acre or more of water.

Pursuant to 40 CFR 172.11(a), the Agency has determined that the following EUP application may be of regional and national significance, and therefore is seeking public comment on the EUP application:

Submitter: Scimetrics Ltd. Corp. (72500–EUP–G).

Pesticide Chemical: Warfarin.

Summary of Request: Applicant seeks permission to test the effectiveness of baits of two concentrations of the anticoagulant rodenticide warfarin for effectiveness in controlling populations of feral hogs (*Sus scrofa*). Applicant requests use of up to 1.5 pounds (lbs.) of the active ingredient in bait-dispenser applications on a total area of up to 2,471 acres, divided into two plots of equal area and located in Hall County, TX. One treated plot is to be baited with a cracked-corn-based formulation containing warfarin at a concentration of 0.005%. The other treated plot is to be treated with a 0.01% warfarin cracked-corn bait. Applicant requests authority to use up to 10,000 lbs. of bait formulated at each of these concentrations. Treated plots are proposed to include areas described as dry land row crops, irrigated row crops, native pasture, and/or brushy washes. The bait dispensers to be used in the proposed field trial are reported to deter direct access to bait by species other than feral hogs.

Following the review of the application and any comments and data received in response to this solicitation, EPA will decide whether to issue or deny the EUP request, and if issued, the conditions under which it is to be conducted. Any issuance of an EUP will be announced in the **Federal Register**.

Authority: 7 U.S.C. 136 *et seq.*

Dated: January 27, 2015.

Susan T. Lewis,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2015–02178 Filed 2–5–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9922–60–OGC]

Proposed Settlement Agreement, Clean Air Act Citizen Suit

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed settlement agreement; request for public comment.

SUMMARY: In accordance with section 113(g) of the Clean Air Act, as amended (''CAA'' or the ''Act''), notice is hereby given of a proposed settlement agreement to address a lawsuit filed by Finger Lakes Zero Waste Coalition, Inc. and Katherine M. Bennett Roll (collectively Plaintiffs''): *Finger Lakes Zero Waste Coalition, Inc.* v. *McCarthy,* No. 6:14-cv-06542 (W.D.N.Y.). On September 16, 2014, Plaintiffs filed this complaint alleging that Gina McCarthy, in her official capacity as Administrator of the United States Environmental Protection Agency (''EPA''), failed to perform a non-discretionary duty to grant or deny within 60 days a petition submitted by Plaintiffs. In their petition, Plaintiffs requested that EPA object to a CAA Title V permit issued by the New

York State Department of Environmental Conservation to Seneca Energy II, LLC, for purposes of operating a landfill gas-to-energy facility in Stanley, New York. The proposed settlement agreement would establish a deadline for EPA to respond to this petition.

DATES: Written comments on the proposed settlement agreement must be received by March 9, 2015.

ADDRESSES: Submit your comments, identified by Docket ID number EPA–HQ–OGC–2015–0080, online at *www.regulations.gov* (EPA's preferred method); by email to *oei.docket@epa.gov;* by mail to EPA Docket Center, Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; or by hand delivery or courier to EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC, between 8:30 a.m. and 4:30 p.m. Monday through Friday, excluding legal holidays. Comments on a disk or CD–ROM should be formatted in Word or ASCII file, avoiding the use of special characters and any form of encryption, and may be mailed to the mailing address above.

FOR FURTHER INFORMATION CONTACT: Zach Pilchen, Air and Radiation Law Office (2344A), Office of General Counsel, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone: (202) 564–2812; fax number (202) 564–5603; email address: *pilchen.zach@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Additional Information About the Proposed Settlement Agreement

This proposed settlement agreement would resolve a lawsuit filed by Plaintiffs seeking to compel the Administrator to take actions under CAA section 505(b)(2). Under the terms of the proposed settlement agreement, EPA would agree to sign a response to the petition by June 30, 2015. The proposed settlement agreement also provides for the possibility that circumstances beyond EPA's reasonable control could delay compliance with the June 30, 2015 deadline, and provides a framework for extending that deadline. In addition, the proposed settlement agreement also enumerates Plaintiffs' costs of litigation, including attorney fees, and provides that payment of those costs will constitute a full and complete settlement of all of Plaintiffs' costs in connection with this litigation.

For a period of thirty (30) days following the date of publication of this notice, the Agency will accept written comments relating to the proposed settlement agreement from persons who are not named as parties or intervenors to the litigation in question. EPA or the Department of Justice may withdraw or withhold consent to the proposed settlement agreement if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act. Unless EPA or the Department of Justice determines that consent to this settlement agreement should be withdrawn, the terms of the settlement agreement will be affirmed.

II. Additional Information About Commenting on the Proposed Settlement Agreement

A. How can I get a copy of the proposed settlement agreement?

The official public docket for this action (identified by Docket ID No. EPA–HQ–OGC–2015–0080) contains a copy of the proposed settlement agreement. The official public docket is available for public viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OEI Docket is (202) 566–1752.

An electronic version of the public docket is available through *www.regulations.gov.* You may use the *www.regulations.gov* to submit or view public comments, access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. Once in the system, key in the appropriate docket identification number then select ''search.''

It is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing online at *www.regulations.gov* without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. Information claimed as CBI and other information whose disclosure is restricted by statute is not included in the official public docket or in the electronic public docket. EPA's policy is that copyrighted material, including copyrighted material contained in a public comment, will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the EPA Docket Center.

B. How and to whom do I submit comments?

You may submit comments as provided in the **ADDRESSES** section. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an email address or other contact information in the body of your comment and with any disk or CD ROM you submit. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Use of the *www.regulations.gov* Web site to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an ''anonymous access'' system, which means EPA will not know your identity, email address, or other contact information unless you provide it in the body of your comment. In contrast to EPA's electronic public docket, EPA's electronic mail (email) system is not an ''anonymous access'' system. If you send an email comment directly to the Docket without going through *www.regulations.gov,* your email address is automatically captured and included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

Dated: January 29, 2015.

Brian L. Doster,

Acting Associate General Counsel.

[FR Doc. 2015–02489 Filed 2–5–15; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–xxxx]

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 collection. 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 March 9, 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 No.: 3060–xxxx.

Title: Section 74.802, Low Power Auxiliary Stations Co-channel Coordination with TV Broadcast Stations.

Form No.: Not Applicable.

Type of Review: New collection.

Respondents: Business or other for-profit entities; not-for-profit institutions; Federal government; and state, local or tribal government.

Number of Respondents and Responses: 400 respondents and 227 responses.

Estimated Time Per Response: 1.0 hour.

Frequency of Response: On occasion reporting requirement and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in 47 U.S.C. 151, 154, 301, 303, 307, 308, 309, 310, 316, 319, 325(b), 332, 336(f), 338, 339, 340, 399b, 403, 534, 535, 1404, 1452, and 1454.

Total Annual Burden: 227 hours.

Total Annual Cost: $56,750.00.

Privacy Act Impact Assessment: There are no impacts under the Privacy Act.

Nature and Extent of Confidentiality: In general there is no need for confidentiality with this collection of information.

Needs and Uses: On June 2, 2014, the Commission released a Report and Order, FCC 14–50, GN Docket No. 12–268, ''Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions.'' This order adopted a revision to a Commission rule, 47 CFR 74.802(b), to permit low power auxiliary stations (LPAS), including wireless microphones, to operate in the bands allocated for TV broadcasting at revised distances from a co-channel television's contour, and provided LPAS operators to operate even closer to television stations provided that any such operations are coordinated with TV broadcast stations that could be affected by the LPAS operations. The Commission seeks Office of Management and Budget (OMB) approval for a new information collection for the coordination process adopted in the Commission's Report and Order, FCC 14–50 for such co-channel operations, in 47 CFR 74.802d(b)(2).

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of the Managing Director.

[FR Doc. 2015–02357 Filed 2–5–15; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0725]

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 the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. 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 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 Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before April 7, 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 Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele at (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0725.

Title: Quarterly Nondiscrimination Recordkeeping (on Quality of Service, Installation and Maintenance) by Bell Operating Companies (BOCs).

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents: 3 respondents; 12 responses.

Estimated Time per Response: 10 hours.

Frequency of Response: Quarterly recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151, 154, 201–205, 215, 218–220, 226 and 276.

Total Annual Burden: 120 hours.

Total Annual Cost: No cost.

Privacy Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: The Commission is not requesting that the respondent submit confidential information to the FCC. Respondents may, however, request confidential treatment for information they believe to be confidential under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: This information collection concerns the nondiscrimination records regarding quality of service, installation and maintenance by Bell Operating Companies (BOCs) pursuant to Computer III and Open Network Architecture (ONA) requirements. Formerly, BOCs were required to submit nondiscrimination reports with regard to payphones to prevent BOCs from discriminating in favor of their own payphones. The reports allowed the Commission to determine how the BOCs provided competing payphone providers with equal access to all the basic underlying network services that are provided to its own payphones.

Since the prior request for authorization, in Report and Order FCC No. 13–69, the Commission eliminated ONA narrowband (*i.e.,* not broadband) quarterly nondiscrimination reporting requirements. However, the underlying recordkeeping obligations remain and the burden hours have decreased.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of the Managing Director.

[FR Doc. 2015–02358 Filed 2–5–15; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0817]

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 the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. 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 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 Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before April 7, 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 Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele at (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0817.

Title: Computer III Further Remand Proceedings: BOC Provision of Enhanced Services (ONA Requirements), CC Docket No. 95–20.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents: 3 respondents; 6 responses.

Estimated Time per Response: 2–50 hours.

Frequency of Response: On occasion; reporting requirements and third party disclosure.

Obligation to Respond: Required to retain or obtain benefits. Statutory authority for this information collection is in 47 U.S.C.s 151, 152, 154, 161, 201–205, 208, 251, 260 and 271–276.

Total Annual Burden: 150 hours.

Total Annual Cost: No cost.

Privacy Impact Assessment: No impact.

Nature and Extent of Confidentiality: The Commission is not requesting that the respondents submit confidential information to the FCC. However, applicants may request confidential treatment of t information they assert is confidential under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: The Commission has eliminated certain reporting requirements because the Bell Operating Companies (BOCs) are no longer required to file semi-annual reports with the Commission addressing Comparably Efficient Interconnection (CEI) and Open Network Architecture (ONA) services. BOCs are required to post their CEI plans and amendments on their publicly accessible Internet sites. The requirement extends to all CEI plans for intraLATA information services, telemessaging, or alarm monitoring

services, and for new or amended payphone services. If the BOC receives a good faith request for a plan from someone who does not have Internet access, the BOC must notify that person where a paper copy of the plan is available for public inspection. The CEI plans will be used to ensure that BOCs comply with Commission policies and regulations safeguarding against potential anticompetitive behavior by the BOCs in the provision of information services.

Federal Communications Commission.

Sheryl D. Todd,

Deputy Secretary, Office of the Secretary, Office of the Managing Director.

[FR Doc. 2015–02412 Filed 2–5–15; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Proposed Collection Renewal; Comment Request (3064–185)

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on the renewal of an existing information collection, as required by the Paperwork Reduction Act of 1995. Currently, the FDIC is soliciting comment on renewal of the information collection described below.

DATES: Comments must be submitted on or before April 7, 2015.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- *http://www.FDIC.gov/regulations/laws/federal/.*
- *Email: comments@fdic.gov* Include the name of the collection in the subject line of the message.
- *Mail:* Gary A. Kuiper, Counsel, (202.898.3877), or John Popeo, Counsel, (202.898.6923), MB–3007, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429. *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street Building (located on F Street), on business days between 7:00 a.m. and 5:00 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Gary A. Kuiper or John Popeo, at the FDIC address above.

SUPPLEMENTARY INFORMATION:

Proposal To Renew the Following Currently-Approved Collection of Information

1. *Title:* Resolution Plans Required for Insured Depository Institutions With $50 Billion or More in Total Assets.

OMB Number: 3064–0185.

Affected Public: Large and highly complex depository institutions.

A. *Estimated Number of Respondents for Contingent Resolution* Plan: 37.

Frequency of Response: Once.

Estimated Time per Response: 7,200 hours per respondent.

Estimated Total Burden: 266,400 hours.

B. *Estimated Number of Respondents for Annual Update of Resolution Plan:* 37.

Frequency of Response: Annual.

Estimated Time per Response: 452 hours per respondent.

Estimated Total Burden: 16,724 hours.

C. *Estimated Number of Respondents for Notice of Material Change Affecting Resolution Plan:* 37.

Frequency of Response: Zero to two times annually.

Estimated Time per Response: 226 hours per respondent.

Estimated Total Burden: 8,362 hours.

General Description of Collection: This Rule requires an insured depository institution with $50 billion or more in total assets to submit periodically to the FDIC a contingent plan for the resolution of such institution in the event of its failure (''Resolution Plan''). This Rule created the requirements for submission and content of a Resolution Plan, as well as procedures for review by the FDIC. The Rule requires a covered insured depository institution (CIDI) to submit a Resolution Plan that should enable the FDIC, as receiver, to resolve the institution under Sections 11 and 13 of the Federal Deposit Insurance Act, 12 U.S.C. 1821 and 1823, in a manner that ensures that depositors receive access to their insured deposits within one business day of the institution's failure (two business days if the failure occurs on a day other than Friday), maximizes the net present value return from the sale or disposition of its assets and minimizes the amount of any loss to be realized by the institution's creditors. The Rule is intended to address the continuing exposure of the banking industry to the risks of insolvency of large and complex insured depository institutions, an exposure that can be mitigated with proper resolution planning.

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Dated at Washington, DC, this 3rd day of February 2015.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2015–02424 Filed 2–5–15; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Proposed Collection Renewal; Comment Request (3064–0179)

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on the renewal of an existing information collection, as required by the Paperwork Reduction Act of 1995. Currently, the FDIC is soliciting comment on renewal of the information collection described below.

DATES: Comments must be submitted on or before April 7, 2015.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- *http://www.FDIC.gov/regulations/laws/federal/.*

• *Email: comments@fdic.gov* Include the name of the collection in the subject line of the message.

• *Mail:* Gary A. Kuiper, Counsel, (202.898.3877), or John Popeo, Counsel, (202.898.6923), MB–3007, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.

Hand Delivery: Comments may be hand-delivered to the guard station at the rear of the 17th Street Building (located on F Street), on business days between 7:00 a.m. and 5:00 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Gary A. Kuiper or John Popeo, at the FDIC address above.

SUPPLEMENTARY INFORMATION:

Proposal To Renew the Following Currently-Approved Collection of Information

1. *Title:* Assessment Rate Adjustment Guidelines for Large and Highly Complex Institutions.

OMB Number: 3064–0179.

Affected Public: Large and highly complex depository institutions.

Estimated Number of Respondents: 11.

Estimated Time per Response: 80 hours.

Frequency of Response: Annual.

Estimated Total Annual Burden: 880 hours.

Total Annual Burden: 880 hours.

General Description of Collection: These guidelines established process through which large and highly complex depository institutions could request a deposit insurance assessment rate adjustment from the FDIC.

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Dated at Washington, DC, this 3rd day of February 2015.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2015–02423 Filed 2–5–15; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL HOUSING FINANCE AGENCY

[No. 2015–N–01]

Notice of Annual Adjustment of the Cap on Average Total Assets That Defines Community Financial Institutions

AGENCY: Federal Housing Finance Agency.

ACTION: Notice.

SUMMARY: The Federal Housing Finance Agency (FHFA) has adjusted the cap on average total assets that defines a ''Community Financial Institution'' to $1,123,000,000, based on the annual percentage increase in the Consumer Price Index for all urban consumers (CPI–U) as published by the Department of Labor (DOL). These changes took effect on January 1, 2015.

FOR FURTHER INFORMATION CONTACT: Amy Tran, Division of Federal Home Loan Bank Regulation, (202) 649–3319, *Amy.Tran@fhfa.gov,* or Eric M. Raudenbush, Assistant General Counsel, (202) 649–3084, *Eric.Raudenbush@fhfa.gov,* (not toll-free numbers), Federal Housing Finance Agency, Constitution Center, 400 Seventh Street SW., Washington, DC 20024.

SUPPLEMENTARY INFORMATION:

I. Statutory and Regulatory Background

The Federal Home Loan Bank Act (Bank Act) confers upon insured depository institutions that meet the statutory definition of a ''Community Financial Institution'' (CFI) certain advantages over non-CFI insured depository institutions in qualifying for Federal Home Loan Bank (Bank) membership, and in the purposes for which they may receive long-term advances and the collateral they may pledge to secure advances.[1] Section 2(10)(A) of the Bank Act and § 1263.1 of FHFA's regulations define a CFI as any Bank member the deposits of which are insured by the Federal Deposit Insurance Corporation and that has average total assets below a statutory cap.[2] The Bank Act was amended in 2008 to set the statutory cap at $1 billion and to require the Director of FHFA to adjust the cap annually to reflect the percentage increase in the CPI–U, as published by the DOL, for the prior year.[3] For 2014, FHFA set the CFI asset cap at $1,108,000,000, which reflected a 1.2 percent increase over 2013, based upon the increase in the CPI–U between 2012 and 2013.[4]

II. The CFI Asset Cap for 2015

As of January 1, 2015, FHFA has increased the CFI asset cap from $1,108,000,000 to $1,123,000,000, which reflects a 1.3 percent increase in the unadjusted CPI–U from November 2013 to November 2014. The new amount was obtained by rounding to the nearest million, as has been the practice for all prior adjustments. Consistent with the practice of other Federal agencies, FHFA bases the annual adjustment to the CFI asset cap on the percentage increase in the CPI–U from November of the year prior to the preceding calendar year to November of the preceding calendar year, because the November figures represent the most recent available data as of January 1st of the current calendar year.

In calculating the CFI asset cap, FHFA uses CPI–U data that have not been seasonally adjusted (*i.e.,* the data have not been adjusted to remove the estimated effect of price changes that normally occur at the same time and in about the same magnitude every year). The DOL encourages use of unadjusted CPI–U data in applying ''escalation'' provisions such as that governing the CFI asset cap, because the factors that are used to seasonally adjust the data are amended annually, and seasonally adjusted data that are published earlier are subject to revision for up to five years following their original release. Unadjusted data are not routinely subject to revision, and previously published unadjusted data are only corrected when significant calculation errors are discovered.

Dated: January 27, 2015.

Melvin L. Watt,

Director, Federal Housing Finance Agency.

[FR Doc. 2015–02402 Filed 2–5–15; 8:45 am]

BILLING CODE 8070–01–P

FEDERAL MARITIME COMMISSION

Sunshine Act Meeting

AGENCY: Federal Maritime Commission.

TIME AND DATE: February 11, 2015; 10:00 a.m.

[1] *See* 12 U.S.C. 1424(a), 1430(a).

[2] *See* 12 U.S.C. 1422(10)(A); 12 CFR 1263.1.

[3] *See* 12 U.S.C. 1422(10); 12 CFR 1263.1 (defining the term *CFI asset cap*).

[4] *See* 79 FR 1862 (Jan. 10, 2014).

PLACE: 800 N. Capitol Street NW., First Floor Hearing Room, Washington, DC.

STATUS: The first portion of the meeting will be held in Open Session; the second in Closed Session.

MATTERS TO BE CONSIDERED:

Open Session

1. Briefing on FMC Continuity of Operations Plan
2. Briefing on FMC Information Technology Upgrade

Closed Session

1. Briefing on Los Angeles and Long Beach Port Infrastructure and Environmental Programs Cooperative Working Agreement, FMC Agreement No. 201219

CONTACT PERSON FOR MORE INFORMATION: Karen V. Gregory, Secretary, (202) 523–5725.

Karen V. Gregory,

Secretary.

[FR Doc. 2015–02558 Filed 2–4–15; 4:15 pm]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

[Petition No. P1–15]

Petition of Compania Sud American De Vapores, S.A. for an Exemption From Commission Regulations; Notice of Filing and Request for Comments

This is to provide notice of filing and to invite comments on or before February 18, 2015, with regard to the Petition described below.

Compania Sud American de Vapores, S.A. (''CSAV'') (Petitioner), has petitioned the Commission pursuant to 46 CFR 502.76 of the Commission's Rules of Practice and Procedure, for an exemption from the Commission's rules requiring individual service contract amendments, 46 CFR 530.10. Specifically, Petitioner explains that ''CSAV transferred the assets and operations comprising its container shipping operation to its wholly-owned subsidiary Norasia Container Lines Limited'' and, as such, requests that the Commission permit the submission of a ''universal notice to the Commission and to all affective service contract parties in lieu of requiring individual filings reflecting amendment by mutual agreement to remove CSAV as a party.'' Petitioner separately commits to provide each service contract shipper counter-party with electronic notice of this corporate change and instructions on how to request preparation of a ''formal consent'' should one be required.

The Petition in its entirety will be posted on the Commission's Web site at *http://www.fmc.gov/p1-15.* Comments filed in response to this Petition also will be posted on the Commission's Web site at this location.

In order for the Commission to make a thorough evaluation of the Petition, interested persons are requested to submit views or arguments in reply to the Petition no later than February 18, 2015. Commenters must send an original and 5 copies to the Secretary, Federal Maritime Commission, 800 North Capitol Street NW., Washington, DC 20573–0001, and be served on Petitioner's counsel, Walter H. Lion, McLaughlin & Stern, LLP, 260 Madison Avenue, New York, NY 10016. A PDF copy of the reply must also be sent as an attachment to *Secretary@fmc.gov.*

Karen V. Gregory,

Secretary.

[FR Doc. 2015–02396 Filed 2–5–15; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than February 23, 2015.

A. Federal Reserve Bank of Atlanta (Chapelle Davis, Assistant Vice President) 1000 Peachtree Street NE., Atlanta, Georgia 30309:

1. *Financial Junk LLC, Spence Limited LP, Spence Limited II LP, and John Spence,* all of Blakely, Georgia; to collectively acquire voting shares of Sevier County Bancshares, Inc., and thereby indirectly acquire voting shares of Sevier County Bank, both in Sevierville, Tennessee.

Board of Governors of the Federal Reserve System, February 3, 2015.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2015–02381 Filed 2–5–15; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than March 5, 2015.

A. Federal Reserve Bank of Dallas (Robert L. Triplett III, Senior Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *Guaranty Bancshares, Inc.,* Mount Pleasant, Texas; to acquire 100 percent of the voting shares of Texas Leadership Bank, Royse City, Texas.

Board of Governors of the Federal Reserve System, February 3, 2015.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2015–02380 Filed 2–5–15; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL TRADE COMMISSION

[File No. 132 3120]

Craig Brittain, Individually; Analysis of Proposed Consent Order To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before March 2, 2015.

ADDRESSES: Interested parties may file a comment at *https://ftcpublic.commentworks.com/ftc/craigbrittainconsent* online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''Craig Brittain—Consent Agreement; File No. 1323120'' on your comment and file your comment online at *https://ftcpublic.commentworks.com/ftc/craigbrittainconsent* by following the instructions on the Web-based form. If you prefer to file your comment on paper, write ''Craig Brittain—Consent Agreement; File No. 1323120'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Melinda Claybaugh, Bureau of Consumer Protection, (202) 326–2203, 600 Pennsylvania Avenue NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for January 29, 2015), on the World Wide Web, at *http://www.ftc.gov/os/actions.shtm*.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before March 2, 2015. Write ''Craig Brittain—Consent Agreement; File No. 1323120'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm*. As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which . . . is privileged or confidential,'' as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[1] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/craigbrittainconsent* by following the instructions on the Web-based form. If this Notice appears at *http://www.regulations.gov/#!home,* you also may file a comment through that Web site.

If you file your comment on paper, write ''Craig Brittain—Consent Agreement; File No. 1323120'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before March 2, 2015. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm*.

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, a consent order applicable to respondent Craig Brittain.

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

From November 2011 to April 2013, Respondent owned and operated the Web site *www.isanybodydown.com,* on which he posted personal information and photographs of individuals with their intimate parts exposed.

[1] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

Respondent used three different methods to obtain photographs for posting on the Web site. First, he requested that submitters send him nude photographs of other people along with personal information about the subject of each photograph, including the subject's first and last name, city, state, phone number, and link to their Facebook profile. Second, Respondent obtained photographs by posing as a woman on the Craigslist advertising Web site and, after sending women photographs purportedly of himself, solicited photographs of them with their intimate parts exposed in return. When they did provide such photographs, Respondent posted them on his Web site without their permission. Third, Respondent instituted a ''bounty system'' on the Web site, whereby anyone could request that others find and post photos of a specific person in exchange for a reward of at least $100. Respondent posted the photographs and personal information he obtained without the permission of the subject of each photograph. In some instances, he added other personal information about the subjects based on his own research. In total, Respondent posted photographs and accompanying personal information of more than 1,000 people, the vast majority of whom were women. Respondent also advertised content removal services called ''Takedown Hammer'' and ''Takedown Lawyer,'' which promised to remove consumers' content from the Web site for a substantial sum of money. In fact, Respondent himself owned these services, thereby attempting to obtain money to remove the same photographs that he had posted.

The Commission's complaint alleges two violations of the FTC Act. Count I alleges that Respondent unfairly disseminated photographs of individuals with their intimate parts exposed, along with personal information about them, for commercial gain and without the knowledge or consent of those depicted, despite the fact that he knew or should have known that the individuals had a reasonable expectation their image would not be disseminated in that manner. Count II alleges that Respondent deceptively solicited photographs from individuals of themselves with their intimate parts exposed by misrepresenting that he would use such photographs solely for his personal private use.

The proposed order contains provisions designed to prevent Respondent from engaging in the future in practices similar to those alleged in the complaint. Part I prohibits Respondent from disseminating, through a Web site or online service, a video or photograph of an individual with his or her intimate parts exposed without: (1) Disclosing to the individual that he will disseminate the image through a Web site and for commercial gain; and (2) obtaining affirmative express consent in writing from the individual for such dissemination.

Part II of the proposed order prohibits Respondent from, in connection with offering for sale any good or service, misrepresenting: (1) His collection, use, disclosure, or deletion of personal information; (2) his identity; or (3) the identity of those providing content or sponsoring advertising on a Web site. Part III of the proposed order prohibits Respondent from disclosing or benefitting from the images and personal information he obtained in connection with his Web site. Further, it requires him to destroy such images and personal information within 30 days of entry of the order.

Parts IV through VIII of the proposed order are reporting and compliance provisions. Part IV requires Respondent to retain documents relating to his compliance with the order for five years. Part V requires dissemination of the order to all current and future employees, agents, and representatives having responsibilities relating to the subject matter of the order. Part VI ensures notification to the FTC of changes in Respondent's business or employment. Part VII mandates that Respondent submit a compliance report to the FTC within 60 days, and periodically thereafter as requested. Part VIII is a provision ''sunsetting'' the order after 20 years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the proposed complaint or order or to modify the order's terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2015–02375 Filed 2–5–15; 8:45 am]

BILLING CODE 6750–01–P

FEDERAL TRADE COMMISSION

[File No. 132 3262]

Finance Select, Inc.; Analysis of Proposed Consent Order To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of Federal law prohibiting unfair or deceptive acts or practices. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before March 3, 2015.

ADDRESSES: Interested parties may file a comment at *https://ftcpublic.commentworks.com/ftc/fastcashpawnconsent/* online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''Finance Select, Inc.—Consent Agreement; File No. 1323262'' on your comment and file your comment online at *https://ftcpublic.commentworks.com/ftc/fastcashpawnconsent/* by following the instructions on the Web-based form. If you prefer to file your comment on paper, write ''Finance Select, Inc.—Consent Agreement; File No. 1323262'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Helen Wong, Bureau of Consumer Protection, (202) 326–3779, 600 Pennsylvania Avenue NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for January 30, 2015), on the World Wide Web, at *http://www.ftc.gov/os/actions.shtm.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before March 3, 2015. Write ''Finance

Select, Inc.—Consent Agreement; File No. 1323262'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm*. As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which . . . is privileged or confidential,'' as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[1] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/fastcashpawnconsent/* by following the instructions on the Web-based form. If this Notice appears at *http://www.regulations.gov/#!home,* you also may file a comment through that Web site.

If you file your comment on paper, write ''Finance Select, Inc.—Consent Agreement; File No. 1323262'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before March 3, 2015. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm*.

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission (''FTC'' or ''Commission'') has accepted, subject to final approval, an agreement containing a consent order from Finance Select, Inc. The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the FTC will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

The respondent is a car title loan company. According to the FTC complaint, respondent has advertised its loans with advertisements that broadly state that the title loans are available for ''1st 30 Days 0%.'' In much smaller print, these advertisements state ''New Customers Only.'' However, respondent's advertisements fail to disclose that unless the loan is completely repaid in 30 days, the 0% offer does not apply and there is a significant finance charge. If a consumer does not repay the loan in full in 30 days, he or she would then be required to pay the finance charge for the first 30 days in addition to any additional finance charges incurred on day 31 (to start the second 30-day period). The advertisements also fail to disclose the amount of the finance charge after expiration of the 30-day introductory period. The proposed complaint alleges that these material omissions constitute a deceptive act or practice under Section 5 of the FTC Act.

The proposed order is designed to prevent the respondent from engaging in similar deceptive practices in the future. Part I prohibits the respondent from stating an introductory or temporary finance charge without disclosing, clearly and conspicuously, the finance charge after the introductory or temporary period ends; or the full effect of failing to make a timely complete repayment of the loan within the introductory or temporary time period. Respondent must further disclose all qualifying terms associated with obtaining the loan at its advertised rate, including but not limited to, minimum loan requirements, new customer requirements, and any other material term; all costs associated with obtaining the loan, including but not limited to transaction costs. Respondent also cannot misrepresent registration costs or fees, recording costs or fees, and title fees; and respondent cannot misrepresent any other material fact about the terms of the loan.

Parts II through VI of the proposed order are reporting and compliance provisions. Part II is an order distribution provision that requires respondent to provide the order to current and future principals, officers, directors, and managers and to all current employees, agents, and representatives having responsibilities with respect to the advertisement of consumer credit. Part III of the proposed order requires respondent to maintain and upon request make available to the Commission certain compliance-related records, including all advertisements and also consumer complaints and records that demonstrate compliance with the proposed order for a period of five years. Part IV requires respondent to notify the Commission of corporate changes that may affect compliance obligations within 30 days of such a change. Part V requires respondent to submit a compliance report to the Commission 60 days after entry of the order, and also additional compliance reports within 10 business days of a written request by the Commission. Part VI ''sunsets'' the order after 20 years, with certain exceptions.

The purpose of this analysis is to aid public comment on the proposed order. It is not intended to constitute an

[1] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

official interpretation of the complaint or proposed order, or to modify in any way the proposed order's terms.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2015–02376 Filed 2–5–15; 8:45 am]

BILLING CODE 6750–01–P

FEDERAL TRADE COMMISSION

[File No. 132 3264]

First American Title Lending of Georgia, LLC; Analysis of Proposed Consent Order To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before March 3, 2015.

ADDRESSES: Interested parties may file a comment at *https://ftcpublic.commentworks.com/ftc/firstamericanlendingconsent/* online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''First American Title Lending of Georgia, LLC—Consent Agreement; File No. 1323264'' on your comment and file your comment online at *https://ftcpublic.commentworks.com/ftc/firstamericanlendingconsent/* by following the instructions on the web-based form. If you prefer to file your comment on paper, write ''First American Title Lending of Georgia, LLC—Consent Agreement; File No. 1323264'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Helen Wong, Bureau of Consumer Protection, (202) 326–3779, 600 Pennsylvania Avenue NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for January 30, 2015), on the World Wide Web, at *http://www.ftc.gov/os/actions.shtm.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before March 3, 2015. Write ''First American Title Lending of Georgia, LLC—Consent Agreement; File No. 1323264'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which . . . is privileged or confidential,'' as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[1] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/firstamericanlendingconsent/* by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov/#!home*, you also may file a comment through that Web site.

If you file your comment on paper, write ''First American Title Lending of Georgia, LLC—Consent Agreement; File No. 1323264'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before March 3, 2015. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission (''FTC'' or ''Commission'') has accepted, subject to final approval, an agreement containing a consent order from First American Title Lending of Georgia, LLC, or respondent. The proposed consent

[1] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the FTC will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

The respondent is a car title loan company. According to the FTC complaint, respondent has advertised its loans with advertisements that broadly state that the title loans are available for ''0% Interest!'' Sometimes, but not always, these advertisements state in much smaller print, ''Certain terms and conditions may apply'' or ''Some restrictions apply.'' However, respondent's advertisements fail to disclose that unless the loan is completely repaid in 30 days, the 0% offer does not apply and there is a significant finance charge. If a consumer does not repay the loan in full in 30 days, he or she would then be required to pay the finance charge for the first 30 days in addition to any additional finance charges incurred on day 31 (to start the second 30-day period). The advertisements also fail to disclose the amount of the finance charge after expiration of the 30-day introductory period. The proposed complaint alleges that these material omissions constitute a deceptive act or practice under Section 5 of the FTC Act.

The Commission is also alleging a Truth in Lending Act (''TILA'') violation against respondent. Some advertisements displayed ''9.5%'' next to the claim of ''0% interest.'' First American allegedly violated TILA by advertising a finance rate (9.5%), but failing to state the rate as an APR.

The proposed order is designed to prevent the respondent from engaging in similar deceptive practices, or violating TILA, in the future. Part I prohibits the respondent from stating an introductory or temporary finance charge without disclosing, clearly and conspicuously, the finance charge after the introductory or temporary period ends; or the full effect of failing to make a timely complete repayment of the loan within the introductory or temporary time period. Respondent must further disclose all qualifying terms associated with obtaining the loan at its advertised rate, including but not limited to, minimum loan requirements, new customer requirements, and any other material term; all costs associated with obtaining the loan, including but not limited to transaction costs, registration costs or fees, recording costs or fees, and title fees. The respondent also cannot misrepresent any other material fact about the terms of the loan.

Part II of the proposed order prohibits the respondent, in connection with any advertisement to promote, directly or indirectly, any extension of consumer credit in or affecting commerce, from expressly or by implication stating the amount or percentage of down payment, the number of payments or period of repayment, the amount of any payment, or the amount of any finance charge, without disclosing clearly and conspicuously all of the terms required by Section 144 of TILA, 15 U.S.C. 1664, and Section 1026.24(c) of Regulation Z, including but not limited to the amount of percentage or the down payment; the terms of repayment; and the annual percentage rate, using that term or the abbreviation ''APR.'' If the annual percentage rate or APR may be increased after the consummation of the credit transaction, that fact must also be disclosed. Moreover, the respondent cannot state a rate of finance charge without stating the rate as an ''annual percentage rate'' using that term or the abbreviation ''APR,'' as required by Section 144 of the TILA, 15 U.S.C. 1664, and Section 1026.24(c) of Regulation Z; or fail to comply in any other respect with the TILA, 15 US.C. §§ 1601–1667, as amended, and its implementing Regulation Z, 12 CFR 1026 as amended.

Parts III through VII of the proposed order are reporting and compliance provisions. Part III is an order distribution provision that requires respondent to provide the order to current and future principals, officers, directors, and managers and to all current employees, agents, and representatives having responsibilities with respect to the advertisement of consumer credit. Part IV of the proposed order requires respondent to maintain and upon request make available to the Commission certain compliance-related records, including all advertisements and also consumer complaints and records that demonstrate compliance with the proposed order for a period of five years. Part V requires respondent to notify the Commission of corporate changes that may affect compliance obligations within 30 days of such a change. Part VI requires respondent to submit a compliance report to the Commission 60 days after entry of the order, and also additional compliance reports within 10 business days of a written request by the Commission. Part VII ''sunsets'' the order after 20 years, with certain exceptions.

The purpose of this analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or proposed order, or to modify in any way the proposed order's terms.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2015–02373 Filed 2–5–15; 8:45 am]

BILLING CODE 6750–01–P

FEDERAL TRADE COMMISSION

[File No. 141 0134]

Sun Pharmaceutical Industries Ltd., Ranbaxy Laboratories Ltd., and Daiichi Sankyo Co., Ltd.; Analysis of Proposed Consent Orders To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent orders—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before March 3, 2015.

ADDRESSES: Interested parties may file a comment at *https://ftcpublic.commentworks.com/ftc/sunpharmaceuticalconsent/* online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''Sun Pharmaceutical Industries Ltd.—Consent Agreement; File No. 141–0134'' on your comment and file your comment online at *https://ftcpublic.commentworks.com/ftc/sunpharmaceuticalconsent/* by following the instructions on the web-based form. If you prefer to file your comment on paper, write ''Sun Pharmaceutical Industries Ltd.—Consent Agreement; File No. 141–0134'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Aylin M. Skroejer, Bureau of Competition, (202–326–2459), 600 Pennsylvania Avenue NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing consent orders to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for January 30, 2015), on the World Wide Web, at *http://www.ftc.gov/os/actions.shtm.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before March 3, 2015. Write ''Sun Pharmaceutical Industries Ltd.—Consent Agreement; File No. 141–0134'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which . . . is privileged or confidential,'' as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[1] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/sunpharmaceuticalconsent/* by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov/#!home,* you also may file a comment through that Web site.

If you file your comment on paper, write ''Sun Pharmaceutical Industries Ltd.—Consent Agreement; File No. 141–0134'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before March 3, 2015. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

Analysis of Agreement Containing Consent Orders To Aid Public Comment

The Federal Trade Commission (''Commission'') has accepted, subject to final approval, an Agreement Containing Consent Orders (''Consent Agreement'') from Sun Pharmaceutical Industries Ltd. (''Sun'') that is designed to remedy the anticompetitive effects resulting from Sun's acquisition of Ranbaxy Laboratories Ltd. (''Ranbaxy'') from Daiichi Sankyo Co., Ltd. (''Daiichi Sankyo''). Under the terms of the proposed Consent Agreement, the parties are required to divest all of Ranbaxy's rights and assets to generic minocycline hydrochloride 50 mg, 75 mg, and 100 mg tablets (''minocycline tablets'') to Torrent Pharmaceuticals Ltd. (''Torrent'').

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the proposed Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw from the proposed Consent Agreement or make final the Decision and Order (''Order'').

Pursuant to an agreement dated April 6, 2014, Sun plans to acquire Ranbaxy in an all-stock deal valued at approximately $4 billion (the ''Proposed Acquisition''). The Commission alleges in its Complaint that the Proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, by lessening future competition in the markets for each dosage strength of generic minocycline tablets in the United States. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that would otherwise be eliminated by the Proposed Acquisition.

I. The Product and Structure of the Markets

The Proposed Acquisition would reduce the number of future suppliers in the markets for generic minocycline tablets, which physicians prescribe to treat bacterial infections including pneumonia and other respiratory tract infections, acne, and other skin, genital, and urinary tract infections. Pharmaceutical companies usually launch generic versions of drugs after a branded product loses its patent protection. When only one generic product is available, the price for the branded product acts as a ceiling above which the generic manufacturer cannot price its product. During this period, the branded product competes directly with the generic. Once multiple generic suppliers enter a market, the branded drug manufacturer usually ceases to provide any competitive constraint on the prices for generic versions of the

[1] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

drug. Rather, generic suppliers compete only against each other. In generic pharmaceutical product markets, price generally decreases as the number of generic competitors increases. The United States is the relevant geographic market for generic drugs because the U.S. Food and Drug Administration (''FDA'') must approve them for sale within the United States.

There are currently only three suppliers of each dosage strength of generic minocycline tablets in the United States: Ranbaxy, Dr. Reddy's Laboratories Ltd., and Par Pharmaceutical Companies, Inc. Sun is one of only a limited number of firms likely to enter the generic minocycline tablets markets in the near future. Sun's acquisition of Ranbaxy would therefore deprive consumers of the increased competition and likely price reductions that would have occurred as a result of Sun's independent entry.

II. Entry

Entry into the markets for generic minocycline tablets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Acquisition. The combination of drug development times and regulatory requirements, including approval by the FDA, is costly and lengthy.

III. Effects

The Proposed Acquisition likely would cause significant anticompetitive harm to consumers by eliminating future competition that would otherwise have occurred when Sun's generic minocycline tablets entered the markets. Market participants characterize generic minocycline tablets as commodities, and each market as one in which the number of generic suppliers has a direct impact on pricing. Customers and competitors have confirmed that the price of generic pharmaceutical products decreases with new entry even after several other suppliers have entered the market. Further, customers generally believe that having at least four suppliers in each generic pharmaceutical market produces more competitive prices than if fewer suppliers are available to them.

The Proposed Acquisition would eliminate significant future competition between Sun and Ranbaxy. The evidence shows that anticompetitive effects are likely to result from the Proposed Acquisition due to the elimination of an additional independent competitor in the markets for generic minocycline tablets, which would have allowed customers to negotiate lower prices. Thus, absent a remedy, the Proposed Acquisition will likely cause U.S. consumers to pay significantly higher prices for generic minocycline tablets.

IV. The Consent Agreement

The proposed Consent Agreement effectively remedies the Proposed Acquisition's anticompetitive effects in the relevant markets. Pursuant to the Consent Agreement and the Order, the parties are required to divest all of Ranbaxy's rights and assets to generic minocycline tablets to Torrent. The parties must accomplish these divestitures and relinquish their rights no later than ten days after the Proposed Acquisition is consummated.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the Proposed Acquisition. If the Commission determines that Torrent is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires the parties to unwind the sale of rights to Torrent and then divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products as required.

The proposed Consent Agreement and Order contain several provisions to help ensure that the divestitures are successful. The Order requires that Ranbaxy transfer to Torrent all confidential business information and requires that Sun and Ranbaxy take all actions that are necessary to maintain the full viability and marketing of the generic minocycline tablets until Torrent commences the distribution, marketing, and sale of the products.

The proposed Order also requires the parties to divest Ranbaxy's generic minocycline hydrochloride 50 mg, 75 mg, and 100 mg capsules (''minocycline capsules'') to Torrent to ensure that Torrent achieves regulatory approval to qualify a new API supplier for its minocycline tablets as quickly as Ranbaxy would have. Torrent will be able to establish the current API supplier of the minocycline capsules as the API supplier for its minocycline tablets through a less time-intensive regulatory process if Torrent controls both products and uses the same API supplier for both. Moreover, the proposed Order requires Sun and Ranbaxy to manufacture and supply generic minocycline tablets and capsules to Torrent following the divestiture to allow Torrent to enter the markets while it validates its manufacturing process and seeks the necessary FDA approvals.

The Commission will appoint Frank Civille to act as an interim monitor to assure that Sun and Ranbaxy expeditiously comply with all of their obligations and perform all of their responsibilities pursuant to the Consent Agreement. In order to ensure that the Commission remains informed about the status of the transfer of rights and assets, the Consent Agreement requires Sun and Ranbaxy to file reports with the interim monitor who will report in writing to the Commission concerning performance by the parties of their obligations under the Consent Agreement.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2015–02461 Filed 2–5–15; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–0990–New–30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for a new collection. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before March 9, 2015.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the Information Collection Request Title and document identifier HHS–OS–0990–New–30D for reference.

Information Collection Request Title: Evaluation of the National Training on Trauma-Informed Care (TIC).

Abstract: The HHS OWH is requesting OMB approval to conduct a new, one time outcome evaluation of the *National Training Initiative on Trauma-Informed Care (TIC) for Community-Based Providers From Diverse Service Systems* training curriculum. Policymakers and providers in many service sectors recognize the central role of trauma in causing or complicating physical and behavioral health conditions and the critical need for trauma-informed care (TIC) systems. The proposed evaluation will capture both knowledge gained and implementation impact achieved as a result of the TIC training and TA. Analyses and findings will be used to further refine the TIC curriculum and training approach, and can help inform OWH and HHS in future policymaking efforts. Information collected will also help researchers and practitioners better understand the impact of adopting a trauma-informed approach on and the quality of care provided by community-based providers.

Likely respondents:

Site Visits

Site visits are designed to capture both the knowledge gained by training participants and the implementation impact achieved in their organizations as a result of the OWH TIC training and technical assistance.

Online Survey

The goal of the online survey is to assess the impact of the training on participants' skills acquired in, knowledge about, and values and beliefs surrounding trauma-informed care.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Online Survey	Leadership and Line/Other Frontline Staff.	300	1	25/60	125
Site Visits	Leadership and Line/Other Frontline Staff.	144	1	40/60	96
Total					221

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2015–02313 Filed 2–5–15; 8:45 am]

BILLING CODE 4150–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Written Comments on the Draft National Adult Immunization Plan

AGENCY: National Vaccine Program Office, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The National Vaccine Advisory Committee (NVAC) was established in 1987 to comply with Title XXI of the Public Health Service Act (Pub. L. 99–660) (§ 2105) (*42 U.S. Code 300aa–5 (PDF—78 KB)*). Its purpose is to advise and make recommendations to the Director of the National Vaccine Program on matters related to program responsibilities. The Assistant Secretary for Health (ASH) has been designated by the Secretary of Health and Human Services (HHS) as the Director of the National Vaccine Program. The National Vaccine Program Office (NVPO) is located within the Office of the Assistant Secretary for Health (OASH), Office of the Secretary, U.S. Department of Health and Human Services (HHS). NVPO provides leadership and fosters collaboration among the various federal agencies involved in vaccine and immunization activities. The NVPO also supports the National Vaccine Advisory Committee (NVAC). The NVAC advises and makes recommendations to the ASH in his capacity as the Director of National Vaccine Program on matters related to vaccine program responsibilities.

Adult vaccination rates remain low in the United States, and significant racial and ethnic disparities exist. In 2011, NVAC recommended the development of a strategic plan with the goal of improving adult immunization.

Through an environmental scan of past reports issued by vaccine stakeholders, a survey, several focus groups, and in-depth interviews with subject matter experts, and in consultation with federal partners, NVPO has developed the draft National Adult Immunization Plan (NAIP). The NAIP details background on the immunization landscape and provides a strategic plan for federal and nonfederal stakeholders.

NVPO is soliciting public comment on the draft NAIP from a variety of stakeholders, including the general public, for consideration as they develop their final report to the Secretary. It is anticipated that the draft NAIP, as revised with consideration given to public comment and stakeholder input, will be presented to the Secretary in the first quarter of 2015.

DATES: Comments for consideration by NVPO should be received no later than 5:00 p.m. EDT on March 9, 2015.

ADDRESSES: (1) The draft NAIP is available on the web at *http://www.hhs.gov/nvpo/*.

(2) Electronic responses are preferred and may be addressed to: *Rebecca.Fish@hhs.gov.*

(3) Written responses should be addressed to: National Vaccine Program Office, U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 733G, Washington, DC 20201. Attn: HHS Adult Immunization c/o Rebecca Fish.

FOR FURTHER INFORMATION CONTACT: Rebecca Fish, National Vaccine Program Office, Office of the Assistant Secretary for Health, Department of Health and Human Services; telephone (202) 260–9283; fax (202) 260–1165; email: *Rebecca.Fish@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Vaccination is one of the most important public health achievements of the 20th century. Vaccines save lives and improve the quality of life by reducing the transmission of infectious diseases. However, the benefits of vaccination are not realized equally across the U.S. population. Adult vaccination rates remain low in the United States and far below Healthy People 2020 targets. In an average year, 95 percent of the approximately 20,000 to 50,000 Americans who die as a result of vaccine-preventable disease are adults, depending on the severity of annual influenza outbreaks. Substantial racial and ethnic disparities also exist.

The National Vaccine Plan (NVP), released in 2010, provides a guiding vision for vaccination in the United States for the decade 2010–2020. While the NVP serves as a roadmap for protecting all U.S. residents from vaccine-preventable diseases, historically low vaccination rates in the adult population and unique attributes of the adult vaccination delivery system highlight the need for focused attention on adult vaccination.

The NAIP is a five year national plan with an emphasis on coordination and prioritization of what federal and non-federal partners can accomplish together. Given this time frame, the NAIP will be informed by emerging science and changing circumstances. The NAIP also aims to leverage the unique opportunity presented by the passage and ongoing implementation of the Affordable Care Act.

Through their analysis and discussion, NVPO identified four major goals:

Goal 1: Strengthen the adult immunization infrastructure

Goal 2: Improve access to adult vaccines

Goal 3: Increase community demand for adult immunizations

Goal 4: Foster innovation in adult vaccine development and vaccination related technologies

Within each goal, the NAIP details measurable objectives and sub-objectives.

II. Request for Comment

NVPO requests input on the draft report and draft recommendations. In addition to general comments on the draft NAIP, NVPO is seeking input on efforts or barriers to adult immunizations not represented in the report where HHS efforts could advance adult immunization efforts. Please limit your comments to six (6) pages.

III. Potential Responders

HHS invites input from a broad range of stakeholders including individuals and organizations that have interests in adult immunization efforts and the role of HHS in advancing those efforts.

Examples of potential responders include, but are not limited to, the following:

—general public;
—advocacy groups, non-profit organizations, and public interest organizations;
—academics, professional societies, and healthcare organizations;
—public health officials and immunization program managers;
—provider groups including all physician and non-physician providers that administer immunization services to adults, including pharmacists; and
—representatives from the private sector.

When responding, please self-identify with any of the above or other categories (include all that apply) and your name. Anonymous submissions will not be considered. Written submissions should not exceed six (6) pages. Please do not send proprietary, commercial, financial, business, confidential, trade secret, or personal information.

Dated: January 27, 2015.

Bruce Gellin,

Deputy Assistant Secretary for Health, Director, National Vaccine Program Office, Executive Secretary, National Vaccine Advisory Committee.

[FR Doc. 2015–02481 Filed 2–5–15; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–15–0964]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. To request more information on the below proposed project or to obtain a copy of the information collection plan and instruments, call 404–639–7570 or send comments to Leroy A. Richardson, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. Written comments should be received within 60 days of this notice.

Proposed Project

Interventions to Reduce Shoulder MSDs in Overhead Assembly (OMB No. 0920–0964, expires 4/30/2015)—Extension—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The mission of the National Institute for Occupational Safety and Health (NIOSH) is to promote safety and health at work for all people through research and prevention. Under Public Law 91–596, sections 20 and 22 (Section 20–22, Occupational Safety and Health Act of 1970), NIOSH has the responsibility to conduct research to advance the health and safety of workers. In this capacity, NIOSH proposes a three year extension

for a study to assess the effectiveness and cost-benefit of occupational safety and health interventions to prevent musculoskeletal disorders (MSDs) among workers in the Manufacturing (MNF) sector.

An extension is requested for this ICR because only one quarter of the necessary sample size was enrolled during the previous cycle. The eligible employee population will be expanded to include other Departments at the facility to achieve the necessary sample size. It is believed that the targeted number of interventions, which was not achieved in the previous year, can be achieved by expanding to additional Departments.

Musculoskeletal disorders (MSDs) represent a major proportion of injury/illness incidence and cost in the U.S. Manufacturing (MNF) sector. In 2008, 29% of non-fatal injuries and illnesses involving days away from work (DAW) in the MNF sector involved MSDs and the MNF sector had some of the highest rates of MSD DAW cases. The rate for the motor vehicle manufacturing sub-sector (NAICS 3361) was among the highest of MNF sub sectors, with MSD DAW rates that were higher than the general manufacturing MSD DAW rates from 2003–2007.

In automotive manufacturing, overhead conveyance of the vehicle chassis requires assembly line employees to use tools in working postures with the arms elevated. These postures are believed to be associated with symptoms of upper limb discomfort, fatigue, and impingement syndromes (Fischer et al., 2007). Overhead working posture, independent of the force or load exerted with the hands, may play a role in the development in these conditions.

Recent studies suggest a more significant role of localized shoulder muscle fatigue in contributing to these disorders. Fatigue of the shoulder muscles may result in changes in normal shoulder kinematics (motion) that affect risk for shoulder impingement disorders (Ebaugh et. al., 2006; Chopp et al., 2010).

The U.S. Manufacturing sector has faced a number of challenges including an overall decline in jobs, an aging workforce, and changes in organizational management systems. Studies have indicated that the average age of industrial workers is increasing and that older workers may differ from younger workers in work capacity, injury risk, severity of injuries, and speed of recovery (Kenny et al., 2008; Gall et al., 2004; Restrepo et al., 2006). As the average age of the industrial population increases and newer systems of work organization (such as lean manufacturing) are changing the nature of labor-intensive work, prevention of MSDs will be more critical to protecting older workers and maintaining productivity.

This study will evaluate the efficacy of two intervention strategies for reducing musculoskeletal symptoms and pain in the shoulder attributable to overhead assembly work in automotive manufacturing. These interventions are, (1) an articulating spring-tensioned tool support device that unloads from the worker the weight of the tool that would otherwise be manually supported, and, (2) a targeted exercise program intended to increase individual employees' strength and endurance in the shoulder and upper arm stabilizing muscle group. As a primary prevention strategy, the tool support engineering control approach is preferred; however, a cost-efficient opportunity exists to concurrently evaluate the efficacy of a preventive exercise program intervention. Both of these intervention approaches have been used in the Manufacturing sector, and preliminary evidence suggests that both approaches may have merit. However, high quality evidence demonstrating their effectiveness, by way of controlled trials, is lacking.

This project will be conducted as a partnership between NIOSH and Toyota Motors Engineering & Manufacturing North America, Inc. (TEMA), with the intervention evaluation study taking place at the Toyota Motor Manufacturing Kentucky, Inc. (TMMK) manufacturing facility in Georgetown, Kentucky.

The prospective intervention evaluation study will be conducted using a group-randomized controlled trial multi-time series design. Four groups of 25–30 employees will be established to test the two intervention treatment conditions (tool support, exercise program), a combined intervention treatment condition, and a control condition. The four groups will be comprised of employees working on two vehicle assembly lines in different parts of the facility, on two work shifts (first and second shift).

Individual randomization to treatment condition is not feasible, so a group-randomization (by work unit) will be used to assign the four groups to treatment and control conditions.

Observations will be made over the 10-month study period and questionnaires will include the Shoulder Rating Questionnaire (SRQ), Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire, a Standardized Nordic Questionnaire for body part discomfort, and a Work Organization Questionnaire. In addition to the monthly questionnaires, a shoulder-specific functional capacity evaluation test battery will be administered pre- and post-intervention, to confirm the efficacy of the targeted exercise program in improving shoulder capacity.

In summary, this study will evaluate the effectiveness of two interventions to reduce musculoskeletal symptoms and pain in the shoulder associated with repetitive overhead work in the manufacturing industry. The evidence-based prevention practices that may result from this associated research project will be disseminated to the greatest audience possible.

NIOSH expects to complete data collection in 2015–2016 and there is no cost to employee respondents, as they will participate in this study during their normal working hours at their regular wage.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Employees	PAR–Q (Physical Activity Readiness)	125	1	2/60	4
	Shoulder Rating Questionnaire (SRQ)	125	10	4/60	83
	Disabilities of the Arm Shoulder and Hand (DASH)	125	10	6/60	125
	Standardized Nordic Questionnaire for Musculoskeletal Symptoms.	125	10	4/60	83
	Work Organization Questionnaire	125	3	26/60	163

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Total	.....	.....	.....	.....	458

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–02328 Filed 2–5–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–R–245]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by March 9, 2015.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, *Attention:* CMS Desk Officer, *Fax Number:* (202) 395–5806 or *Email: OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*
3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare and Medicaid Programs OASIS Collection Requirements as Part of the CoPs for HHAs and Supporting Regulations; *Use:* The Outcome and Assessment Information Set (OASIS) data set is currently mandated for use by Home Health Agencies (HHAs) as a condition of participation (CoP) in the Medicare program. Since 1999, the Medicare CoPs have mandated that HHAs use the OASIS data set when evaluating adult non-maternity patients receiving skilled services. The OASIS is a core standard assessment data set that agencies integrate into their own patient-specific, comprehensive assessment to identify each patient's need for home care that meets the patient's medical, nursing, rehabilitative, social, and discharge planning needs.

The Office of Management and Budget (OMB) approved the OASIS–C1 information collection request on February 6, 2014. We originally planned to use OASIS–C1 to coincide with the original implementation of ICD–10 on October 1, 2014. However, on April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted. This legislation prohibits CMS from adopting ICD–10 coding prior to October 1, 2015. Because OASIS–C1 is based on ICD–10 coding, it is not possible to implement OASIS–C1 prior to October 1, 2015, when ICD–10 is implemented. The passage of the PAMA Act left us with the dilemma of how to collect OASIS data in the interim, until ICD–10 is implemented.

The OASIS–C1/ICD–9 version is an interim version of the OASIS–C1 data item set that was created in response to the legislatively mandated ICD–10 delay. There are five items in OASIS–C1 that require ICD–10 codes. In the OASIS–C1/ICD–9 version, these items have been replaced with the corresponding items from OASIS–C that use ICD–9 coding. The OASIS–C1/ICD–9 version also incorporates updated clinical concepts, modified item wording and response categories and improved item clarity. In addition, the OASIS–C1/ICD–9 version includes a significant decrease in provider burden that was accomplished by the deletion of a number of non-essential data items from the OASIS–C data item set. *Form Number:* CMS–R–245 (OMB control number: 0938–0760); *Frequency:* Occasionally; *Affected Public:* Private sector—business or other for-profit and not-for-profit institutions; *Number of Respondents:* 12,014; *Total Annual*

Responses: 17,268,890; *Total Annual Hours:* 15,305,484. (For policy questions regarding this collection contact Cheryl Wiseman at 410–786–1175.)

Dated: February 3, 2015.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015–02413 Filed 2–5–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–15–15MZ]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. To request more information on the below proposed project or to obtain a copy of the information collection plan and instruments, call 404–639–7570 or send comments to Leroy A. Richardson, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. Written comments should be received within 60 days of this notice.

Proposed Project

Digital Media and Tobacco Outcomes Study—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In 2012, CDC launched the first federally funded, national mass media campaign to educate consumers about the adverse health consequences of tobacco use (the National Tobacco Prevention and Control Public Education Campaign, or ''the campaign''). The campaign continued in 2013 and 2014 with advertisements known as ''Tips from Former Smokers.'' CDC plans to continue the campaign in 2015 and 2016, with new ads scheduled for release between March and July, 2015. CDC is conducting a series of longitudinal surveys to assess campaign impact in both smokers and nonsmokers (OMB No. 0920–0923, exp. 3/31/2017). The campaign evaluation strategy is based on self-reported measures of consumer awareness of and exposure to specific campaign advertisements; changes in consumer knowledge, attitudes, and beliefs relating to smoking and secondhand smoke; smokers' behaviors related to cessation; and nonsmokers' encouragement of smokers to quit smoking and seek cessation services.

The campaign includes digital advertising, which is now a mainstay of tobacco prevention campaigns because of the efficiency of digital ad placement, lower costs associated with digital ads, and the ability to reach individuals who do not use traditional media. Digital advertising also offers a unique opportunity to examine the relationship between ad exposure and consumer behavior. For example, Internet analytic tools can be used to verify an individual's exposure to a digital ad or to ascertain whether an individual has visited Web-based sources of information about tobacco use or tobacco cessation. These tools and methods provide objective measures of ad exposure and information-seeking behavior and are not subject to the recall bias inherent in self-reported data.

To supplement ongoing campaign evaluation efforts, CDC proposes to employ Internet analytic tools as part of an enhanced evaluation of the digital ad component of the mass media campaign. The evaluation study will not be conducted in the general U.S. population of Internet users. Individuals who participate in the proposed evaluation will be smokers recruited from an existing panel of adult Internet users who have agreed to allow monitoring of their Internet usage. Panels of this type are established and utilized by market research firms to elucidate consumer behavior. Panelists agree to download software on their computers that enables the market research company to unobtrusively track their web behavior, including Web sites visited, searches they conduct, purchases they make, and ads that are delivered on sites visited, regardless of whether the ads are selected (clicked) or not. These data are then aggregated and weighted to provide estimates of online consumer behaviors.

CDC will employ an evaluation contractor to interface with a market research company and tobacco smokers who are part of an existing panel. For panelists who agree to participate in the Digital Media and Tobacco Outcomes Study, the contractor will analyze Internet usage data in conjunction with additional information collected directly from the study participants. All information collection will be coordinated with key events in the 2015 mass media campaign.

In the recruitment phase of the study, panelists will be notified about the CDC-sponsored study and will have the opportunity to voluntarily consent to participate or decline to participate. They will also provide demographic information and be screened for eligibility. In the second phase, respondents will complete an online questionnaire soon after the digital ads have been aired (Wave 1 survey). Information will be collected about smokers' exposure to campaign digital advertisements and self-reported knowledge, attitudes, and beliefs related to smoking, and smoking-related information seeking. The questionnaire will also measure behaviors related to smoking cessation and intentions to quit smoking. In the third phase of the study, the same online questionnaire will be administered to respondents approximately 30 days after completion of the first survey (Wave 2 survey).

CDC and the evaluation contractor will use the Internet usage data and the survey information collected from study participants to examine the statistical relationships between confirmed exposure (or non-exposure) to the campaign's digital and social media advertising and outcomes of interest for campaign evaluation. The study will provide CDC with new, timely, and relevant information regarding the reach and efficacy of the digital advertising component of the campaign in 2015. All findings will be interpreted in light of known limitations of the methodology, such as use of a convenience sample of respondents.

OMB approval is requested for one year. Participation is voluntary and there are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Market Research Panelists	Screening and Consent Questionnaire.	50,000	1	2/60	1,667
Adult Panelists Who Are Tobacco Smokers.	Digital Media and Tobacco Outcomes Questionnaire (Wave 1).	5,000	1	20/60	1,667
	Digital Media and Tobacco Outcomes Questionnaire (Wave 2).	2,400	1	20/60	800
Total					4,134

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–02327 Filed 2–5–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers CMS–10410, CMS–R–74, CMS–2552–10 and CMS–855R]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by *April 7, 2015.*

ADDRESSES: When commenting, please reference the document identifier or OMB control number (OCN). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10410 Medicaid Program; Eligibility Changes under the Affordable Care Act of 2010

CMS–R–74 Income and Eligibility Verification System Reporting and Supporting Regulations

CMS–2552–10 Hospital and Hospital Health Care Complex Cost Report

CMS–855R Medicare Enrollment Application: Reassignment of Medicare Benefits

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing

collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Program; Eligibility Changes under the Affordable Care Act of 2010; *Use:* The eligibility systems are essential to the goal of increasing coverage in insurance affordability programs while reducing administrative burden on states and consumers. The electronic transmission and automation of data transfers are key elements in managing the expected insurance affordability program caseload that started in 2014. Accomplishing the same work without these information collection requirements would not be feasible. *Form Number:* CMS–10410 (OMB control number 0938–1147); *Frequency:* Occasionally; *Affected Public:* Individuals or households, and State, Local, and Tribal Governments; *Number of Respondents:* 25,500,096; *Total Annual Responses:* 76,500,149; *Total Annual Hours:* 21,278,142. (For policy questions regarding this collection contact Brenda Sheppard at 410–786–8534).

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Income and Eligibility Verification System Reporting and Supporting Regulations; *Use:* A state Medicaid agency that currently obtains and uses information from certain sources, or with more frequency than specified, could continue to do so to the extent that the verifications are useful and not redundant. An agency that has found it effective to verify all wage or benefit information with another agency or with the recipient is encouraged to continue these practices if it chooses. On the other hand, the agency may implement an approved targeting plan under 42 CFR 435.953. The agency's experience should guide its decision whether to exceed these regulatory requirements on income and eligibility verification. While states may target resources when verifying income of course, agencies are still held accountable for their accuracy in eligibility determinations. *Form Number:* CMS–R–74 (OMB control number 0938–0467); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 50; *Total Annual Responses:* 71; *Total Annual Hours:* 134,865. (For policy questions regarding this collection contact Brenda Sheppard at 410–786–8534).

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Hospital and Hospital Health Care Complex Cost Report; *Use:* Providers of services participating in the Medicare program are required under sections 1815(a) and 1861(v)(1)(A) of the Social Security Act (42 U.S.C. 1395g) to submit annual information to achieve settlement of costs for health care services rendered to Medicare beneficiaries. In addition, regulations at 42 CFR 413.20 and 413.24 require adequate cost data and cost reports from providers on an annual basis.

We are requesting the Office of Management and Budget review and approve this revision to the Form CMS–2552–10, Hospital and Hospital Health Care Complex Cost Report. These cost reports are filed annually by hospitals participating in the Medicare program to determine the reasonable costs incurred to provide medical services to patients. The revisions made to the hospital cost report are in accordance with the statutory requirement for hospice payment reform in § 3132 of the Patient Protection and Affordable Care Act (ACA) (March 23, 2010) and the statutory requirement establishing a prospective payment system for Federally Qualified Health Centers in § 10501(i)(3)(A) of the ACA, codified in section 1834(o) of the Act. *Form Number:* CMS–2552–10 (OMB control number 0938–0050); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments, private sector (for-profit and not-for-profit institutions); *Number of Respondents:* 6,157; *Total Annual Responses:* 6,157; *Total Annual Hours:* 4,143,661. (For policy questions regarding this collection contact Gail Duncan at 410–786–7278).

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Enrollment Application: Reassignment of Medicare Benefits; *Use:* The primary function of the CMS 855R enrollment application is to allow physicians and non-physician practitioners to reassign their Medicare benefits to a group practice and to gather information from the individual that tells us who he/she is, where he or she renders services, and information necessary to establish correct claims payment. The goal of periodically evaluating and revising the CMS 855R enrollment application is to simplify and clarify the information collection without jeopardizing our need to collect specific information.

At this time, CMS is making very few minor revisions to the CMS 855R (Reassignment of Benefits) Medicare enrollment application (OMB No. 0938–1179). Two sections within the form are being reversed to maintain sync with online and paper forms. The previously approved CMS 855R section 2 collected information regarding the individual practitioner who is reassigning benefits and section 3 collected information regarding the organization/group receiving the reassigned benefits. These two sections have been reversed so that section 2 now collects information on the regarding the organization/group receiving the reassigned benefits and section 3 now collects information on the individual practitioner who is reassigning benefits. No information or data collection within these sections was revised. The sections were merely re-sequenced and re-numbered to maintain sync between online and paper forms. With the exception of this section reversal and adding the word ''optional'' to sections 4 and 5 (primary practice location and contact person information), there are no other revisions. These revisions offer no new data collection in this revision package. The addition of the optional choice in sections 4 and 5 could potentially reduce the burden to providers who choose not to complete either or both optional sections. *Form Number:* CMS–855R (OMB control number 0938–1179); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments, private sector (for-profit and not-for-profit institutions); *Number of Respondents:* 379,619; *Total Annual Responses:* 379,619; *Total Annual Hours:* 94,905. (For policy questions regarding this collection contact Kim McPhillips at 410–786–5374).

Dated: February 3, 2015.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015–02414 Filed 2–5–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Administration on Intellectual and Developmental Disabilities (AIDD); Notice of Meeting

AGENCY: President's Committee for People with Intellectual Disabilities (PCPID).

ACTION: Notice of meeting.

DATES: Thursday, February 19, 2015 from 9:00 a.m. to 4:30 p.m.; and Friday, February 20, 2015 from 9:00 a.m. to 2:00 p.m. (EST)

These meetings will be open to the general public.

ADDRESSES: These meetings will be held in the U.S. Department of Health and Human Services/Hubert H. Humphrey Building located at 200 Independence Avenue SW., Conference Room 505A, Washington, DC 20201.

Individuals who would like to participate via conference call may do so by dialing toll-free 888–935–0260, when prompted enter pass code: 3656064. Individuals whose full participation in the meeting will require special accommodations (*e.g.,* sign language interpreting services, assistive listening devices, materials in alternative format such as large print or Braille) should notify Dr. MJ Karimi, PCPID Team Lead, via email at *MJ.Karimie@acl.hhs.gov*, or via telephone at 202–357–3588, no later than Friday, February 13, 2015. The PCPID will attempt to accommodate requests made after that date, but cannot guarantee the ability to grant requests received after this deadline. All meeting sites are barrier free, consistent with the Americans with Disabilities Act (ADA) and the Federal Advisory Committee Act (FACA).

Agenda: The Committee Members will discuss preparation of the PCPID 2015 Report to the President, including its content and format, and related data collection and analysis required to complete the writing of the Report. They will also receive presentations from selected experts in the field of Technology for People with Intellectual and Developmental Disabilities.

Additional Information: For further information, please contact Dr. MJ Karimi, Team Lead, President's Committee for People with Intellectual Disabilities, One Massachusetts Avenue NW., Room 4206, Washington, DC 20201. Telephone: 202–357–3588. Fax: 202–205–8037. Email: *MJ.Karimie@acl.hhs.gov*.

SUPPLEMENTARY INFORMATION: The PCPID acts in an advisory capacity to the President and the Secretary of Health and Human Services, through the Administration on Intellectual and Developmental Disabilities, on a broad range of topics relating to programs, services and supports for persons with intellectual disabilities. The PCPID Executive Order stipulates that the Committee shall: (1) Provide such advice concerning intellectual disabilities as the President or the Secretary of Health and Human Services may request; and (2) provide advice to the President concerning the following for people with intellectual disabilities: (A) Expansion of educational opportunities; (B) promotion of homeownership; (C) assurance of workplace integration; (D) improvement of transportation options; (E) expansion of full access to community living; and (F) increasing access to assistive and universally designed technologies.

Dated: January 28, 2015.

Aaron Bishop,

Commissioner, Administration on Intellectual and Developmental Disabilities (AIDD).

[FR Doc. 2015–02514 Filed 2–5–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0161]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Export of Food and Drug Administration Regulated Products: Export Certificates

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 9, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0498. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Export of Food and Drug Administration Regulated Products: Export Certificates—(OMB Control Number 0910–0498)—Extension

In April 1996, a law entitled ''The FDA Export Reform and Enhancement Act of 1996'' (FDAERA) amended sections 801(e) and 802 of the FD&C Act (21 U.S.C. 381(e) and 382). It was designed to ease restrictions on exportation of unapproved pharmaceuticals, biologics, and devices regulated by FDA. Section 801(e)(4) of the FDAERA provides that persons exporting certain FDA regulated products may request FDA to certify that the products meet the requirements of 801(e) and 802 or other requirements of the FD&C Act. This section of the law requires FDA to issue certification within 20 days of receipt of the request and to charge firms up to $175 for the certifications.

This section of the FD&C Act authorizes FDA to issue export certificates for regulated pharmaceuticals, biologics, and devices that are legally marketed in the United States, as well as for these same products that are not legally marketed but are acceptable to the importing country, as specified in sections 801(e) and 802 of the FD&C Act. FDA has developed four types of certificates that satisfy the requirements of section 801(e)(4)(B) of the FD&C Act: (1) Certificates to Foreign Governments, (2) Certificates of Exportability, (3) Certificates of a Pharmaceutical Product, and (4) Non-Clinical Research Use Only Certificates. Table 1 of this document lists the different certificates and details their use:

TABLE 1—CERTIFICATES AND USES

Type of certificate	Use
''Supplementary Information Certificate to Foreign Government Requests''. ''Exporter's Certification Statement Certificate to Foreign Government''. ''Exporter's Certification Statement Certificate to Foreign Government (For Human Tissue Intended for Transplantation)''.	For the export of products legally marketed in the United States.
''Supplementary Information Certificate of Exportability Requests''. Exporter's Certification Statement Certificate of Exportability''.	For the export of products not approved for marketing in the United States (unapproved products) that meet the requirements of sections 801(e) or 802 of the FD&C Act.
''Supplementary Information Certificate of a Pharmaceutical Product''. ''Exporter's Certification Statement Certificate of a Pharmaceutical Product''.	Conforms to the format established by the World Health Organization and is intended for use by the importing country when the product in question is under consideration for a product license that will authorize its importation and sale or for renewal, extension, amending, or reviewing a license.
''Supplementary Information Non-Clinical Research Use Only Certificate''. ''Exporter's Certification Statement (Non-Clinical Research Use Only)''.	For the export of a non-clinical research use only product, material, or component that is not intended for human use which may be marketed in, and legally exported from the United States under the FD&C Act.

FDA will continue to rely on self-certification by manufacturers for the first three types of certificates listed in table 1 of this document. Manufacturers are requested to self-certify that they are in compliance with all applicable requirements of the FD&C Act, not only at the time that they submit their request to the appropriate center, but also at the time that they submit the certification to the foreign government.

The appropriate FDA centers will review product information submitted by firms in support of their certificate and any suspected case of fraud will be referred to FDA's Office of Criminal Investigations for follow up. Making or submitting to FDA false statements on any documents may constitute violations of 18 U.S.C. 1001, with penalties including up to $250,000 in fines and up to 5 years imprisonment.

In the **Federal Register** of November 14, 2014 (79 FR 68277), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA center and FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Center for Biologics Evaluation and Research ..... FDA 3613. FDA 3613a. FDA 3613b. FDA 3613c.	2,114	1	2,114	1	2,114
Center for Devices and Radiological Health ..... FDA 3613. FDA 3613a. FDA 3613c.	10,528	1	10,528	2	21,056
Center for Veterinary Medicine ..... FDA 3613. FDA 3613a. FDA 3613b.	855	1	855	1	855
Total	.....	.....	.....	.....	24,025

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–02348 Filed 2–5–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1168]

Generic Drug User Fee Amendments of 2012; September 2014 Public Hearing on Policy Development; Reopening of Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the reopening of the docket to solicit public comment on certain topics related to implementation of the Generic Drug User Fee Amendments of 2012 (GDUFA) and the GDUFA Commitment Letter that accompanies the legislation. A public hearing in September 2014 provided an opportunity for public input on future

policy priorities. FDA is seeking additional written comments from all interested parties, including, but not limited to, regulated industry, consumers, patients, caregivers, health care professionals, and patient groups.

DATES: Submit electronic or written comments by March 9, 2015.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Giaquinto, Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 75, Rm. 1670, Silver Spring, MD 20993–0002, 240–402–7930, *elizabeth.giaquinto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the Hatch-Waxman Amendments) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The Hatch-Waxman Amendments created section 505(j) of the FD&C Act (21 U.S.C. 355(j)), which established the abbreviated new drug application (ANDA) approval pathway, which allows lower-priced generic versions of previously approved innovator drugs to be approved and marketed.

On July 9, 2012, GDUFA was signed into law by the President to help speed the delivery of safe and effective generic drugs to the public and to reduce costs to industry. Under GDUFA, FDA agreed to certain obligations as laid out in the GDUFA Commitment Letter that accompanies the legislation.[1] To support these obligations, FDA is developing numerous guidance documents. At the time of the September 2014 public hearing, FDA had developed the following draft guidances for industry:[2]

- ''ANDA Submissions—Content and Format of Abbreviated New Drug Applications''
- ''ANDA Submissions—Refuse to Receive for Lack of Proper Justification of Impurity Limits''
- ''ANDA Submissions—Amendments and Easily Correctable Deficiencies Under GDUFA''
- ''ANDA Submissions—Prior Approval Supplements Under GDUFA''
- ''Controlled Correspondence Related to Generic Drug Development''

II. Purpose and Scope of the September 2014 Public Hearing

A. GDUFA Implementation: Draft Guidance Documents

The purpose of the public hearing was to: (1) Solicit public comment on the five draft guidance documents described in section I that FDA had issued to facilitate implementation of GDUFA and (2) recommend future policy priorities, including recommendations for additional guidance topics to facilitate GDUFA implementation. We continue to solicit comments from interested members of the public, including industry, consumers, patient groups, caregivers, and health care professionals, on the following topics related to GDUFA implementation guidances:

- Are there comments on the five guidances described in section I?
- Are there GDUFA implementation issues related to the five draft guidances described in section I that have not been addressed?
- What other GDUFA implementation topics need the development of guidance?
- Are there any topics or issues related to generic drug development other than those related to GDUFA implementation that need the development of guidance?

B. GDUFA Implementation Related to Generic Drug Exclusivity

Another purpose of the hearing was to solicit feedback on issues that may arise in FDA's consideration of 180-day exclusivity provided for in section 505(j)(5)(B)(iv) of the FD&C Act.

Timing of ANDA approval is directly affected by an applicant's eligibility for 180-day exclusivity, and thus FDA's consideration of any issues related to 180-day exclusivity is a component of approval actions. FDA decisions regarding 180-day exclusivity are fact-specific, and the facts that have the potential to determine eligibility for exclusivity may shift up to the time when an ANDA that is eligible for 180-day exclusivity, or another ANDA referencing the same listed drug, is ready for approval.

With the enactment of GDUFA, FDA will take actions on pending applications consistent with the timeframes agreed upon in the GDUFA Commitment Letter. During the hearing, we sought input on possible processes FDA might introduce under GDUFA for making determinations on 180-day exclusivity, as described in the following questions:

- Should FDA's consideration of eligibility for 180-day exclusivity for a specific drug product be a public process, including consideration of whether a first applicant has forfeited its eligibility for exclusivity under section 505(j)(5)(D) of the FD&C Act? If a public process is advisable, would it be so in all instances, or is there a subset of circumstances in which the process should be public? Also, what administrative mechanisms would best facilitate such a process?
- Legal challenges to FDA's decisions on 180-day exclusivity often must be resolved on an expedited basis that can be inconvenient for the parties and the court. What legal or regulatory mechanisms, if any, are available to better facilitate FDA's determination of and orderly resolution of sponsors' challenges to 180-day exclusivity determinations?
- Are there other topics related to 180-day exclusivity on which you would like to comment?
- Are there topics related to 180-day exclusivity that would benefit from FDA guidance?

We continue to seek comment on these topics. When submitting input on the questions provided in this notice, we encourage commenters to consider FDA's statutory and regulatory authorities, including any restrictions on FDA's authority to disclose certain information related to unapproved ANDAs.

C. GDUFA Implementation and Potential First Generics

At the public hearing, we also sought comment on meeting the goals of the GDUFA Commitment Letter with regard to the ''first generics'' review prioritization category. Subsequent to that hearing, the Agency opened a separate, dedicated docket, Docket No. FDA–2014–N–1741, seeking comment on ''first generic'' criteria, as described in the **Federal Register** notice ''Proposed Criteria for 'First Generic' Submissions for Purposes of Abbreviated New Drug Application Review Prioritization Under the Generic Drug User Fee Amendments; Establishment of a Public Docket.'' This

[1] See Generic Drug User Fee Act Program Performance Goals and Procedures (GDUFA Commitment Letter) for fiscal years 2013 through 2017, available at *http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf*).

[2] The draft guidance documents referenced in this document are available on the FDA Drugs guidance Web page at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

docket opened on November 19, 2014, and closed on December 19, 2014. We are no longer seeking comment on the ''first generic'' review prioritization category at this time.

III. How To Submit 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.*

Dated: February 2, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–02401 Filed 2–5–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0824]

Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Anesthetic and Analgesic Drug Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 18, 2015, from 8 a.m. to 5 p.m.

Location: Holiday Inn Gaithersburg, Grand Ballroom, 2 Montgomery Village Ave., Gaithersburg, MD 20879. The hotel's telephone number is 301–948–8900. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

Contact Person: Stephanie L. Begansky, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *AADPAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss new drug application (NDA) 022225, sugammadex sodium injection, submitted by Organon USA Inc., for the proposed indication of reversal of moderate or deep neuromuscular blockade induced by rocuronium or vecuronium.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 4, 2015. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 24, 2015. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 25, 2015.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Stephanie L. Begansky at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 2, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015–02408 Filed 2–5–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0179]

Training Program for Regulatory Project Managers; Information Available to Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research (CDER) is announcing the continuation of the Regulatory Project Management Site Tours and Regulatory Interaction Program (the Site Tours Program). The purpose of this document is to invite pharmaceutical companies interested in participating in this program to contact CDER.

DATES: Pharmaceutical companies may submit proposed agendas to the Agency by April 7, 2015.

FOR FURTHER INFORMATION CONTACT: Dan Brum, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5480, Silver Spring, MD 20993–0002, 301–796–0578, *dan.brum@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

An important part of CDER's commitment to make safe and effective drugs available to all Americans is optimizing the efficiency and quality of the drug review process. To support this primary goal, CDER has initiated various training and development programs to promote high performance in its regulatory project management staff. CDER seeks to significantly enhance review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is continuing its training program to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide the following: (1) Firsthand exposure to industry's drug development processes, and (2) a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

II. The Site Tours Program

In this program, over a 2- to 3-day period, small groups (five or less) of regulatory project managers, including a senior level regulatory project manager, can observe operations of pharmaceutical manufacturing and/or packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. Neither this tour nor any part of the program is intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but is meant rather to improve mutual understanding and to provide an avenue for open dialogue. During the Site Tours Program, regulatory project managers will also participate in daily workshops with their industry counterparts, focusing on selective regulatory issues important to both CDER staff and industry. The primary objective of the daily workshops is to learn about the team approach to drug development, including drug discovery, preclinical evaluation, tracking mechanisms, and regulatory submission operations. The overall benefit to regulatory project managers will be exposure to project management, team techniques, and processes employed by the pharmaceutical industry. By participating in this program, the regulatory project manager will grow professionally by gaining a better understanding of industry processes and procedures.

III. Site Selection

All travel expenses associated with the Site Tours Program will be the responsibility of CDER; therefore, selection will be based on the availability of funds and resources for each fiscal year. Selection will also be based on firms having a favorable facility status as determined by FDA's Office of Regulatory Affairs District Offices in the firms' respective regions. Firms interested in offering a site tour or learning more about this training opportunity should respond by submitting a proposed agenda to Dan Brum (see **DATES** and **FOR FURTHER INFORMATION CONTACT**).

Dated: February 2, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–02426 Filed 2–5–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than April 7, 2015.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10C–03, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Nurse Corps Scholarship Program, OMB No. 0915–0301—Revision.

Abstract: The Nurse Corps Scholarship Program (Nurse Corps SP) is a competitive Federal program, which awards scholarships to individuals for attendance at accredited schools of nursing. The Bureau of Health Workforce (BHW) in HRSA administers the program. The scholarship consists of payment of tuition, fees, other reasonable educational costs, and a monthly support stipend. In return, the students agree to provide a minimum of 2 years of full-time clinical service (or an equivalent part-time commitment, as approved by the Nurse Corps SP) at a health care facility with a critical shortage of nurses as defined by the program. Nurse Corps SP recipients must be willing to (and are required to) fulfill their Nurse Corps SP service commitment at a health care facility with a critical shortage of nurses in the United States, which includes, in addition to the several states, only: The District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau.

Students who are uncertain of their commitment to provide nursing care in a health care facility with a critical shortage of nurses in the United States or these territories are advised not to participate in the program.

Need and Proposed Use of the Information: The Nurse Corps Scholarship Program needs to collect data to determine an applicant's eligibility for the program, to monitor a participant's continued enrollment in a school of nursing, to monitor the participant's compliance with the Nurse Corps Scholarship Program service obligation, and to obtain data on its program to ensure compliance with statutory mandates and prepare annual reports to Congress. The following information will be collected: (1) From

the applicants and/or the schools—general applicant and nursing school data such as full name, location, tuition/fees, and enrollment status; (2) from the schools, on an annual basis—data concerning tuition/fees and student enrollment status; and (3) from the participants and their health care facilities with a critical shortage of nurses, on a biannual basis—data concerning the participant's employment status, work schedule and leave usage. BHW enters the cost information into its data system, along with the projected amount for the monthly stipend, to determine the amount of each scholarship award.

Likely Respondents: Nurse Corps Scholarship Program scholars in school and graduates.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

Total Estimated Annualized burden hours:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Eligible Applications	2,600	1	2,600	2	5,200
In-School Monitoring	500	2	1,000	2	2,000
In-Service Monitoring	500	2	1,000	1	1,000
Total	3,600		4,600		8,200

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–02314 Filed 2–5–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Dietary Supplements 2015–2020 Strategic Plan Request for Comments

SUMMARY: The Office of Dietary Supplements (ODS) at the National Institutes of Health (NIH) has initiated a strategic planning process that will culminate in the ODS Strategic Plan for 2015–2020. To assist with this process, the ODS requests input from research communities—academic, government, and industry—and from other interested parties.

DATES: In order to ensure full consideration, all responses must be submitted by midnight, March 6, 2015.

ADDRESSES: Interested individuals and organizations should submit their responses to *ODSplan@od.nih.gov.*

FOR FURTHER INFORMATION CONTACT: Anne L. Thurn, Ph.D., Office of Dietary Supplements, National Institutes of Health, 6100 Executive Boulevard, Room 3B01, Bethesda, MD 20892–7517, Phone: 301–435–2920, Fax: 301–480–1845, Email: *ODSplan@od.nih.gov.*

SUPPLEMENTARY INFORMATION: The overall purpose of the strategic planning effort is to identify both new opportunities and emerging needs for incorporation in the programmatic efforts of the Office. A background paper, ODS Strategic Plan 2010–2014 Progress Report, summarizes progress in five key areas of ODS activities. The background paper and related information are available on the ODS Web site at *http://ods.od.nih.gov/strategicplan.*

Guidance is being requested from all interested parties on these important issues.

- Are the current strategic goals adequate?
- Is ODS meeting its stakeholders' needs?
- In the future, should some of ODS's current programs or activities be given higher (or lower) priority?
- How can ODS more effectively provide useful information to the ODS user community, including consumers, investigators, practitioners, industry, media, policy makers, government, and other interested parties?

Dated: January 30, 2015.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2015–02370 Filed 2–5–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2014–0973; OMB Control Number 1625–0077]

Collection of Information Under Review by Office of Management and Budget

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding Information Collection Requests (ICRs), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval of an extension of a currently approved collection of information: 1625–0077, Security Plans for Ports, Vessels, Facilities, Outer Continental Shelf Facilities and Other Security-Related Requirements. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before April 7, 2015.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2014–0973] to the Docket Management Facility (DMF) at the U.S. Department of Transportation (DOT) and/or to OIRA. To avoid duplicate submissions, please use only one of the following means:

(1) Online: (a) To Coast Guard docket at *http://www.regulations.gov.* (b) To OIRA by email via: *OIRA-submission@omb.eop.gov* .

(2) Mail: (a) DMF (M–30), DOT, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. (b) To OIRA, 725 17th Street NW., Washington, DC 20503, attention Desk Officer for the Coast Guard.

(3) Hand Delivery: To DMF address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(4) Fax: (a) To DMF, 202–493–2251. (b) To OIRA at 202–395–6566. To ensure your comments are received in a timely manner, mark the fax, attention Desk Officer for the Coast Guard.

The DMF maintains the public docket for this Notice. Comments and material received from the public, as well as documents mentioned in this Notice as being available in the docket, will become part of the docket and will be available for inspection or copying at Room W12–140 on the West Building Ground Floor, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find the docket on the Internet at *http://www.regulations.gov.*

Copies of the ICRs are available through the docket on the Internet at *http://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–612), Attn: Paperwork Reduction Act Manager, US Coast Guard, 2703 Martin Luther King Jr. Ave. SE., Stop 7710, Washington DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: Contact Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532 or fax 202–372–8405, for questions on these documents. Contact Ms. Cheryl Collins, Program Manager, Docket Operations, 202–366–9826, for questions on the docket.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICRs referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG 2014–0973], and must be received by March 9, 2015. We will post all comments received, without change, to *http://www.regulations.gov.* They will include any personal information you provide. We have an agreement with DOT to use their DMF. Please see the ''Privacy Act'' paragraph below.

Submitting Comments

If you submit a comment, please include the docket number [USCG–2014–0973]; indicate the specific section of the document to which each comment applies, providing a reason for each comment. You may submit your comments and material online (via *http://www.regulations.gov*), by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via *www.regulations.gov,* it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the DMF. We recommend you include your name, mailing address, an email address, or other contact information in the body of your document so that we can contact you if we have questions regarding your submission.

You may submit comments and material by electronic means, mail, fax, or delivery to the DMF at the address under **ADDRESSES**, but please submit them by only one means. To submit your comment online, go to *http://www.regulations.gov,* and type ''USCG–2014–0973'' in the ''Search'' box. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and will address them accordingly.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this Notice as being available in the docket, go to *http://www.regulations.gov*, click on the ''read comments'' box, which will then become highlighted in blue. In the ''Search'' box insert ''USCG–2014–0973'' and click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column. You may also visit the DMF in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

OIRA posts its decisions on ICRs online at *http://www.reginfo.gov/public/do/PRAMain* after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Numbers: 1625–0077.

Privacy Act

Anyone can search the electronic form of comments received in dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act statement regarding Coast Guard public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (79 FR 69870, November 24, 2014) required by 44 U.S.C. 3506(c)(2). That Notice elicited no comments.

Information Collection Request

1. *Title:* Security Plans for Ports, Vessels, Facilities, Outer Continental Shelf Facilities and Other Security-Related Requirements.

OMB Control Number: 1625–0077.

Type of Request: Extension of a currently approved collection.

Respondents: Vessel and facility owners and operators.

Abstract: This information collection is associated with the maritime security requirements mandated by the Maritime Transportation Security Act (MTSA) of 2002. Security assessments, security plans and other security-related requirements are found in Title 33 CFR chapter I, subchapter H, and 33 CFR parts 120 and 128.

Forms: CG–6025 and CG–6025A.

Burden Estimate: The estimated burden remains 1,108,043 hours a year.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: February 2, 2015.

Thomas P. Michelli,

Chief Information Officer, Acting, U.S. Coast Guard.

[FR Doc. 2015–02446 Filed 2–5–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2015–0006; OMB Control Number 1625–0034]

Information Collection Request to Office of Management and Budget

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICRs) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval of an extension of a currently approved collection: 1625–0034, Ships' Stores Certification for Hazardous Materials Aboard Ships. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before April 7, 2015.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2015–0006] to the Docket Management Facility (DMF) at the U.S. Department of Transportation (DOT). To avoid duplicate submissions, please use only one of the following means:

(1) Online: *http://www.regulations.gov.*

(2) Mail: DMF (M–30), DOT, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

(3) Hand delivery: Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(4) Fax: 202–493–2251. To ensure your comments are received in a timely manner, mark the fax, to attention Desk Officer for the Coast Guard.

The DMF maintains the public docket for this Notice. Comments and material received from the public, as well as documents mentioned in this Notice as being available in the docket, will become part of the docket and will be available for inspection or copying at room W12–140 on the West Building Ground Floor, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find the docket on the Internet at *http://www.regulations.gov.*

Copies of the ICR(s) are available through the docket on the Internet at *http://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–612), Attn: Paperwork Reduction Act Manager, US Coast Guard, 2703 Martin Luther King Jr Ave. SE., Stop 7710, Washington DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents. Contact Ms. Cheryl Collins, Program Manager, Docket Operations, 202–366–9826, for questions on the docket.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether these ICRs should be granted based on the Collections being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. In response to your comments, we may revise these ICRs or decide not to seek approval of revisions of the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2015–0006], and must be received by April 7, 2015. We will post all comments received, without change, to *http://www.regulations.gov.* They will include any personal information you provide. We have an agreement with DOT to use their DMF. Please see the ''Privacy Act'' paragraph below.

Submitting Comments

If you submit a comment, please include the docket number [USCG–2015–0006], indicate the specific section of the document to which each comment applies, providing a reason for each comment. You may submit your comments and material online (via *http://www.regulations.gov*), by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via *www.regulations.gov,* it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the DMF. We recommend you include your name, mailing address, an email address, or other contact information in the body of your document so that we can contact you if we have questions regarding your submission.

You may submit your comments and material by electronic means, mail, fax, or delivery to the DMF at the address under **ADDRESSES**; but please submit them by only one means. To submit your comment online, go to *http://www.regulations.gov,* and type ''USCG–

2015–0006'' in the ''Search'' box. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and will address them accordingly.

Viewing comments and documents: To view comments, as well as documents mentioned in this Notice as being available in the docket, go to *http://www.regulations.gov,* click on the ''read comments'' box, which will then become highlighted in blue. In the ''Search'' box insert ''USCG–2015–0006'' and click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column. You may also visit the DMF in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act

Anyone can search the electronic form of comments received in dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act statement regarding Coast Guard public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Information Collection Request

1. *Title:* Ships' Stores Certificates for Hazardous Materials Aboard Ships.

OMB Control Number: 1625–0034.

Summary: The information is used by the Coast Guard to ensure that personnel aboard ships are made aware of the proper usage and stowage instructions for certain hazardous materials. Provisions are made for waivers of products in special Department of Transportation (DOT) hazard classes.

Need: Section 3306 of 46 U.S.C. authorizes the Coast Guard to prescribe regulations for the transportation, stowage, and use of ships' stores and supplies of a dangerous nature. Part 147 of 46 CFR prescribes the regulations for hazardous ships' stores.

Forms: None.

Respondents: Owners and operators of ships, suppliers and manufacturers of hazardous materials used on ships.

Frequency: On occasion.

Burden Estimate: The estimated burden remains 8 hours a year.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: February 2, 2015.

Thomas P. Michelli,

Chief Information Officer, Acting, U.S. Coast Guard.

[FR Doc. 2015–02493 Filed 2–5–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2014–0665; OMB Control Number 1625–0068]

Collection of Information Under Review by Office of Management and Budget

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding Information Collection Requests (ICRs), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval of an extension to the following collection of information: 1625–0068, State access to the Oil Spill Liability Trust Fund for removal costs under the Oil Pollution Act of 1990. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before March 9, 2015.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2014–0665] to the Docket Management Facility (DMF) at the U.S. Department of Transportation (DOT) and/or to OIRA. To avoid duplicate submissions, please use only one of the following means:

(1) *Online:* (a) To Coast Guard docket at *http://www.regulations.gov.* (b) To OIRA by email via: *OIRA-submission@omb.eop.gov.*

(2) *Mail:* (a) DMF (M–30), DOT, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. (b) To OIRA, 725 17th Street NW., Washington, DC 20503, attention Desk Officer for the Coast Guard.

(3) *Hand Delivery:* To DMF address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(4) *Fax:* (a) To DMF, 202–493–2251. (b) To OIRA at 202–395–6566. To ensure your comments are received in a timely manner, mark the fax, attention Desk Officer for the Coast Guard.

The DMF maintains the public docket for this Notice. Comments and material received from the public, as well as documents mentioned in this Notice as being available in the docket, will become part of the docket and will be available for inspection or copying at Room W12–140 on the West Building Ground Floor, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find the docket on the Internet at *http://www.regulations.gov.*

Copies of the ICRs are available through the docket on the Internet at *http://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–612), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr Ave SE., STOP 7710, Washington, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: Contact Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532 or fax 202–372–8405, for questions on these documents. Contact Ms. Cheryl Collins, Program Manager, Docket Operations, 202–366–9826, for questions on the docket.

SUPPLEMENTARY INFORMATION:

Public Participation and Request For Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collections. There is one ICR for each Collection.

The Coast Guard invites comments on whether these ICRs should be granted based on the Collections being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection;

and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG–2014–0665], and must be received by March 9, 2015. We will post all comments received, without change, to *http://www.regulations.gov*. They will include any personal information you provide. We have an agreement with DOT to use their DMF. Please see the ''Privacy Act'' paragraph below.

Submitting Comments

If you submit a comment, please include the docket number [USCG–2014–0665]; indicate the specific section of the document to which each comment applies, providing a reason for each comment. You may submit your comments and material online (via *http://www.regulations.gov*), by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via *www.regulations.gov,* it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the DMF. We recommend you include your name, mailing address, an email address, or other contact information in the body of your document so that we can contact you if we have questions regarding your submission.

You may submit comments and material by electronic means, mail, fax, or delivery to the DMF at the address under **ADDRESSES**, but please submit them by only one means. To submit your comment online, go to *http://www.regulations.gov,* and type ''USCG–2014–0665'' in the ''Search'' box. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and will address them accordingly.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this Notice as being available in the docket, go to *http://www.regulations.gov,* click on the ''read comments'' box, which will then become highlighted in blue. In the ''Search'' box insert ''USCG–2014–0665'' and click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column. You may also visit the DMF in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

OIRA posts its decisions on ICRs online at *http://www.reginfo.gov/public/do/PRAMain* after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Numbers: 1625–0068.

Privacy Act

Anyone can search the electronic form of comments received in dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act statement regarding Coast Guard public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (79 FR 56082, September 18, 2014) required by 44 U.S.C. 3506(c)(2). That Notice elicited no comments.

Information Collection Request

1. *Title:* State access to the Oil Spill Liability Trust Fund for removal costs under the Oil Pollution Act of 1990.

OMB Control Number: 1625–0068.

Type of Request: Extension of a currently approved collection.

Respondents: Governor of a state or their designated representative.

Abstract: State access to the Oil Spill Liability Trust Fund. The documentation will be used to verify that the requested funds were expended for proper purposes.

Forms: None.

Burden Estimate: The estimated burden is 3 hours a year.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: February 2, 2015.

Thomas P. Michelli,

Chief Information Officer, Acting, U.S. Coast Guard.

[FR Doc. 2015–02466 Filed 2–5–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2014–0027; OMB No. 1660–0106]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Integrated Public Alert and Warning Systems (IPAWS) Inventory

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission will describe the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort and resources used by respondents to respond) and cost, and the actual data collection instruments FEMA will use.

DATES: Comments must be submitted on or before March 9, 2015.

ADDRESSES: Submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the Desk Officer for the Department of Homeland Security, Federal Emergency Management Agency, and sent via electronic mail to *oira.submission@omb.eop.gov* or faxed to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Director, Records Management Division, 500 C Street SW., 7NE, Washington, DC 20472–3100, facsimile number (202) 212–4701, or email address *FEMA-Information-Collections-Management@fema.dhs.gov*.

SUPPLEMENTARY INFORMATION:

Collection of Information

Title: Integrated Public Alert and Warning Systems (IPAWS) Inventory.

Type of information collection: Revision of a currently approved collection.

Form Titles and Numbers: FEMA Form 142–1–1 IPAWS Inventory.

Abstract: FEMA will be conducting an inventory, evaluation and assessment of the capabilities of Federal, State, territorial, Tribal, and local government alert and warning systems. The IPAWS Inventory and Evaluation Survey collects data to facilitate the integration of public alert and warning systems. It also reduces Federal planning cost by leveraging existing State systems.

Affected Public: State, local, or Tribal Government.

Estimated Number of Respondents: 3,200.

Estimated Total Annual Burden Hours: 6,400.

Estimated Cost: The estimated annual cost to respondents for the hour burden is $245,120.00. There are no annual costs to respondents' operations and maintenance costs for technical services. There are no annual start-up or capital costs. The cost to the Federal Government is $766,396.15.

Dated: February 2, 2015.

Charlene D. Myrthil,

Director, Records Management Division, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2015–02458 Filed 2–5–15; 8:45 am]

BILLING CODE 9111–AB–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5831–N–10]

30-Day Notice of Proposed Information Collection: Manufactured Housing Dispute Resolution

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD has submitted the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, in accordance with the Paperwork Reduction Act. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: *Comments Due Date:* March 9, 2015.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email at *Colette Pollard @hud.gov* or telephone 202–402–3400. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD has submitted to OMB a request for approval of the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on November 17, 2014.

A. Overview of Information Collection

Title of Information Collection: Manufactured Housing Dispute Resolution.

OMB Approval Number: 2502–0562.

Type of Request: Extension.

Form Number: HUD–310–DRSC and HUD–311–DR.

Description of the need for the information and proposed use: 310–DRSC is used to collect information on an individual state that would like to have a dispute resolution program either as part of their state plan or outside of the state plan. The HUD–311–DR form is used to collect pertinent information from the party seeking dispute resolution.

Respondents: (*i.e.* affected public) Individuals or Households.

Estimated Number of Respondents: 114.

Estimated Number of Responses: 114.

Frequency of Response: Once per complaint.

Average Hours per Response: 1.5 hourly.

Total Estimated Burdens: 511.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(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 through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: January 29, 2015.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2015–02464 Filed 2–5–15; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5831–N–09]

30-Day Notice of Proposed Information Collection: New Construction Subterranean Termite Protection for New Homes

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD has submitted the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, in accordance with the Paperwork Reduction Act. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: *Comments Due Date: March 9, 2015.*

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email at *Colette Pollard@hud.gov* or telephone 202–402–3400. Persons with hearing or speech impairments may access this

number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD has submitted to OMB a request for approval of the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on October 24, 2014.

A. Overview of Information Collection

Title of Information Collection: New Construction Subterranean Termite Protection for new homes.

OMB Approval Number: 2502–0525.

Type of Request: Extension of a currently approved collection.

Form Number: HUD NPFA–99A and HUD NPFA–99B.

Description of the need for the information and proposed use: HUD regulations at 24 CFR 200.926d(b)(3) require that the sites for HUD insured structures must be free of termite hazards. The HUD–NPCA–99–A requires the builder to certify that all required treatment for termites was performed by an authorized pest control company and further that the builder guarantees the treated area against infestation for one year. The form HUD–NPCA–99–B requires a licensed pest control company to provide to the builder a record of specific treatment information in those cases when the soil treatment method is used for prevention of subterranean termite infestation. When applicable the HUD–NPCA–99–B must accompany the HUD–NPCA–99–A. If the requested data is not collected, new home purchasers and HUD are subject to the risk of purchasing or insuring a home that could be immediately infested by termites and would have no recourse against the builder.

Respondents: Business.

Estimated Number of Respondents: 30,000.

Estimated Number of Responses: 60,000.

Frequency of Response: On Occasions.

Average Hours per Response: 0.083 and .25, respectively.

Total Estimated Burdens: 9,990.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(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 through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: *January 29, 2015.*

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2015–02478 Filed 2–5–15; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5838–N–01]

60-Day Notice of Proposed Information Collection: Family Unification Program

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, PIH, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* April 7, 2015.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Arlette Mussington, Office of Policy, Programs and Legislative Initiatives, PIH, Department of Housing and Urban Development, 451 7th Street SW., (L'Enfant Plaza, Room 2206), Washington, DC 20410; telephone 202–402–4109, (this is not a toll-free number). Persons with hearing or speech impairments may access this number via TTY by calling the Federal Information Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Mussington.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Family Unification Program (FUP).

OMB Approval Number: 2577–0259.

Type of Request: Extension of currently approved collection.

Form Number: HUD–52515; HUD–50058; HUD–2993; HUD–96011; HUD–2990; HUD–2991; and HUD–2880; SF–424; SF–LLL.

Description of the need for the information and proposed use: The Family Unification Program (FUP) is a program, authorized under section 8(x) of the United States Housing Act of 1937 (42 U.S.C. 1437(X), that provides housing choice vouchers to PHAs to assist families for whom the lack of adequate housing is a primary factor in the imminent placement of the family's child or children in out-of-home care; or the delay in the discharge of the child, or children, to the family from out-of-home care. Youths at least 18 years old and not more than 21 years old (have not reached 22nd birthday) who left foster care at age 16 or older and who do not have adequate housing are also eligible to receive housing assistance under the FUP. As required by statute, a FUP voucher issued to such a youth may only be used to provide housing assistance for the youth for a maximum of 18 months. Vouchers awarded under FUP are administered by PHAs under HUD's regulations for the Housing Choice Voucher program (24 CFR part 982).

Respondents: Public Housing Agencies.

Description of information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
SF424 (0348–0043) Application for Federal Assistance.	265	Annual	1	0.75	198.75	$35.03	$6,962.21
SF LLL (0348–0046) Lobbying Form.	10	Annual	1	0.17	1.7	35.03	59.55
HUD–96011 (2535–0118) 3rd Party Documentation Facsimile Transmittal.	265	Annual	1	0.1	26.5	35.03	928.30
HUD–2993 Acknowledgement of Application Receipt (2577–0259).	13	Annual	1	0	0	35.03	0.00
Logic Model-HUD–96010 (2535–0114).	265	Annual	1	0	0	35.03	0.00
PCWA Statement of Need (maximum of 5 pages).	265	Annual	1	2.25	596.25	35.03	20,886.64
Memorandum of Understanding between PHA and PCWA.	265	Annual	1	6	1590	35.03	55,697.70
Rating Criteria 1: Area-Wide Housing Opportunities. Narratives (up to 20 pages). Logic Model (HUD–96010).	265	Annual	1	3	795	35.03	27,848.85
Rating Criteria 2: PCWA Commitments. Narratives (up to 10 pages). Other Documentation.	265	Annual	1	1.25	331.25	35.03	11,603.69
Rating Criteria 3: Self-Sufficiency Programs. Narrative: (up to 6 pages) Documentation: Excerpt from Administrative Plan or policies manual for FSS program operations Certification: FUP recipients enrolled in FSS.	265	Annual	1	0.5	132.5	35.03	4,641.48
Rating Criteria 4: Local Coordination Letter of Support.	265	Annual	1	1	265	35.03	9,282.95
PCWA Contractor Documentation.	265	Annual	1	1	265	35.03	9,282.95
HUD2990, Certification of Consistency with the RC/EZ/EC–IIs Strategic Plan.	265	Annual	1	0	0	35.03	0.00
Funding Application HUD–52515 (2577–0169). Includes leasing schedule.	265	Annual	1	1	265	35.03	9,282.95
Affirmatively Furthering Fair Housing Statement (addendum).	265	Annual	1	1	265	35.03	9,282.95
HUD2880, Applicant/Recipient Disclosure/Update Report (2510–0011).	265	Annual	1	0	0	35.03	0.00
HUD2991, Certification of Consistency with the Consolidated Plan.	265	Annual	1	0	0	35.03	0.00
Subtotal (Application).	265	Annual	1	18.02	4731.95	35.03	165,760.21
Family Report HUD–50058 (2577–0083).	242	Annual	75	.02	363	35.03	12,715.89
Baseline adjustment	10	Annual	1	.5	5	35.03	175.15

Description of information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Program and Accounting Recordkeeping.	242	Annual	1	5	1210	35.03	42,386.30
Subtotal (Reporting/ Recordkeeping).	.....	.....	.....	10.5	1,456.5	35.03	55,277.34
Total	265	Annual	1	28.52	6,188.45	35.03	221,037.55

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(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 through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: January 29, 2015.

Merrie Nichols-Dixon,

Deputy Director, Office of Policy, Programs and Legislative Initiatives.

[FR Doc. 2015–02455 Filed 2–5–15; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5828–N–06]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7266, Washington, DC 20410; telephone (202) 402–3970; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, and suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for ''off-site use only'' recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Theresa Ritta, Ms. Theresa M. Ritta, Chief Real Property Branch, the Department of Health and Human Services, Room 5B–17, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, (301)–443–2265 (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Ann Marie Oliva at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.,* acreage, floor plan, existing

sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: AGRICULTURE: Ms. Debra Kerr, Department of Agriculture, Reporters Building, 300 7th Street SW., Room 300, Washington, DC 20024, (202)–720–8873; AIR FORCE: Mr. Robert E. Moriarty, P.E., AFCEC/CI, 2261 Hughes Avenue, Ste. 155, JBSA, Lackland, TX 78236–9853; ARMY: Ms. Veronica Rines, Office of the Assistant Chief of Staff for Installation Management, Department of Army, Room 5A128, 600 Army Pentagon, Washington, DC 20310, (571)–256–8145; ENERGY: Mr. David Steinau, Department of Energy, Office of Property Management, 1000 Independence Ave. SW., Washington, DC 20585 (202) 287–1503; GSA: Mr. Flavio Peres, General Services Administration, Office of Real Property Utilization and Disposal, 1800 F Street NW., Room 7040, Washington, DC 20405, (202) 501–0084; INTERIOR: Mr. Michael Wright, Acquisition & Property Management, Department of the Interior, 3960 N. 56th Ave. #104, Hollywood, FL 33021; (443) 223–4639; NASA: Mr. Frank T. Bellinger, Facilities Engineering Division, National Aeronautics & Space Administration, Code JX, Washington, DC 20546, (202)–358–1124; NAVY: Mr. Steve Matteo, Department of the Navy, Asset Management Division, Naval Facilities Engineering Command, Washington Navy Yard, 1330 Patterson Ave. SW., Suite 1000, Washington, DC 20374, (202)–685–9426 (These are not toll-free numbers).

Dated: January 29, 2015.

Norman A. Suchar,

Director, Office of Special Needs Assistance Programs.

TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM FEDERAL REGISTER REPORT FOR 02/06/2015

Suitable/Available Properties

Building

California

Tent Cabin #B
1045-San Jacinto Wilderness
Idyllwild CA 92220
Landholding Agency: Agriculture
Property Number: 15201510006
Status: Unutilized
Comments: offsite removal only; no future agency need; 42+ yrs. old.; wood structure; 144 sq. ft.; poor condition; administrative; 24+ months vacate; contact Agriculture for more info.

2311–Applewhite Campground
Storage
Applewhite Campground
Lytle Creek CA 92358
Landholding Agency: Agriculture
Property Number: 15201510007
Status: Unutilized
Comments: offsite removal only; no future agency need; Storage shed; 80 sq. ft.; 25+months vacant; structure in poor condition; contact Agriculture for more info.

Tent Cabin #A
1044 San Jacinto Wilderness
Idyllwild CA 92220
Landholding Agency: Agriculture
Property Number: 15201510008
Status: Unutilized
Comments: offsite removal only; no future agency need; 42+ yrs. old.; wood structure; 144 sq. ft.; poor condition; administrative; 24+ months vacate; contact Agriculture for more info.

Unsuitable Properties

Building

California

Storage Warehouse #525
Map Crid Q28, Edguiba Road
Mountain View CA
Landholding Agency: NASA
Property Number: 71201510004
Status: Unutilized
Comments: public access denied & no alternative method to gain access w/out compromising national security.
Reasons: Secured Area

Michigan

Bldg. 951
44580 N. Jefferson Ave.
Selfridge ANGB MI 48045
Landholding Agency: Air Force
Property Number: 18201510004
Status: Unutilized
Comments: public access denied & no alternative method to gain access w/out compromising national security.
Reasons: Secured Area

New Mexico

7 Buildings
Los Alamos National Laboratory
Los Alamos NM 87545
Landholding Agency: Energy
Property Number: 41201510002
Status: Excess
Directions: 890110515: TA03–0154; TA08–0070; TA16–0542; TA41–0007; TA48–0143; TA53–0553; 0758
Comments: public access denied & no alternative method to gain access w/out compromising national security.
Reasons: Secured Area

114 General Purposes Bldg. 437
Steam Generator Diesel Control Bldg.
12600 NASA Road White Sands Test Facility
Las Cruces NM 88012
Landholding Agency: NASA
Property Number: 71201510003
Status: Unutilized
Directions: 1069/72/99
Comments: public access denied & no alternative method to gain access w/out compromising national security.
Reasons: Secured Area

114 General Purposes Bldg.;
437 Steam Generator Diesel Control Bldg.
White Sand Test Facility, 12600 NASA Road
Las Cruces NM 88012
Landholding Agency: NASA
Property Number: 71201510005
Status: Unutilized
Directions: 1029/72/22; 1069/22/99
Comments: public access denied & no alternative method to gain access w/out compromising national security.
Reasons: Secured Area

New York

QTP Radio Comm. Link
Repeater Facility
N. of Tennanah Rd.
Fremont NY 12736
Landholding Agency: GSA
Property Number: 54201510006
Status: Excess
GSA Number: 1–U–NY–0988–AA
Directions: Disposal Agency: GSA; Landholding Agency: FAA
Comments: property can be reached only by crossing private property and there is no established right or means of entry.
Reasons: Other—Landlocked; Not accessible by road

Bldg. #86, Boiler House &
Bldg. #101 Fuel Oil Pump House
Jamaica Bay Unit, Floyd Bennett Field
Brooklyn NY 11234
Landholding Agency: Interior
Property Number: 61201510001
Status: Excess
Comments: both properties are located in a floodway that has not been contained or corrected.
Reasons: Floodway

Ohio

Bldg. 911 Res Forces Opl Tng.
7600 Tuskegee Airmen Rd.
Columbus OH 43217
Landholding Agency: Air Force
Property Number: 18201510001
Status: Underutilized
Comments: public access denied & no alternative method to gain access w/out compromising national security.
Reasons: Secured Area

Oregon

Portland IAP (ANG) TQKD
Bldg. 495
6801 NE Cornfoot Rd.
Portland OR 97218–2797
Landholding Agency: Air Force
Property Number: 18201510006
Status: Unutilized
Comments: public access denied & no alternative method to gain access w/out compromising national security.
Reasons: Secured Area

Pennsylvania

Letterkenny Army Depot
Bldg. 2365; 1465; 1456
Intersection of Georgia Avenue
Chambersburg PA 17201
Landholding Agency: Army
Property Number: 21201510001
Status: Unutilized
Directions: 2365; 1465; 1456
Comments: public access denied & no alternative method to gain access w/out compromising national security.
Reasons: Secured Area

South Carolina

Migrant Camp A-Walsh; 2 Bldg.

3003A; 3003B
3003A Ann's Point Road
Beaufort SC
Landholding Agency: Navy
Property Number: 77201510005
Status: Unutilized
Directions: 3003A; 3003B
Comments: properties located within an Airport runway clear zone.
Reasons: Within airport runway clear zone

Seventh Day Church, Bldg. 3002
Intersection of Stanley Farm Road & Laurel Bay Road
Beaufort SC
Landholding Agency: Navy
Property Number: 77201510006
Status: Unutilized
Comments: properties located within an Airport runway clear zone.
Reasons: Within airport runway clear zone

10 Buildings
MCRD Parris Island
MCRD Parris Island SC
Landholding Agency: Navy
Property Number: 77201510007
Status: Excess
Directions: 410; 417; 418; 419; 420; 421; 422; 423; 424; 771
Comments: public access denied & no alternative method to gain access w/out compromising national security.
Reasons: Secured Area

Tennessee

4 Buildings
320 Post Ave. McGhee Tyson ANG Base
Louisville TN 37777
Landholding Agency: Air Force
Property Number: 18201510005
Status: Underutilized
Directions: Bldg. 261; 254; 245; 271
Comments: public access denied & no alternative method to gain access w/out compromising national security.
Reasons: Secured Area

Utah

Salt Lake City Air Nat'l Guard
Base, Bldg. #1522
765 N. 2200 West
Salt Lake City UT 84116–2999
Landholding Agency: Air Force
Property Number: 18201510003
Status: Unutilized
Comments: public access denied & no alternative method to gain access w/out compromising national security.
Reasons: Secured Area

Washington

4 Buildings
Naval Base Kitsap Bangor
Bremerton WA 98314
Landholding Agency: Navy
Property Number: 77201510004
Status: Unutilized
Directions: B–6034; B–6035; B–6036; B–6037
Comments: public access denied & no alternative method to gain access w/out compromising national security.
Reasons: Secured Area

[FR Doc. 2015–02260 Filed 2–5–15; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5735–N–04]

Home Equity Conversion Mortgage (HECM) Program: Mortgagee Optional Election Assignment for Home Equity Conversion Mortgages (HECMs) With FHA Case Numbers Assigned Prior to August 4, 2014—Solicitation of Comment

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

ACTION: Notice.

SUMMARY: On January 29, 2015, the Federal Housing Administration (FHA) issued Mortgagee Letter 2015–03, setting out an alternative path to claim payment—the Mortgagee Optional Election Assignment—for certain HECMs. FHA issued this Mortgagee Letter pursuant to the authority granted to it in the Reverse Mortgage Stabilization Act of 2013 and Section 230 of the National Housing Act. This alternative path to claim payment is necessary in order to ensure the financial viability of the HECM program and the FHA insurance funds. The mortgagee letter was issued for immediate effect and only applies to HECMs assigned an FHA Case Number prior to August 4, 2014, where there is a Non-Borrowing Spouse. This notice solicits comment for a period of 30 days on the alternative option for claim payment announced in Mortgagee Letter 2015–03.

DATES: *Comment Due Date:* March 9, 2015.

ADDRESSES: Interested persons are invited to submit comments regarding this notice to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500. Communications must refer to the above docket number and title. There are two methods for submitting public comments. All submissions must refer to the above docket number and title.

1. Submission of Comments by Mail. Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500.

2. Electronic Submission of Comments. Interested persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the notice.

No Facsimile Comments. Facsimile (FAX) comments are not acceptable.

Public Inspection of Public Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an appointment to review the public comments must be scheduled in advance by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay Service at 1–800–877–8339 (this is a toll-free number). Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Ivery Himes, Director, Office of Single Family Asset Management, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 9172, Washington, DC 20410; telephone number 202–708–1672 (this is not a toll-free number). Persons with hearing or speech impairments may access this number by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION: FHA has a statutory obligation to ensure the fiscal soundness of the FHA insurance funds and must take into account the financial and administrative burden of any potential alternative to claim payment that may be afforded to mortgagees holding any eligible HECMs that were assigned FHA Case Numbers prior to August 4, 2014. FHA also has the ability, pursuant to the Reverse Mortgage Stabilization Act of 2013 (Pub. L. 113–29), to establish, by notice or mortgagee letter, any additional or alternative requirements that the

Secretary, in the Secretary's discretion, determines are necessary to improve the fiscal safety and soundness of the HECM program authorized by section 255 of the National Housing Act.

FHA provided two alternative paths to claim payment in pending litigation: The Hold Election and the Mortgagee Optional Election Assignment, which are further discussed in Mortgagee Letter 2015–03.[1] When analyzed in the aggregate, these options are costly; either option, even if offered alone, poses a significant financial impact to the FHA insurance funds. The Hold Election, when applied to the potential universe of mortgages involving Non-Borrowing Spouses of HECM borrowers, imposes a financial risk to the insurance funds that is simply too great. FHA's obligation to protect the soundness of the insurance funds makes it impossible to offer this option broadly. Even though the Mortgagee Optional Election Assignment also poses a financial risk to the FHA insurance funds, the risk is significantly less; therefore, FHA has determined that the only alternative path to claim payment that FHA will permit mortgagees to elect, pursuant to Mortgagee Letter 2015–03, is the Mortgagee Optional Election Assignment.

In Mortgagee Letter 2015–03, FHA set out the Mortgagee Optional Election Assignment path to claim payment for existing HECMs with FHA Case Numbers issued prior to August 4, 2014. FHA alerted mortgagees that aside from the present procedures for either the sale of the home or foreclosure of the HECM in accordance with the contract as endorsed, or the Mortgagee Optional Election Assignment alternative, no other path to claim payment exists.

Comments on the changes announced in Mortgagee Letter 2015–03 will be accepted for a period of 30 days and will be considered by HUD.

Dated: February 3, 2015.

Biniam Gebre,

Acting Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 2015–02452 Filed 2–5–15; 8:45 am]

BILLING CODE 4210–67–P

[1] Mortgagee Letter 2015–03 is available at *http://portal.hud.gov/hudportal/documents/huddoc?id=15-03ml.pdf.*

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5843–N–02]

Computer Matching and Privacy Protection Act of 1988—Computer Matching Program Between the U.S. Department of Housing and Urban Development (HUD), Office of Inspector General (OIG) and the Office of Personnel Management (OPM)

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice of a new computer matching program between HUD OIG and OPM.

SUMMARY: Pursuant to the Computer Matching and Privacy Protection Act (CMPPA) of 1988, as amended, and in accordance with the requirements of the Privacy Act of 1974 (5 U.S.C. 552a), as amended, HUD OIG is providing notice of its intent to execute a new computer matching agreement with OPM for a matching program initiated by HUD's OIG involving comparisons of income data provided by participants in HUD's various rental housing assistance programs with independent income sources available in OPM systems of records. This computer match is similar to matches that were previously published in the **Federal Register** on March 9, 2004 (69 FR 11033) and January 27, 2005 (70 FR 3939).

DATES: *Effective Date:* HUD OIG will file a report of the subject matching program with the Committee on Oversight and Government Reform of the Housing of Representatives, the Committee on Homeland Security and Governmental Affairs of the Senate, and the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs. The matching program will become effective as cited in Section V of this notice.

Comments Due Date: March 9, 2015.

ADDRESSES: Interested persons are invited to submit comments regarding this notice to the Rules Docket Clerk, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street SW., Room 10276, Washington, DC 20410–3000. Communications should refer to the above docket number and title. Comments sent by fax are not acceptable. A copy of each communication submitted will be available for public inspection and copying between 8:00 a.m. and 5:00 p.m., weekdays at the above address.

FOR FURTHER INFORMATION CONTACT: For Privacy Act inquiries, contact: Donna Robinson-Staton, Chief Privacy Officer, Department of Housing and Urban Development, 451 Seventh Street SW., Capital View Building, 4th Floor, Washington, DC 20410, telephone number (202) 402–8073. For legal inquiries, contact: Jeremy Kirkland, Counsel to the Inspector General, Department of Housing and Urban Development, Office of Inspector General, 451 Seventh Street SW., Room 8260, Washington, DC 20410, (202) 708–1613. For computer matching program inquiries, contact Nicole Faison, Deputy Director for the Data and Predictive Analytics Division, Department of Housing and Urban Development, Office of Inspector General, 451 Seventh Street SW., Room 8254, Washington, DC 20410, (202) 402–2445. A telecommunications device for hearing- and speech-impaired individuals (TTY) is available at (800) 877–8339 (Federal Information Relay Service).

SUPPLEMENTARY INFORMATION: The Computer Matching and Privacy Protection Act (CMPPA) of 1988, an amendment to the Privacy Act of 1974 (*5 U.S.C. 552a*), OMB's guidance on this statute entitled ''Final Guidance Interpreting the Provisions of *Public Law 100–503,* and OMB Circular No. A–130 requires publication of notices of computer matching programs. Appendix I to OMB's Revision of Circular No. A–130, ''Transmittal Memorandum No. 4, Management of Federal Information Resources,'' prescribes Federal agency responsibilities for maintaining records about individuals. In compliance with the CMPPA and Appendix I to OMB Circular No. A–130, copies of this notice are being provided to the Committee on Government Reform and Oversight of the House of Representatives, the Committee of Homeland Security and Governmental Affairs of the Senate, and OMB's Office of Information and Regulatory Affairs.

I. Authority

This matching program is being conducted pursuant to the Improper Payments Elimination and Recovery Improvement Act of 2012 (Pub. L. 112–248); section 542(b) of the 1998 Appropriations Act (Pub. L. 105–65); section 904 of the Stewart B. McKinney Homeless Assistance Amendments Act of 1988 (42 U.S.C. 3544); section 165 of the Housing and Community Development Act of 1987 (42 U.S.C. 3543); the National Housing Act (12 U.S.C. 1701–1750g); the United States Housing Act of 1937 (42 U.S.C. 1437–1437z); section 101 of the Housing and Community Development Act of 1965 (12 U.S.C. 1701s); the Native American Housing Assistance and Self-

Determination Act of 1996 (25 U.S.C. 4101 *et seq.*); and the QHWRA Act of 1998 (42 U.S.C. 1437a(f)).

HUD OIG will obtain from OPM income information of persons (tenants) participating in any HUD rental housing assistance program authorized by:

i. The United States Housing Act of 1937 (42 U.S.C. 1437 et seq);

ii. Section 202 of the Housing Act of 1959 (12 U.S.C. 1701q);

iii. Section 221(d)(3), 221(d)(5) or 236 of the National Housing Act (12 U.S.C. 1751(d) and 1715z–1);

iv. Section 811 of the Cranston-Gonzalez National Affordable Housing Act (42 U.S.C. 80130); or

v. Section 101 of the Housing and Urban Development Act of 1965.

This matching program also assists HUD in complying with the following federal laws, requirements, and guidance related to identifying and reducing improper payments: Improper Payments Elimination and Recovery Act of 2010 (IPERA) (Pub. L. 111–204); Presidential Memorandum on Enhancing Payment Accuracy Through a ''Do Not Pay List'' (June 18, 2010). Office of Management and Budget M–10–13, Issuance of Part III to OMB Circular A–123, Appendix C; Presidential Memorandum on Finding and Recapturing Improper Payments (March 10, 2010); Reducing Improper Payments and Eliminating Waste in Federal Programs (Executive Order 13520, November 2009); Improper Payments Information Act of 2002 (Pub. L. 107–300); and Office of Management and Budget M–03–13, Improper Payments Information Act of 2002 Implementation Guide.

II. Objectives To Be Met by the Matching Program

The primary objective of the matching program is to (1) verify income of individuals participating in the housing programs identified in Section I of this notice; (2) increase the availability of rental assistance to qualified individuals; (3) identify tenants receiving excess housing assistance resulting from unreported or underreported tenant income; (4) collect excess assistance from tenants; and (5) detect, deter, and correct fraud, waste, and abuse in rental housing assistance programs. Appropriate administrative or legal action against tenants who inaccurately report their income may be taken by HUD OIG, HUD program office staff, federal agencies, and administrators of HUD rental housing assistance programs: Public Housing Agencies/Authorities (PHAs), owners (Os), and agents (As), collectively referred to as POAs.

III. Program Description

In this matching program, HUD OIG will compare tenant income included in HUD's automated systems of records identified as: Tenant Housing Assistance and Contract Verification Data (THACVD), HUD–H–11; and Inventory Management System (IMS) formerly and also known as the Public and Indian Housing Information Center (PIC) (IMS/PIC), HUD/PIH.01, with income data maintained in the following OPM systems of records: OPM/GOVT–1, General Personnel Records System; and OPM/Central-1, Civil Service Retirement and Insurance Records. The notices for the aforementioned systems were published as follows:

1. THACVD, HUD/H–11, originally published in the **Federal Register** Privacy Act Issuances, 1995 Compilation, and subsequently amended and last published at 62 FR 11909–11910 on March 13, 1997;

2. IMS/PIC, HUD/PIH.01, last published at 77 FR 22337–22340 on April 13, 2012;

3. OPM/GOVT–1, General Personnel Records System, published at 76 FR 32997 on June 7, 2011, and amended and republished at 77 FR 73694 on December 11, 2012. The disclosure of information contained in this system of records is permissible pursuant to routine use ''hh'' described in the published system of records notice (SORN); and

4. OPM/Central–1, Civil Service Retirement and Insurance Records, published at 64 FR 54930 on October 8, 1999, as amended at 65 FR 2772 on May 3, 2000, and amended and republished at 73 FR 15013 on March 20, 2008. The disclosure of information contained in this system of records is permissible pursuant to routine use ''cc'' described in the published SORN.

HUD OIG will match the tenant name (first and last name), social security number, date of birth, sex, income, and/or address included in HUD's systems of records to the same or similar data extracted from the following OPM Information Technology (IT) systems to identify tenant income disparities which require further verification to determine if the tenants received appropriate levels of rental assistance:

1. Enterprise Human Resource Integration (EHRI) which contains records that are covered by OPM/GOVT–1 General Personnel Records; and

2. Retirement Annuity Master File (RAMF) which contains records that are covered by OPM/Central–1 Civil Service Retirement Records.

A. Income Verification

Any disparity between tenant-reported income and/or income sources and the income and sources derived from the match (*i.e.* a ''hit'') will be further reviewed and independently verified by HUD OIG, HUD program office staff, and/or POAs to determine whether income reported by tenants is correct and complies with HUD and program administrator requirements.

B. Administrative or Legal Actions

Regarding all the matching described in this notice, HUD requires that POAs or HUD staff take the following appropriate actions in consultation with tenants to: (1) Resolve income disparities between tenant-reported and independent income source data; and (2) Use correct income amounts in determining housing rental assistance. POAs must compute the rent in full compliance with all applicable occupancy regulations. POAs must ensure that they use the correct income and correctly compute the rent. POAs may not suspend, terminate, reduce, or make a final denial of any rental housing assistance to any tenant as the result of information produced by this matching program until: (a) The POA or HUD has independently verified the disparate income and confirmed the amount of the income involved, whether the individual actually has or had access to the income for the individual's own use, and the period or periods when the individual actually had the income; (b) The tenant has received notice from the POA of its findings and has been informed of the opportunity to contest such findings; and (c) either the notice period provided in applicable regulations of the program, or 30 days, whichever is later, has expired. In most cases, POAs will resolve income discrepancies in consultation with tenants. (3) Additionally, serious or egregious violations, which POAs, HUD program office staff, or the HUD OIG verify, may be referred for full investigation and initiation of appropriate civil and/or criminal proceedings.

IV. Records To Be Matched

A description of tenant records (one record for each family member) in THACVD and IMS/PIC include the following data elements for each family member: (1) SSN; (2) Last Name, First Name, and Middle Initial; (3) Date of Birth; and (4) the Address of the assisted family.

For matched tenants' SSNs (*i.e.,* ''hits''), HUD OIG will extract the following information from EHRI: SSN,

Date of Birth, Name, Sex, Work Schedule, Annual Salary, Location Code, Standard Metropolitan Statistical Area, Submitting Office Number (SON), Agency Code, and File Date. HUD OIG will extract the following information from RAMF: File ID, SSN, Date of Birth, Sex, Last name, Annualized Salary, Annuity Commence Date, Pay Status, OPM Claim Number, Health Benefit Enrollment Code, Date of Death, Zip Code, Contact Address, and ''As of'' Date of File. In addition, HUD OIG will use the SON Master File to obtain the address of the agencies so that employer verification letters can be sent to such agencies. This information includes: SON, Agency Code and sub-element, SON name and address, zip code, and File Date.

V. Period of the Match

The matching program will become effective and the matching may commence after the respective Data Integrity Boards (DIBs) of both agencies approve and sign the computer matching agreement, and after, the later of the following: (1) 40 days after report of the matching program is sent to Congress and OMB; (2) at least 30 days after publication of this notice in the **Federal Register**, unless comments are received, which would result in a contrary determination. The matching program will be conducted according to the computer matching agreement between HUD OIG and OPM.

The Improper Payments Elimination and Recovery Improvement Act of 2012 (IPERIA) authorizes each Inspector General and the head of each agency to enter into computer matching agreements with other inspector general and agency heads that allow ongoing data matching (which includes automated data matching) in order to assist in the detection and prevention of improper payments. IPERIA further authorizes such matching agreements to have a termination date of less than 3 years (Pub. L. 112–248, Section 5(e)(2)(C)(i)). The computer matching agreement for the planned match will terminate either when the purpose of the matching program is accomplished, or less than 36 months from the effective date of the computer matching agreement, whichever occurs first.

IPERIA provides that within three months prior to the expiration of a matching agreement, the Data Integrity Boards (DIBs) may renew the matching agreement for a current, ongoing matching program for not more than 3 years. (Pub. L. 112–248, Section 5(e)(2)(C)(ii)). The agreement may be renewed for a period not to exceed 3 years, with the mutual agreement of all involved parties, if the following conditions are met: (1) Within three months of the expiration date, all DIBs review the agreement, find that the program will be conducted without change, and find a continued favorable examination of benefit/cost results; and (2) All parties certify that the program has been conducted in compliance with the computer matching agreement.

The agreement may be terminated, prior to accomplishment of the computer matching purpose or less than 36 months from the effective date of the computer matching agreement, (whichever occurs first), by the mutual agreement of all involved parties within 30 days of written notice.

Dated: January 22, 2015.

Rafael C. Diaz,

Chief Information Officer.

[FR Doc. 2015–02469 Filed 2–5–15; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

U.S. Geological Survey

[GX15DA009DU2000]

Agency Information Collection Activities: Request for Comments

AGENCY: U.S. Geological Survey (USGS), Department of the Interior.

ACTION: Notice of a new information collection, National Ground-Water Monitoring Network Cooperative Funding Application.

SUMMARY: We (the U.S. Geological Survey) will ask the Office of Management and Budget (OMB) to approve the information collection (IC) described below. As required by the Paperwork Reduction Act (PRA) of 1995, and as part of our continuing efforts to reduce paperwork and respondent burden, we invite the general public and other Federal agencies to take this opportunity to comment on this IC.

DATES: To ensure that your comments are considered, we must receive them on or before April 7, 2015.

ADDRESSES: You may submit comments on this information collection to the Information Collection Clearance Officer, U.S. Geological Survey, 12201 Sunrise Valley Drive MS 807, Reston, VA 20192 (mail); (703) 648–7197 (fax); or *gs-info_collections@usgs.gov* (email). Please reference ''Information Collection 1028–NEW, National Ground-Water Monitoring Network Cooperative Funding Application'' in all correspondence.

FOR FURTHER INFORMATION CONTACT: Daryll Pope, USGS, at (609) 771–3933 or *dpope@usgs.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The USGS is working with the Federal Advisory Committee on Water Information (ACWI) and its Subcommittee on Ground Water (SOGW) to develop and administer a National Ground-Water Monitoring Network (NGWMN). This network is required as part of Public Law 111–11, Subtitle F—Secure Water: Section 9507 ''Water Data Enhancement by the United States Geological Survey''. The Network will consist of an aggregation of well data from existing Federal, Multistate, State, Tribal, and local groundwater monitoring networks. To support data providers for the National Ground-Water Monitoring Network, the USGS will be providing funding through cooperative agreements to water-resource agencies that collect groundwater data. The USGS will be soliciting applications for funding that will request information from the Agency collecting the data. Elements will include contact information (phone number and email address), and a proposal describing their existing data collection and a plan to evaluate their data for incorporation into the NGWMN. The proposal will be evaluated by the USGS and the NGWMN Program Board to appropriate funding. The proposal will describe the groundwater networks to be included in the NGWMN, the purpose of the networks, an estimate of the number of wells they would submit for the network, an overview of the methods they would use to select and classify wells for the network a description of data collection techniques, and information on their databases. The proposal would also require estimates of one-time costs to complete the above tasks and annual costs to participate in the network.

II. Data

OMB Control Number: 1028–NEW.

Title: National Ground-Water Monitoring Network Cooperative Funding Application.

Type of Request: New information collection.

Affected Public: Multistate, State, Tribal, or Local water-resource agencies who operate groundwater monitoring networks.

Respondent's Obligation: Mandatory to be considered for funding.

Frequency of Collection: Annually.

Estimated Annual Number of Respondents: 100.

Estimated Total Number of Annual Responses: 100.

Estimated Time per Response: Initial application will take 30 hours to prepare the proposal. This includes time to review the NGWMN Framework Document to understand the Network design and requirements for data providers. Annual proposal renew will take 4 hours.

Estimated Annual Burden Hours: 3000 hours for initial proposal, 400 hours for annual renewal.

Estimated Reporting and Recordkeeping ''Non-Hour Cost'' Burden: None.

Public Disclosure Statement: The PRA (44 U.S.C. 3501, *et seq.*) provides that an agency may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number and current expiration date.

III. Request for Comments

We are soliciting comments as to: (a) Whether the proposed collection of information is necessary for the agency to perform its duties, including whether the information is useful; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, usefulness, and clarity of the information to be collected; and (d) how to minimize the burden on the respondents, including the use of automated collection techniques or other forms of information technology.

Please note that the comments submitted in response to this notice are a matter of public record. Before including your personal mailing address, phone number, email address, or other personally identifiable information in your comment, you should be aware that your entire comment, including your personally identifiable information, may be made publicly available at any time. While you can ask us in your comment to withhold your personally identifiable information from public view, we cannot guarantee that we will be able to do so.

William Cunningham,

Chief, Office of Groundwater.

[FR Doc. 2015–02332 Filed 2–5–15; 8:45 am]

BILLING CODE 4311–AM–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNVS01000.L13400000.DJ0000 241A MO# 4500076407]

Notice of Extension of the Public Comment Period for the Notice of Availability of the Las Vegas and Pahrump Field Offices Draft Resource Management Plan and Environmental Impact Statement, Nevada

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management (BLM) published a Notice of Availability for the Las Vegas and Pahrump Field Offices Draft Resource Management Plan (RMP) and Draft Environmental Impact Statement (EIS) in the **Federal Register** on October 10, 2014 [FR Doc. 2014–24135] and announced the availability of these documents. On December 23, 2014, the BLM announced the extension the public comment period for the Draft RMP and Draft EIS until February 6, 2015 in the **Federal Register** [FR Doc. 2014–29923]. In response to requests, the BLM is extending the public comment period for the Draft RMP and Draft EIS until March 9, 2015.

DATES: The comment period is extended to March 9, 2015.

ADDRESSES: You may submit comments related to the Las Vegas and Pahrump Field Offices Draft RMP/Draft EIS by any of the following methods:

- *Web site: http://tinyurl.com/qzvaht7.*
- *Email: sndo_rmp_revision@blm.gov.*
- *Fax:* 702–515–5023.
- *Mail:* BLM Southern Nevada District Office, Las Vegas/Pahrump Field Offices Draft RMP/Draft EIS, 4701 N. Torrey Pines Drive, Las Vegas, NV 89130.

Copies of the Las Vegas and Pahrump Field Offices Draft RMP/Draft EIS are available in the Southern Nevada District Office at the above address or on the following Web site *http://tinyurl.com/qzvaht7*

FOR FURTHER INFORMATION CONTACT: Lee Kirk, RMP Team Lead, telephone: 702–515–5026; address: 4701 N. Torrey Pines Drive, Las Vegas, NV 89130; email: *sndo_rmp_revision@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The Las Vegas and Pahrump Field Offices Draft RMP/Draft EIS would replace the existing 1998 Las Vegas Field Office RMP. The Draft RMP/Draft EIS was developed through a collaborative planning process. The Las Vegas and Pahrump Field Offices Draft RMP/Draft EIS decision area encompasses approximately 3.1 million acres of public land administered by the BLM Southern Nevada District in Clark and Southern Nye counties, Nevada. It does not include private lands, State lands, Indian reservations, Federal lands not administered by BLM or lands addressed in the Red Rock Canyon National Conservation Area RMP (2005) and Sloan Canyon National Conservation Area RMP (2006). The Las Vegas and Pahrump Field Offices Draft RMP/Draft EIS includes goals, objectives and management actions for protecting and preserving natural resources which includes air quality, soil and water resources, vegetation, fish and wildlife, special status species, wild horses and burros, wildland fire management, cultural and paleontological resources, visual resource values, and lands with wilderness characteristics. Multiple resource uses are addressed which include management and forage allocations for livestock grazing; delineation of lands open, closed, or subject to special stipulations or mitigation measures for minerals development; recreation and travel management designations; management of lands and realty actions, including delineation of avoidance and exclusion areas applicable to rights-of-ways (ROWs), land tenure adjustments, and solar and wind energy development. The planning effort will consider establishment of a national trail management corridor for the congressionally-designated Old Spanish National Historic Trail. Eligible river segments will be evaluated for suitability as components of the National Wild and Scenic River System and 23 new Areas of Critical Environmental Concern (ACECs) are proposed. The ACECs are proposed to protect natural and cultural resource values and traditional Native American use areas.

Authority: 40 CFR 1506.6, 40 CFR 1506.10, 43 CFR 1610.2.

Raul Morales,

Acting State Director, Nevada.

[FR Doc. 2015–02371 Filed 2–5–15; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMTM01000 L14300000.ET0000 14XL1109AF; MO#4500069247; MTM 89170]

Notice of Proposed Withdrawal Extension and Opportunity for Public Meeting; Montana

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Assistant Secretary of the Interior for Land and Minerals Management proposes to extend the duration of Public Land Order (PLO) No. 7464, as extended by PLO Nos. 7643 and 7753, for an additional 5-year term. PLO No. 7464 withdrew 3,530.62 acres of public land in Phillips County, Montana, from settlement, sale, location, or entry under the general land laws, including the mining laws, to protect the reclamation of the Zortman-Landusky mining area. The withdrawal created by PLO No. 7464, as extended, will expire on October 4, 2015, unless further extended. This notice also gives an opportunity to comment on the proposed action and to request a public meeting.

DATES: Comments and requests for a public meeting must be received by May 7, 2015.

ADDRESSES: Comments and meeting requests should be sent to the BLM Malta Field Manager, 501 South 2nd Street East, Malta, Montana 59538.

FOR FURTHER INFORMATION CONTACT: Micah Lee, BLM Havre Field Office, 406–262–2851, or Cyndi Eide, BLM Montana/Dakotas State Office, 406–896–5094. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The Bureau of Land Management (BLM) has filed an application requesting that the Assistant Secretary for Land and Minerals Management extend the withdrawal established by Public Land Order No. 7464 (65 FR 59463 (2000)), as extended by PLO Nos. 7643 and 7753, which withdrew 3,530.62 acres of public land in Phillips County, Montana, from settlement, sale, location, or entry under the general land laws, including the United States mining laws, for an additional 5-year term, subject to valid existing rights. PLO 7464 is incorporated herein by reference.

The purpose of the proposed extension is to continue to protect reclamation at the Zortman and Landusky mining area.

The use of a right-of-way, interagency agreement, or cooperative agreement would not provide adequate protection.

There are no suitable alternative sites available where the withdrawal would facilitate mine reclamation since the location of the mines and necessary reclamation materials are fixed.

No water rights will be needed to fulfill the purpose of the requested withdrawal.

All persons who wish to submit comments, suggestions, or objections in connection with the proposed withdrawal extension may present their views in writing to the BLM Malta Field Manager by May 7, 2015, at the address above.

Comments, including names and street addresses of respondents, will be available for public review at the Malta Field Office, 501 South 2nd Street East, Malta, Montana 59538, during regular business hours.

Before including your address, phone number, email address, or other personal identifying information in your comment, be advised that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask in your comment to withhold from public review your personal identifying information, we cannot guarantee that we will be able to do so.

Notice is hereby given that an opportunity for a public meeting is afforded in connection with the proposed withdrawal extension. All interested persons who desire a public meeting for the purpose of being heard on the proposed withdrawal extension must submit a written request to the BLM Malta Field Manager at the address above by May 7, 2015. Upon determination by the authorized officer that a public meeting will be held, a notice of the time and place will be published in the **Federal Register** and in at least one local newspaper not less than 30 days before the scheduled date of the meeting.

This application will be processed in accordance with the regulations set forth in 43 CFR 2310.4.

Renee Johnson,

Acting Chief, Branch of Land Resources.

[FR Doc. 2015–02494 Filed 2–5–15; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNVS00560 L58530000 EU0000 241A; N–93072, et al.; 14–08807; MO# 4500074460; TAS: 14X5232]

Notice of Realty Action; Competitive Sale of 29 Parcels of Public Land in Clark County, NV

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management (BLM) proposes to offer 29 parcels of public land totaling 597.59 acres in the Las Vegas Valley by competitive sale, at not less than the appraised fair market values (FMV). The BLM is proposing to offer the parcels for sale pursuant to the Southern Nevada Public Land Management Act of 1998 (SNPLMA), as amended. The sale will be subject to the applicable provisions of the Federal Land Policy and Management Act of 1976 (FLPMA) and BLM land sale regulations.

DATES: Interested parties may submit written comments regarding the proposed sale until March 23, 2015. The sale by sealed bid and oral public auction will be held on May 5, 2015, at the City of North Las Vegas, 2250 Las Vegas Boulevard North, Council Chambers, North Las Vegas, Nevada 89030 at 10 a.m., Pacific Time. The FMV for the parcels will be available 30 days prior to the sale. The BLM will accept sealed bids beginning

April 22, 2015. Sealed bids must be received by the BLM, Las Vegas Field Office (LVFO) no later than 4:30 p.m. Pacific Time, on April 30, 2015. The BLM will open sealed bids on the day of the sale just prior to oral bidding.

ADDRESSES: Mail written comments and submit sealed bids to the BLM LVFO, Assistant Field Manager, 4701 North Torrey Pines Drive, Las Vegas, NV 89130.

FOR FURTHER INFORMATION CONTACT: Manuela Johnson by email: *manuela_johnson@blm.gov,* or by telephone: 702–515–5224. For general information on previous BLM public land sales, go to: *http://www.blm.gov/nv/st/en/snplma/Land_Auctions.html.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The BLM proposes to offer 29 parcels of public land in the southwest Las Vegas Valley. The subject public lands are legally described as:

Mount Diablo Meridian, Nevada

N–93072, 2.50 acres:
T. 22 S., R. 60 E.,
section 15, NW¼SE¼NE¼SE¼.

N–93074, 2.50 acres:
T. 22 S., R 60 E.,
section 15, NW¼NE¼SE¼SE¼.

N–93075, 17.50 acres:
T. 22 S., R. 60 E.,
section 17, N½NW¼NW¼SE¼,
SW¼NW¼NW¼SE¼,
E½NE¼NE¼SW¼,
N½SE¼NE¼SW¼.

N–81949, 5.00 acres:
T. 22 S., R. 60 E.,
section 17, W½SW¼SE¼SW¼.

N–93077, 2.50 acres:
T. 22 S., R. 60 E.,
section 17, SW¼NE¼SE¼SW¼.

N–81950, 2.50 acres:
T. 22 S., R. 60 E.,
section 17, SW¼SE¼SW¼SW¼.

N–93078, 5.00 acres:
T. 22 S., R. 60 E.,
section 19, NW¼SE¼NE¼NE¼,
NE¼SW¼NE¼NE¼.

N–93079, 10.00 acres:
T. 22 S., R. 60 E.,
section 21, SW¼SE¼NE¼NE¼,
S½SW¼NE¼NE¼,
SE¼SE¼NW¼NE¼.

N–93080, 1.25 acres:
T. 22 S., R. 61 E.,
section 30, W½SW¼NW¼SW¼NE¼.

N–93081, 3.75 acres:
T.22 S., R. 61 E.,
section 30, E½SE¼NE¼SW¼NE¼,
NE¼SE¼SW¼NE¼.

N–84197, 12.50 acres:
T. 22 S., R. 61 E.,
section 30, SW¼NE¼SW¼NE¼,
W½NW¼SE¼SW¼NE¼,
SE¼NW¼SW¼NE¼,
NE¼SW¼SW¼NE¼,
E½SE¼SW¼SW¼NE¼,
E½NW¼SW¼SW¼NE¼,
E½SW¼SW¼SW¼NE¼.

N–91124, 247.59 acres:
T. 20 S., R. 62 E.,
section 14, lots 1 and 2, E½NW¼,
N½SW¼.

N–93057, 5.00 acres:
T. 22 S., R. 63 E.,
section 9, W½SW¼SW¼NW¼.

N–93058, 10.00 acres:
T. 22 S., R. 63 E.,
section 9, E½SE¼SW¼NW¼,
W½SW¼SE¼NW¼.

N–93059, 60 acres:
T. 22 S., R. 63 E.,
section 9, N½NW¼NE¼, N½NE¼NE¼,
E½SW¼NW¼NE¼, SW¼NE¼NE¼,
E½SE¼NE¼NE¼.

N–93060, 5.00 acres:
T. 22 S., R. 63 E.,
section 9, W½NE¼SW¼NE¼.

N–93061, 10.00 acres:
T. 22 S., R. 63 E.,
section 9, SW¼SW¼NE¼.

N–65967, 10.00 acres:
T. 22 S., R. 63 E.,
section 9, W½NE¼SE¼NE¼,
W½SE¼SE¼NE¼.

N–93062, 10.00 acres:
T. 22 S., R. 63 E.,
section 9, E½SE¼SW¼NE¼,
W½SW¼SE¼NE¼.

N–93063, 15.00 acres:
T. 22 S., R. 63 E.,
section 9, NE¼NE¼SE¼,
E½SE¼NE¼SE¼.

N–93064, 50.00 acres:
T. 22 S., R. 63 E.,
section 9, NW¼SE¼SE¼,
SW¼SW¼SE¼, E½SE¼SW¼SE¼,
W½NW¼SW¼SE¼,
W½SW¼NW¼SE¼, NW¼NW¼SE¼,
W½SE¼NW¼SE¼.

N–93065, 35.00 acres:
T. 22 S., R. 63 E.,
section 16, NW¼NE¼NE¼,
NE¼NW¼NE¼, E½NW¼NW¼NE¼,
E½SW¼SW¼NE¼,
S½NW¼SW¼NE¼.

N–93066, 5.00 acres:
T. 22 S., R. 63 E.,
section 16, E½SE¼NE¼NE¼.

N–93067, 15.00 acres:
T. 22 S., R. 63 E.,
section 16, W½NW¼SE¼NE¼,
E½NE¼SW¼NE¼, E½SE¼SW¼NE¼.

N–93068, 5.00 acres:
T. 22 S., R. 63 E.,
section 16, E½SE¼SE¼NE¼.

N–93069, 5.00 acres:
T. 22 S., R. 63 E.,
section 16, E½NW¼NW¼SE¼.

N–93070, 5.00 acres:
T. 22 S., R. 63 E.,
section 16, E½NW¼NE¼SE¼.

N–93071, 15.00 acres:
T. 22 S., R. 63 E.,
section 16, E½NE¼SW¼SE¼,
E½SE¼SW¼SE¼, E½SE¼NW¼SE¼.

N–80739, 25.00 acres:
T. 23 S., R. 61 E.,
section 10, NW¼SW¼SE¼,
S½NE¼SW¼SE¼,
N½SW¼SW¼SE¼,
S½NE¼SE¼SW¼.

The areas described contain 597.59 acres.

A sales matrix is available on the BLM Web site at: *http://www.blm.gov/snplma.* The sales matrix provides information specific to each sale parcel such as legal description, physical location, encumbrances, acreage, and FMV. The FMV for each parcel is available in the sales matrix as soon as approved and no later than 30 days prior to the sale.

The sale parcel (N–91124) consists of split-estate lands. The parcel of approximately 247.59 acres overlies privately owned sand and gravel deposits patented out of Federal ownership pursuant to Private Law 96–67 signed on December 5, 1980, for the relief of two mining claimants. The patent provides for the private ownership and use of the sand and gravel deposits and such use of the surface that is reasonably required for mining. The northern portion of the sale parcel is near the southern boundary of Nellis Air Force Base near the Live Ordnance Loading Area. The existing explosion evacuation arcs extend onto the northern portion of the sale parcel.

This proposed competitive sale is in conformance with the BLM, Las Vegas Resource Management Plan and decision LD–1, approved by Record of Decision on October 5, 1998, and complies with Section 203 of FLPMA. The sale parcels were analyzed in the Las Vegas Valley Disposal Boundary Environmental Impact Statement and approved by Record of Decision on December 23, 2004. A parcel-specific Determination of National Environmental Policy Act Adequacy document numbered DOI–BLM–NV–S010–2014–0135–DNA was prepared in connection with this Notice of Realty Action.

Submit comments on this sale Notice to the address in the **ADDRESSES** section. 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 any personal identifying information—might 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. The BLM will also publish this Notice once a week for three consecutive weeks in the *Las Vegas Review-Journal.*

Sale procedures: Registration for oral bidding will begin at 8 a.m. Pacific Time and will end at 10 a.m. Pacific Time at the City of North Las Vegas, 2250 Las Vegas Boulevard North, Council Chambers, North Las Vegas, Nevada 89030, on the day of the sale. There will be no prior registration before the sale date. To participate in the competitive sale, all registered bidders must submit a bid guarantee deposit in the amount of $10,000 by certified check, postal money order, bank draft, or cashier's check made payable to the Department of the Interior-Bureau of Land Management on the day of the sale or submit the bid guarantee deposit along

with the sealed bids. The public sale auction will be through sealed and oral bids. Sealed bids will be opened and recorded on the day of the sale to determine the high bids among the qualified bids received. Sealed bids above the FMV will set the starting point for oral bidding on a parcel. Parcels that receive no qualified sealed bids will begin at the established FMV. Bidders who are participating and attending the oral auction on the date of the sale are not required to submit a sealed bid, but may choose to do so.

Sealed-bid envelopes must be clearly marked on the lower front left corner with the parcel number and name of the sale, for example: ''N–XXXXX, 29-parcel SNPLMA Sale 2015.'' Sealed bids must include an amount not less than 20 percent of the total amount bid and the $10,000 bid guarantee by certified check, postal money order, bank draft, or cashier's check made payable to the ''Department of the Interior-Bureau of Land Management.'' The bid guarantee and bid deposit may be combined into one form of deposit; the bidder must specify the amounts of the bid deposit and the bid guarantee. The BLM will not accept personal or company checks. The sealed-bid envelope *must* contain the 20 percent bid deposit, bid guarantee, and a completed and signed ''Certificate of Eligibility'' form stating the name, mailing address, and telephone number of the entity or person submitting the bid. Certificate of Eligibility and registration forms are available at the BLM, LVFO at the address listed in the **ADDRESSES** section and on the BLM Web site at: *http://www.blm.gov/nv/st/en/snplma/Land_Auctions.html.* Pursuant to 43 CFR 2711.3–1(c), if two or more sealed-bid envelopes containing valid bids of the same amount are received, oral bidding will start at the sealed-bid amount. If there are no oral bids on the parcel, the authorized officer will determine the winning bidder. Bids for less than the federally approved FMV will not be qualified. The highest qualifying bid for any parcel will be declared the high bid. The apparent high bidder must submit a deposit of not less than 20 percent of the successful bid delivered no later than 3:00 p.m. Pacific Time on the day of the sale and in the form of a certified check, postal money order, bank draft, or cashier's check made payable in U.S. dollars to the ''Department of the Interior—Bureau of Land Management.'' Funds must be delivered no later than 3:00 p.m. Pacific Time on the day of the sale to the BLM Collection Officers at the City of North Las Vegas, 2250 Las Vegas Boulevard North, Council Chambers, North Las Vegas, Nevada 89030. The BLM–LVFO will accept funds. The BLM will send the successful bidder(s) a high-bidder letter with detailed information for full payment.

All funds submitted with unsuccessful bids will be returned to the bidders or their authorized representative upon presentation of acceptable photo identification at the BLM LVFO or by certified mail. If the apparent high bidder so chooses, the bid guarantee may be applied towards the required deposit. Failure to submit the deposit following the close of the sale under 43 CFR 2711.3–1(d) will result in forfeiture of the bid guarantee. For bidders who offer to purchase more than one parcel, the BLM will retain the bid guarantee, and may cancel the sale of all the parcels to that bidder, if the bidder fails to submit the bid deposit on any single parcel following the sale. If an offer to purchase one parcel results in default, the BLM may retain the bid deposit and cancel the sale to that bidder. If a high bidder is unable to consummate the transaction for any reason, the second highest bid may be considered to purchase the parcel. If there are no acceptable bids, a parcel may remain available for sale at a future date in accordance with competitive sale procedures without further legal notice.

Federal law requires that bidders must be: (1) A citizen of the United States 18 years of age or older; (2) A corporation subject to the laws of any State or of the United States; (3) A State, State instrumentality, or political subdivision authorized to hold property; or (4) An entity legally capable of conveying and holding lands or interests therein under the laws of the State of Nevada.

Evidence of United States citizenship is a birth certificate, passport, or naturalization papers. Failure to submit the above requested documents to the BLM within 30 days from receipt of the high-bidder letter will result in cancellation of the sale and forfeiture of the bid deposit. The successful bidder is allowed 180 days from the date of the sale to submit the remainder of the full purchase price.

Publication of this Notice in the **Federal Register** segregates the subject lands from all forms of appropriation under the public land laws. Any subsequent application will not be accepted, will not be considered and filed, and will be returned to the applicant if the Notice segregates from the use applied for in the application. The segregative effect of this Notice terminates upon issuances of a patent or other document of conveyance to such lands, publication in the **Federal Register** of a termination of the segregative, or two years after the date of this publication, whichever occurs first. The segregation period may not exceed two years unless extended by the BLM Nevada State Director in accordance with 43 CFR 2711.1–2(d) prior to the termination date.

Terms and Conditions: All minerals for the sale parcels will be reserved to the United States. The patents, when issued, will contain a mineral reservation to the United States for all minerals.

The parcels are subject to limitations prescribed by law and regulation, and certain encumbrances in favor of third parties. Prior to patent issuance, a holder of any right-of-way (ROW) within the sale parcels will have the opportunity to amend the ROW for conversion to a new term, including perpetuity, if applicable, or conversion to an easement. The BLM will notify valid existing ROW holders of record of their ability to convert their compliant ROW to perpetual ROW or easement. In accordance with Federal regulations at 43 CFR 2807.15, once notified, each valid holder may apply for the conversion of their current authorization.

The following numbered terms and conditions will appear on the conveyance documents for the sale parcels:

1. All minerals deposits in the lands so patented, and to it, or persons authorized by it, the right to prospect for, mine, and remove such deposits from the same under applicable law and regulations to be established by the Secretary of the Interior are reserved to the United States, together with all necessary access and exit rights;

2. A right-of-way is reserved for ditches and canals constructed by authority of the United States under the Act of August 30, 1890 (43 U.S.C. 945);

3. The parcels are subject to valid existing rights;

4. The parcels are subject to reservations for road, public utilities and flood control purposes, both existing and proposed, in accordance with the local governing entities' transportation plans; and

5. An appropriate indemnification clause protecting the United States from claims arising out of the lessee's/patentee's use, occupancy, or occupations on the leased/patented lands.

Pursuant to the requirements established by Section 120(h) of the Comprehensive Environmental Response, Compensation and Liability

Act, 42 U.S.C. 9620(h) (CERCLA), as amended, notice is hereby given that the lands have been examined and no evidence was found to indicate that any hazardous substances have been stored for one year or more, nor had any hazardous substances been disposed of or released on the subject property.

No warranty of any kind, express or implied, is given by the United States as to the title, whether or to what extent the land may be developed, its physical condition, future uses, or any other circumstance or condition. The conveyance of a parcel will not be on a contingency basis. However, to the extent required by law, the parcel is subject to the requirements of Section 120(h) of the CERCLA.

Unless the BLM authorized officer approved other satisfactory arrangements in advance, conveyance of title will be through the use of escrow. Designation of the escrow agent will be through mutual agreement between the BLM and the prospective patentee, and costs of escrow will be borne by the prospective patentee.

Request for escrow instructions must be received by the BLM, LVFO prior to 30 days before the prospective patentee's scheduled closing date. No exceptions will be made.

All name changes and supporting documentation must be received at the BLM, LVFO 30 days from the date on the high-bidder letter by 4:30 p.m. Pacific Time. There are no exceptions. To submit a name change, the apparent high bidder must submit the name change in writing on the Certificate of Eligibility form to the BLM, LVFO.

The remainder of the full bid price for the parcel must be received no later than 4:30 p.m. Pacific Time, within 180 days following the day of the sale. Payment must be submitted in the form of a certified check, postal money order, bank draft, cashier's check, or made available by electronic fund transfer made payable in U.S. dollars to the ''Department of the Interior—Bureau of Land Management'' to the BLM LVFO. The BLM will not accept personal or company checks.

Arrangements for electronic fund transfer to the BLM for payment of the balance due must be made a minimum of two weeks prior to the payment date. Failure to pay the full bid price prior to the expiration of the 180th day will disqualify the high bidder and cause the entire 20 percent bid deposit to be forfeited to the BLM. Forfeiture of the 20 percent bid deposit is in accordance with 43 CFR 2711.3–1(d). No exceptions will be made. The BLM cannot accept the remainder of the bid price after the 180th day of the sale date.

The BLM will not sign any documents related to 1031 Exchange transactions. The timing for completion of such an exchange is the bidder's responsibility. The BLM cannot be a party to any 1031 Exchange.

In accordance with 43 CFR 2711.3–1(f), within 30 days the BLM may accept or reject any or all offers to purchase, or withdraw any parcel of land or interest therein from sale if, in the opinion of a BLM authorized officer, consummation of the sale would be inconsistent with any law, or for other reasons as may be provided by applicable law or regulations. No contractual or other rights against the United States may accrue until the BLM officially accepts the offer to purchase and the full bid price is paid.

Upon publication of this Notice and until completion of this sale, the BLM is no longer accepting land use applications affecting the parcel identified for sale. However, land use applications may be considered after the sale if the parcel is not sold. The parcel may be subject to land use applications received prior to publication of this Notice if processing the application would have no adverse effect on the marketability of title, or the FMV of the parcel. Information concerning the sale, encumbrances of record, appraisals, reservations, procedures and conditions, CERCLA, and other environmental documents that may appear in the BLM public files for the proposed sale parcels are available for review during business hours, 7:30 a.m. to 4:30 p.m. Pacific Time, Monday through Friday, at the BLM, LVFO, except during Federal holidays.

In order to determine the FMV through appraisal, certain extraordinary assumptions and hypothetical conditions may have been made concerning the attributes and limitations of the lands and potential effects of local regulations and policies on potential future land uses. Through publication of this Notice, the BLM advises that these assumptions may not be endorsed or approved by units of local government.

It is the buyer's responsibility to be aware of all applicable Federal, State, and local government laws, regulations and policies that may affect the subject lands, including any required dedication of lands for public uses. It is also the buyer's responsibility to be aware of existing or prospective uses of nearby properties. When conveyed out of Federal ownership, the lands will be subject to any applicable laws, regulations, and policies of the applicable local government for proposed future uses. It is the responsibility of the buyer to be aware through due diligence of those laws, regulations, and policies, and to seek any required local approvals for future uses. Buyers should make themselves aware of any Federal or State law or regulation that may affect the future use of the property. Any land lacking access from a public road or highway will be conveyed as such, and future access acquisition will be the responsibility of the buyer. Any comments regarding the proposed sale will be reviewed by the BLM Nevada State Director or other authorized official of the Department of the Interior, who may sustain, vacate, or modify this realty action in response to such comments. In the absence of any comments, this realty action will become the final determination of the Department of the Interior.

Authority: 43 CFR 2711.1–2.

Catrina Williams,

Acting Assistant Field Manager, Division of Lands.

[FR Doc. 2015–02368 Filed 2–5–15; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–17402; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: California State University, Sacramento, Sacramento, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: California State University, Sacramento has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to California State University, Sacramento. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian tribe or

Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to California State University, Sacramento at the address in this notice by March 9, 2015.

ADDRESSES: Orn Bodvarsson, Dean of the College of Social Sciences and Interdisciplinary Studies, CSUS, 6000 J Street, Sacramento, CA 95819–6109, telephone (916) 278–4864, email *obbodvarsson@csus.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of California State University, Sacramento. The human remains and associated funerary objects were removed from sites located within Sacramento, San Joaquin, and Yolo counties, CA.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by California State University, Sacramento professional staff in consultation with representatives of Buena Vista Rancheria of Me-Wuk Indians of California; Cachil DeHe Band of Wintun Indians of the Colusa Indian Community of the Colusa Rancheria, California; California Valley Miwok Tribe, California; Ione Band of Miwok Indians of California; Santa Rosa Indian Community of the Santa Rosa Rancheria, California; Shingle Springs Band of Miwok Indians, Shingle Springs Rancheria (Verona Tract), California; Susanville Indian Rancheria, California; United Auburn Indian Community of the Auburn Rancheria of California; Wilton Rancheria, California; and Nashville-Eldorado Miwok, a non-Federally recognized Native American group. Chicken Ranch Rancheria of Me-Wuk Indians of California; Cortina Indian Rancheria of Wintun Indians of California; Jackson Rancheria of Me-Wuk Indians of California; Picayune Rancheria of Chukchansi Indians of California; Table Mountain Rancheria of California; Tuolumne Band of Me-Wuk Indians of the Tuolumne Rancheria of California; Tule River Indian Tribe of the Tule River Reservation, California; Wiyot Tribe, California (previously listed as the Table Bluff Reservation-Wiyot Tribe); Yocha Dehe Wintun Nation, California (previously listed as the Rumsey Indian Rancheria of Wintun Indians of California); and the Miwok Tribe of the El Dorado Rancheria, a non-Federally recognized Native American group, were also contacted by California State University, Sacramento.

History and Description of the Remains

Sometime during the 1920s and 1930s, human remains representing, at minimum, two individuals were removed from CA–SAC–006 (also known as Johnson Mound), located approximately 1.3 miles west of the Cosumnes River and 5.5 miles northeast of the intersection of the Mokelumne and Cosumnes Rivers in southern Sacramento County, CA. The human remains were in the possession of Anthony Zallio, a private collector, who posthumously donated his collection in 1951 to the Department of Anthropology at Sacramento State College, CA (now California State University, Sacramento). No known individuals were identified. The two associated funerary objects are one fish vertebra and one chert projectile point embedded in a human vertebra.

Archeological data suggests occupation occurred at the site as early as the Middle Horizon with historic occupation occurring until the Sutter Period. Ethnographic and historic data suggests that this site was once the tribelet center for the *Consomne* Plains Miwok. Historic records indicate that the site was attacked by the Spanish in 1820 with conflicts occurring with the Mexicans in 1826. Ethnohistoric records indicate that the *Consomne* eventually banded together in defense with other Plains Miwok groups, such as the *Ylamne* and *Sisumne,* who collectively led a series of uprisings against pioneer John Sutter in the 1840s. Eventually the *Consomne* abandoned the village site at CA–SAC–006 in 1844 to relocate to Sutter's New Helvetia (Sutter's Fort).

Sometime during the 1920s and 1930s, human remains representing at minimum, one individual were removed from CA–SAC–021 (also known as Hollister, Allister, or S–29), located immediately adjacent to Snodgrass Slough, approximately 1.3 miles southeast of the intersection of Snodgrass Slough and the Sacramento River, in southwestern Sacramento County, CA. The human remains were in possession of Anthony Zallio, a private collector, who posthumously donated his collection in 1951 to the Department of Anthropology at Sacramento State College, CA (now California State University, Sacramento). No known individuals were identified. No associated funerary objects were present.

The site location places CA–SAC–021 in the aboriginal territory of the Plains Miwok. Archeological evidence suggests occupation at the site occurred during the Middle Horizon through Phase 1 of the Late Horizon.

Sometime during the 1920s and 1930s, human remains representing, at minimum, four individuals were removed from CA–SAC–056 (also known as Mosher, Mosler, Hathaway No. 1, and S–56), located on the east bank of the Sacramento River near Stone Lake, approximately thirteen miles south of the confluence of the American and Sacramento Rivers, in southwest Sacramento County, CA. The human remains were in the possession of Anthony Zallio, a private collector, who posthumously donated his collection in 1951 to the Department of Anthropology at Sacramento State College, CA (now California State University, Sacramento). No known individuals were identified. No associated funerary objects are present.

Archeological evidence suggests occupation at the village occurred as early as Phase 1 of the Late Horizon. Archeological and ethnographic records indicate that the site may be *Walak,* a tribelet center for the *Gualacomne* Plains Miwok. The site was occupied historically between the Mission Period and early Sutter Period from 1769–1845. Mission records indicate that 67 individuals were baptized from this site, and historical records note *Walak* as the first Native American village visited by pioneer John Sutter.

Sometime during the 1920s and 1930s, human remains representing, at minimum, four individuals were removed from CA–SAC–066 (also known as Morse or Mores Mound) located on the north bank of the Mokelumne River, approximately 1.5 miles west of Mokelumne City in southwest Sacramento County, CA. The human remains were in the possession of Anthony Zallio, a private collector, who posthumously donated his collection in 1951 to the Department of Anthropology at Sacramento State College, CA (now California State University, Sacramento). No known individuals were identified. No associated funerary objects are present.

Archeological data suggest occupation at the site occurred during Phase 1 of

the Middle to Late Horizon. CA–SAC–066 is located within the aboriginal territory of the Plains Miwok.

Sometime during the 1920s and 1930s, human remains representing, at minimum, 16 individuals were removed from either CA–SAC–072 or CA–SAC–073 (also known as Herzog, Van Lobensels, and Vorden), located on the west bank of Snodgrass Slough in southwest Sacramento County, California. The human remains were in the possession of Anthony Zallio, a private collector, who posthumously donated his collection in 1951 to the Department of Anthropology at Sacramento State College, California (now California State University, Sacramento). No known individuals were identified. The four associated funerary objects include three obsidian projectile points and one basalt projectile point all embedded in human bone.

Archeological data suggests occupation occurring at CA–SAC–072 during Phase 2 of the Late Horizon, and occupation at CA–SAC–73 occurring sometime during the Middle Horizon. CA–SAC–072 and CA–SAC–73 are within the aboriginal territory of the Plains Miwok.

Sometime during the 1920s and 1930s, human remains representing, at minimum, one individual were removed from CA–SAC–075 (also known as Locke Mound #1, Locke Mound #2, S–76, CA–SAC–047, CA–SAC–076), located a half mile from the east bank of the Sacramento River approximately one mile north of Walnut Grove in southwestern Sacramento County, CA. The human remains were in the possession of Anthony Zallio, a private collector, who posthumously donated his collection in 1951 to the Department of Anthropology at Sacramento State College, CA (now California State University, Sacramento). No known individuals were identified. No associated funerary objects are present.

Ethnohistoric accounts indicate that the site was occupied by the *Junizumne* Plains Miwok. The *Junizumne* resisted baptism during the Mission period, and were attacked in 1813 and again in 1830 for harboring fugitive neophytes. Historic occupation at the site lasted until at least the Mission period when the malaria epidemic took hold in the region. Archeological data indicating the earliest occupation at the site is currently unavailable.

Sometime during the 1920s and 1930s, human remains representing, at minimum, 12 individuals were removed from CA–SAC–085 (also known as Nicolaus Site #2 or Nicholas), located on private property one mile south of the confluence of Morrison Creek and the Sacramento River in west-central Sacramento County, CA. The human remains were in the possession of Anthony Zallio, a private collector, who posthumously donated his collection in 1951 to the Department of Anthropology at Sacramento State College, CA (now California State University, Sacramento). The three associated funerary objects include one lot of *Olivella* shell beads, one stone ball, and one stone mortar fragment.

CA–SAC–085 may have been a suburb tribelet of a *Hulpumne* Plains Miwok village site located nearby at CA–SAC–086. Archeological records indicate occupation occurred during Phase 1 of the Late Horizon until the Mission Period from 1769 to 1839. It is believed that the site may have been abandoned during the 1833 malaria epidemic, with resettlement occurring by the *Gualacomne* Plains Miwok around the center of *Walak* (CA–SAC–056).

Sometime during the 1920s and 1930s, human remains representing, at minimum, six individuals were removed from CA–SAC–109 (also known as Drescher, C–109), located 3.5 miles southeast of Elk Grove in central Sacramento County, CA. CA–SAC–109 is frequently confused with C–117, Woodward, CA–SAC–117, and CA–SAC–200. The human remains were in the possession of Anthony Zallio, a private collector, who posthumously donated his collection in 1951 to the Department of Anthropology at Sacramento State College, CA (now California State University, Sacramento). No known individuals were identified. No associated funerary objects are present.

Archeological evidence indicates that occupation occurred at the site from the Middle to the Late Horizon. The site location places CA–SAC–109 within the aboriginal territory of the Plains Miwok Indians.

Sometime during the 1920s and 1930s, human remains representing, at minimum, two individuals were removed from CA–SAC–113 (also known as Calhoun #1, Calquehoun, or C–113), located on private property on the west bank of the Cosumnes River, east of Elk Grove in Sacramento County, CA. The human remains were in the possession of Anthony Zallio, a private collector, who posthumously donated his collection in 1951 to the Department of Anthropology at Sacramento State College, CA (now California State University, Sacramento). No known individuals were identified. No associated funerary objects are present.

This site may represent *Sukididi,* a subsidiary settlement for the *Shalachmushumne* Plains Miwok. It is believed that the village was abandoned after the 1833 malaria epidemic. A known archeological historic component is not present at the site, and its association with *Sukididi* has not been verified. Archeological data from the site indicate that it was occupied during Phase 2 of the Late Horizon.

Sometime during the 1920s and 1930s, human remains representing, at minimum, one individual were removed from CA–SAC–120 (also known as Goethe Mound #1 and #2), located on the east Bank of Deer Creek in northwest Elk Grove in central Sacramento County, CA. The human remains were in the possession of Anthony Zallio, a private collector, who posthumously donated his collection in 1951 to the Department of Anthropology at Sacramento State College, CA (now California State University, Sacramento). No known individuals were identified. No associated funerary objects are present.

Limited archeological and ethnohistorical data is available for CA–SAC–120, but it is believed to represent a small Plains Miwok Village known as *Shalachmushumne.* Archeological evidence suggests occupation at the site occurred during the Late Horizon. A census produced by Gatten recorded a population of fifty individuals at the village site in 1846. Historical documents suggest that the *Shalachmushumne* resisted missionization, and the survivors of the 1833 malaria epidemic may have become incorporated into the *Amuchamne* Plains Miwok in 1847.

In 1937, human remains representing, at minimum, one individual were removed from CA–SAC–122 (also known as Eichenburger or Hikinburger), located on the west bank of the Cosumnes River, approximately 9.5 miles-northwest of Elk Grove, in central Sacramento County, CA. The human remains were in possession of Anthony Zallio, a private collector, who posthumously donated his collection in 1951 to Sacramento State College (now California State University, Sacramento). No known individuals were identified. No associated funerary objects are present.

Archeological evidence indicates occupation occurred as early as Phase 1 of the Middle to Late Horizon. The site location places CA–SAC–122 within the aboriginal territory of the Plains Miwok.

Sometime during the 1920s and 1930s, human remains representing, at minimum, one individual were removed from CA–SAC–126 (also known as Boothe Mound), located on private property on the east bank of Deer Creek,

southwest of Sloughhouse in central Sacramento County, CA. The human remains were in the possession of Anthony Zallio, a private collector, who posthumously donated his collection in 1951 to the Department of Anthropology at Sacramento State College, CA (now California State University, Sacramento). No known individuals were identified. No associated funerary objects are present.

Archeological evidence indicates that occupation of the site occurred from the Late Middle Horizon with dispersal most likely occurring after the 1833 malaria epidemic. Archeological and ethnographic evidence indicates that CA–SAC–126 may have been the tribelet center of the *Amuchamne* Plains Miwok. The *Amuchamne* may have been the leading group of a series of cooperating tribelets that resisted missionization consisting of the *Newachumne, Shalachmushumne,* and *Lopotsimne.* Ethnohistoric records suggest the *Shalachmushumne* may have diffused into the *Amuchamne* in efforts to resist the *Yumhui* Nisenan migration into the area in 1847, which resulted from pioneer Jared Sheldon's increased reliance on Nisenan labor on his ranch along the Cosumnes River.

Sometime during the 1920s and 1930s, human remains representing, at minimum, five individuals were removed from CA–SJO–068 (also known as the Blossom Site), located approximately one mile south of Mokelumne River and three miles east of Walnut Grove, in northern San Joaquin County, CA. The human remains were in the possession of Anthony Zallio, a private collector, who posthumously donated his collection in 1951 to the Department of Anthropology at Sacramento State College, CA (now California State University, Sacramento). No known individuals were identified. No associated funerary objects are present.

The site location places CA–SJO–068 within the aboriginal territory of the Plains Miwok. Archeological data from the site suggest occupation occurred during the Early Horizon.

Sometime during the 1920s and 1930s, human remains representing, at minimum, three individuals were removed from CA–YOL–045 (also known as Indian Head or Holy Ghost), located on the west bank of the Sacramento River, approximately 8.75 miles due south of the confluence of the American and Sacramento Rivers, in southeast Yolo County, California. The human remains were in the possession of Anthony Zallio, a private collector, who posthumously donated his collection in 1951 to the Department of Anthropology at Sacramento State College, California (now California State University, Sacramento). No known individuals were identified. The twenty-four associated funerary objects include six lots of charred textiles, seven *Haliotis* shell ornaments, one quartz crystal, and ten lots of shell beads.

CA–YOL–045 is located within the aboriginal territory of the Plains Miwok. Archeological data indicates occupation occurred during Phase 1 of the Late Horizon.

Sometime during the 1920s and 1930s, human remains representing, at minimum, one individual were removed from CA–YOL–049 (also known as the Engwall Mound), located on the west bank of the Sacramento River, approximately 10.5 miles due south of the confluence of the American and Sacramento Rivers, in southeast Yolo County, CA. The human remains were in the possession of Anthony Zallio, a private collector, who posthumously donated his collection in 1951 to the Department of Anthropology at Sacramento State College, CA (now California State University, Sacramento). No known individuals were identified. No associated funerary objects are present.

CA–YOL–049 is likely associated with the Plains Miwok village of *Nasune,* and may have been a subsidiary settlement associated with the *Hulpumne* tribelet of the Plains Miwok. CA–YOL–049 was a protohistoric site likely abandoned after the 1833 malaria epidemic.

Sometime during the 1920s and 1930s, human remains representing, at minimum, six individual were removed from CA–YOL–053 (also known as the Frank King Mound), located on private property on the west bank of Elk Slough 2.5 miles southwest of Clarksburg in Yolo County, CA. The human remains were in the possession of Anthony Zallio, a private collector, who posthumously donated the collection in 1951 to the Department of Anthropology at Sacramento State College, CA (now California State University, Sacramento). No known individuals were identified. No associated funerary objects are present.

Ethnographic evidence indicates that CA–YOL–053 may have been the tribelet center for the *Ylamne* Plains Miwok. Earliest known occupation occurred from Phase 2 of the Early Horizon and lasted until the Late Mission Period from 1769 to 1839. The site is believed to have been abandoned after the 1833 malaria epidemic with survivors shifting residence to neighboring tribelets and to Mission San Jose.

Archeological evidence indicates the lower Sacramento Valley and Delta regions were continuously occupied since at least the Early Horizon (5550–550 B.C.). Cultural changes indicated by artifact typologies and burial patterns, historical linguistic evidence, and biological evidence reveal that the populations in the region were not static, with both *in situ* cultural changes and migrations of outside populations into the area. Linguistic evidence suggests that ancestral-Penutian speaking groups related to modern day Miwok, Nisenan, and Patwin groups occupied the region during the Middle (550 B.C.–A.D. 1100) and Late (A.D. 1100–Historic) Horizons, with some admixing between these groups and Hokan-speaking groups that occupied the region at an earlier date. The genetic data suggests that the Penutians may have arrived later than suggested by the glottochronology.

Geographical data from ethnohistoric and ethnographic sources indicate that the site was most likely occupied by Plains Miwok-speaking groups at the beginning of the historic period, with Patwin-speakers occupying the valley west of the Sacramento River and Nisenan-speakers north of the American River. Ethnographic data and expert testimony from Tribes support the high level of interaction between groups in the lower Sacramento Valley and Delta regions that crosscut linguistic boundaries. Historic population movements resulted in an increased level of shifting among populations impacted by disease, violence, and Euro-American activities relating to Sutter's Fort and later gold-rush activities.

Due to the collecting methodology used by Zallio, the age of the human remains and associated funerary objects from the above archeological sites is currently unknown. However, Zallio excavated mound sites prior to leveling for agriculture and development, and it is believed that the most recent occupation of the sites was likely intact at the time. Based on this circumstantial evidence, it is more likely than not that Zallio collected human remains and cultural items from the youngest deposits. Such deposits date to the Historic Period and Late Horizon; the preponderance of evidence indicates that these temporal periods are most closely culturally affiliated with the Plains Miwok, with more distant ties to neighboring groups, such as the Nisenan, Patwin, and Yokuts.

Determinations Made by California State University, Sacramento

Officials of California State University, Sacramento have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 66 individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 33 objects described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and the Buena Vista Rancheria of Me-Wuk Indians of California; California Valley Miwok Tribe, California; Chicken Ranch Rancheria of Me-Wuk Indians of California; Ione Band of Miwok Indians of California; Jackson Rancheria of Me-Wuk Indians of California; Shingle Springs Band of Miwok Indians, Shingle Springs Rancheria (Verona Tract), California; Tuolumne Band of Me-Wuk Indians of the Tuolumne Rancheria of California; United Auburn Indian Community of the Auburn Rancheria of California; Wilton Rancheria, California; and two non-Federally recognized Native American groups: El Dorado Miwok Rancheria; and Nashville-Eldorado Miwok (if joined to the request of one or more of the foregoing Indian tribes).

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Orn Bodvarsson, Dean of the College of Social Sciences and Interdisciplinary Studies, CSUS, 6000 J Street, Sacramento, CA 95819–6109, telephone (916) 278–4864, email *obbodvarsson@csus.edu,* by March 9, 2015. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to the Buena Vista Rancheria of Me-Wuk Indians of California; California Valley Miwok Tribe, California; Chicken Ranch Rancheria of Me-Wuk Indians of California; Ione Band of Miwok Indians of California; Jackson Rancheria of Me-Wuk Indians of California; Shingle Springs Band of Miwok Indians, Shingle Springs Rancheria (Verona Tract), California; Tuolumne Band of Me-Wuk Indians of the Tuolumne Rancheria of California; United Auburn Indian Community of the Auburn Rancheria of California; Wilton Rancheria, California and two non-Federally recognized Native American groups: El Dorado Miwok Rancheria; and Nashville-Eldorado Miwok (if joined to the request of one or more of the foregoing Indian tribes) may proceed.

California State University, Sacramento is responsible for notifying Buena Vista Rancheria of Me-Wuk Indians of California; Cachil DeHe Band of Wintun Indians of the Colusa Indian Community of the Colusa Rancheria, California; California Valley Miwok Tribe, California; Chicken Ranch Rancheria of Me-Wuk Indians of California; Cortina Indian Rancheria of Wintun Indians of California; Ione Band of Miwok Indians of California; Jackson Rancheria of Me-Wuk Indians of California; Picayune Rancheria of Chukchansi Indians of California; Santa Rosa Indian Community of the Santa Rosa Rancheria, California; Shingle Springs Band of Miwok Indians, Shingle Springs Rancheria (Verona Tract), California; Susanville Indian Rancheria, California; Table Mountain Rancheria of California; Tule River Indian Tribe of the Tule River Reservation, California; Tuolumne Band of Me-Wuk Indians of the Tuolumne Rancheria of California; United Auburn Indian Community of the Auburn Rancheria of California; Wilton Rancheria, California; Wiyot Tribe, California (previously listed as the Table Bluff Reservation-Wiyot Tribe); and Yocha Dehe Wintun Nation, California (previously listed as the Rumsey Indian Rancheria of Wintun Indians of California) that this notice has been published. California State University, Sacramento will also notify El Dorado Miwok Rancheria; and Nashville-Eldorado Miwok, two non-Federally recognized Native American groups, that this notice has been published.

Dated: December 29, 2014.

Melanie O'Brien,

Acting Manager, National NAGPRA Program.

[FR Doc. 2015–02259 Filed 2–5–15; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NERO–CACO–17530: PPNECACOS0, PPMPSD1Z.YM0000]

Notice of March 30, 2015, Meeting for Cape Cod National Seashore Advisory Commission

AGENCY: National Park Service, Interior.

ACTION: Meeting Notice.

SUMMARY: This notice sets forth the date of the 298th Meeting of the Cape Cod National Seashore Advisory Commission.

DATES: The public meeting of the Cape Cod National Seashore Advisory Commission will be held on Monday, March 30, 2015, at 1:00 p.m. (EASTERN).

ADDRESSES: The Commission members will meet in the conference room at park headquarters, 99 Marconi Site Road, Wellfleet, Massachusetts 02667.

The 298th meeting of the Cape Cod National Seashore Advisory Commission will take place on Monday, March 30, 2015, at 1:00 p.m., in the conference room at Headquarters, 99 Marconi Station Road, in Wellfleet, Massachusetts to discuss the following:

1. Adoption of Agenda
2. Approval of Minutes of Previous Meeting
   (January 12, 2015)
3. Reports of Officers
4. Reports of Subcommittees
   Update of Pilgrim Nuclear Plant Emergency Planning Subcommittee
   State Legislation Proposals
5. Superintendent's Report
   Shorebird Management Planning
   Nauset Spit Update
   Proposed Recreational Fee Increase
   Use of Unmanned Aircraft Systems
   National Park Service Centennial
   Improved Properties/Town Bylaws
   Herring River Wetland Restoration
   Highlands Center Update
   Ocean Stewardship Topics—Shoreline Change
   Climate Friendly Parks
6. Old Business
   Live Lightly Campaign Progress Report
7. New Business
8. Date and Agenda for Next Meeting
9. Public Comment
10. Adjournment

FOR FURTHER INFORMATION CONTACT: Further information concerning the meeting may be obtained from George E. Price, Jr., Superintendent, Cape Cod National Seashore, 99 Marconi Site Road, Wellfleet, MA 02667, or via telephone at (508) 771–2144.

SUPPLEMENTARY INFORMATION: The Commission was reestablished pursuant to Public Law 87–126, as amended by Public Law 105–280. The purpose of the Commission is to consult with the Secretary of the Interior, or her designee, with respect to matters relating to the development of Cape Cod National Seashore, and with respect to carrying out the provisions of sections 4 and 5 of the Act establishing the Seashore.

The meeting is open to the public. It is expected that 15 persons will be able to attend the meeting in addition to Commission members. Interested persons may make oral/written presentations to the Commission during the business meeting or file written statements. Such requests should be made to the park superintendent prior to the meeting. Before including your address, telephone 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 may 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.

Dated: January 29, 2015.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2015–02098 Filed 2–5–15; 8:45 am]

BILLING CODE 4310–EE–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–AKRO–ANIA–DENA–17509; PPAKAKROR4; PPMPRLE1Y.LS0000]

Aniakchak National Monument Subsistence Resource Commission SRC Denali National Park SRC Meeting Dates

AGENCY: National Park Service, Interior.

ACTION: Meeting Notice.

SUMMARY: As required by the Federal Advisory Committee Act (5 U.S.C. Appendix 1–16), the National Park Service (NPS) is hereby giving notice that the Aniakchak National Monument Subsistence Resource Commission (SRC) and Denali National Park SRC, will hold meetings to develop and continue work on NPS subsistence program recommendations, and other related regulatory proposals and resource management issues. The NPS SRC program is authorized under Section 808 of the Alaska National Interest Lands Conservation Act (16 U.S.C. 3118), Title VIII.

Aniakchak National Monument SRC Meeting Dates and Location: The Aniakchak National Monument SRC will meet from 1:00 p.m. to 5:00 p.m. or until business is completed on Friday, February 20, 2015, at the Port Heiden Community in Hall Port Heiden, AK. The meeting is open to the public.

For more detailed information regarding the Aniakchak National Monument SRC meeting, or if you are interested in applying for SRC membership, contact Designated Federal Official Diane Chung, Superintendent, at (907) 246–3305, or via email *diane_chung@nps.gov,* or Clarence Summers, Subsistence Manager, at (907) 644–3603, or via email *clarence_summers@nps.gov.*

Denali National Park SRC Meeting/ Teleconference Dates and Location: The Denali National Park SRC will meet/ teleconference from 9:00 a.m. to 5:00 p.m. or until business is completed on Wednesday, February 25, 2015, at Pike's Waterfront Lodge in Fairbanks, AK. The teleconference will be open to the public. Teleconference participants must call Amy Craver, Subsistence Manager, at (907) 683–9544 or via email *amy_craver@nps.gov,* by Monday, February 23, 2015, prior to the meeting to receive teleconference passcode information.

For more detailed information regarding the Denali National Park SRC meetings, or if you are interested in applying for SRC membership, contact Designated Federal Official Don Striker, Superintendent, at (907) 683–2294, or via email *don_striker@nps.gov,* or Clarence Summers, Subsistence Manager, at (907) 644–3603, or via email *clarence_summers@nps.gov.*

Proposed Meeting Agenda: The agenda may change to accommodate SRC business. The proposed meeting agenda for each meeting includes the following:

1. Call to Order—Confirm Quorum
2. Welcome and Introductions
3. Review and Adoption of Agenda
4. Approval of Minutes
5. Superintendent's Welcome and Review of the Commission Purpose
6. Commission Membership Status
7. SRC Chair and Members' Reports
8. Superintendent's Report—NPS
9. Old Business
10. New Business
11. Federal Subsistence Board Update
12. Alaska Boards of Fish and Game Update
13. National Park Service Reports
    a. Ranger Update
    b. Resource Management Update
    c. Subsistence Manager's Report
14. Public and Other Agency Comments
15. Work Session
16. Set Tentative Date and Location for Next SRC Meeting
17. Adjourn Meeting

SRC meeting locations and dates may change based on inclement weather or exceptional circumstances. If the meeting date and location are changed, the Superintendent will issue a press release and use local newspapers and radio stations to announce the rescheduled meeting.

SUPPLEMENTARY INFORMATION: SRC meetings are open to the public and will have time allocated for public testimony. The public is welcome to present written or oral comments to the SRC. SRC meetings will be recorded and meeting minutes will be available upon request from the Superintendent for public inspection approximately six weeks after the meeting. Before including your address, telephone 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 may 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.

Dated: January 29, 2015.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2015–02099 Filed 2–5–15; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–17527; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

Nominations for the following properties being considered for listing or related actions in the National Register were received by the National Park Service before January 10, 2015. Pursuant to section 60.13 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation. Comments may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St. NW., MS 2280, Washington, DC 20240; by all other carriers, National Register of Historic

Places, National Park Service, 1201 Eye St. NW., 8th floor, Washington, DC 20005; or by fax, 202–371–6447. Written or faxed comments should be submitted by February 23, 2015. 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.

Dated: January 20, 2015.

James Gabbert,

Acting Chief, National Register of Historic Places, National Historic Landmarks Program.

ARIZONA

Maricopa County

Sun City DEVCO Model No.1, 10801 W. Oakmont Dr., Sun City, 15000022

CALIFORNIA

San Bernardino County

Guapiabit—Serrano Homeland Archeological District, Address Restricted, Hesperia, 15000023

GEORGIA

Bibb County

Bowden, Charles L., Golf Course, 3111 Millerfield Rd., Macon, 15000024

Fulton County

Utoy Cemetery, 1465 Cahaba Dr., Atlanta, 15000025

NEW MEXICO

Colfax County

Immanuel Lutheran Church, 307 Summit Ave., Springer, 15000026

Dona Ana County

Mesilla Park Elementary School, 304 Bell Ave., Las Cruces, 15000039

NEW YORK

Albany County

Washington Park Historic District (Boundary Increase), Henry Johnson Blvd., Sprague Pl. & Spring St., Albany, 15000027

Franklin County

Valentine, Chester, House, 182 Lake St., Saranac Lake, 15000028

Livingston County

Elmwood, 19 N. Walnut St., Nunda, 15000030

New York County

Congregation Shaare Zedek of Harlem, 23 W. 118th St., New York, 15000031

Saratoga County

Dunning Street Cemetery, Dunning St., Malta, 15000033

St. Lawrence County

Potsdam State Normal School Campus, 41 Elm & 56–60 Main Sts., Potsdam, 15000032

Steuben County

Bolton, James H., House, 117 W. Washington St., Bath, 15000034

Warren County

Queensbury Quaker Burying Ground, Bay & Quaker Rds., Queensbury, 15000035

Westchester County

Leffingwell—Batcheller House, 250 Palisade Ave., Yonkers, 15000036

OHIO

Clermont County

Groesbeck, Grace, House, 4949 Tealtown Rd., Perintown, 15000037

Cuyahoga County

Fairmont Creamery Company Ice Cream Building, 1720 Willey Ave., 2306 W. 17th St., Cleveland, 15000038

Franklin County

Hamlet, The, 138–166 E. 5th & 1193–1195 Hamlet Sts., Columbus, 15000040

Greene County

Xenia Carnegie Library, 194 E. Church St., Xenia, 15000041

Hamilton County

Crosley Building, 1329–1333 Arlington St., Cincinnati, 15000042

Montgomery County

Bombeck, Erma, House, 162 Cushwa Dr., Centerville, 15000043

OREGON

Benton County

Gorman, Hannah and Eliza, House, 641 NW. 4th St., Corvallis, 15000045

[FR Doc. 2015–02366 Filed 2–5–15; 8:45 am]

BILLING CODE 4312–51–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–17535; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

Nominations for the following properties being considered for listing or related actions in the National Register were received by the National Park Service before January 17, 2015. Pursuant to section 60.13 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation. Comments may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St. NW., MS 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 1201 Eye St. NW., 8th floor, Washington, DC 20005; or by fax, 202–371–6447. Written or faxed comments should be submitted by February 23, 2015. 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.

Dated: January 21, 2015.

Kevin Moriarty,

Acting Chief, National Register of Historic Places, National Historic Landmarks Program.

KANSAS

Shawnee County

United States Post Office and Court House, 424 S. Kansas Ave., Topeka, 15000046

MASSACHUSETTS

Berkshire County

Rice, A.H., Silk Mill, 55 Spring St., Pittsfield, 15000047

Suffolk County

Boston Police Station Number One—Traffic Tunnel Administration Building, 128, 150 North & 130–140 Richmond Sts., Boston, 15000048

NEW JERSEY

Hudson County

Hook and Ladder No. 3, 218 Central Ave., Jersey City, 15000049

West Bergen—East Lincoln Park Historic District, Roughly bounded by Bergen, Harrison, West Side, Kensington & Fairmount Aves., Kennedy Blvd. & Montgomery St., Jersey City, 15000050

Morris County

Mount Tabor Historic District, Roughly bounded by Tabor & Dickerson Rds., Simpson & Ridgewood Aves. & Mount Tabor Golf Course, Parsippany-Troy Hills Township, 15000051

OREGON

Marion County

Adams, Louise, House, (Silverton, Oregon, and Its Environs MPS), 401 Main St., Silverton, 15000052

DeGuire—Ludowitzki House, (Silverton, Oregon, and Its Environs MPS), 840 Water St., Silverton, 15000053

Multnomah County

Lewis, C. Hunt and Gertrude McClintock, House, 11645 SW. Military Ln., Portland, 15000054

RHODE ISLAND

Providence County

Standard Paper Box Corporation, 110 Kenyon Ave., Pawtucket, 15000055

WISCONSIN

Adams County

Gunning-Purves Building, 311 Main St., Friendship, 15000056

A request for removal has been received for the following resources:

TEXAS

Garza County

Old Algerita Hotel, S. corner of Main and Ave. I, Post, 75001983

Montgomery County

Arnold-Simonton House, Rankin St., Montgomery, 79002996

[FR Doc. 2015–02367 Filed 2–5–15; 8:45 am]

BILLING CODE 4312–51–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[MMAA104000]

Central Gulf of Mexico Planning Area (CPA) Outer Continental Shelf (OCS) Oil and Gas Lease Sale 235 (CPA Sale 235)

AGENCY: Bureau of Ocean Energy Management, Interior.

ACTION: Final notice of sale.

SUMMARY: On Wednesday, March 18, 2015, BOEM will open and publicly announce bids for blocks offered in CPA Sale 235 in accordance with the provisions of the OCS Lands Act (OCSLA, 43 U.S.C. 1331–1356, as amended) and the implementing regulations issued pursuant thereto (30 CFR parts 550 and 556).

The CPA 235 Final Notice of Sale (NOS) Package (Final NOS Package) contains information essential to potential bidders; bidders are charged with knowing the contents of the documents contained in the Final NOS Package. The Final NOS Package is available at the address and Web site below.

DATES: Public bid reading for CPA Sale 235 will begin at 9:00 a.m. on Wednesday, March 18, 2015, at the Mercedes-Benz Superdome, 1500 Sugarbowl Drive, New Orleans, Louisiana 70112. The lease sale will be held in the St. Charles Club Room on the second floor (Loge Level). Entry to the Superdome will be on the Poydras Street side of the building through Gate A on the Ground Level; parking will be available at Garage 6. All times referred to in this document are local times in New Orleans, unless otherwise specified.

Bid Submission Deadline: BOEM must receive all sealed bids between 8:00 a.m. and 4:00 p.m. on normal working days, or from 8:00 a.m. to the Bid Submission Deadline of 10:00 a.m. on Tuesday, March 17, 2015, the day before the lease sale. For more information on bid submission, see Section VII, ''Bidding Instructions,'' of this document.

ADDRESS: Interested parties, upon request, may obtain a compact disc (CD–ROM) containing the Final NOS Package by contacting the BOEM Gulf of Mexico (GOM) Region at the following address: Gulf of Mexico Region Public Information Office, Bureau of Ocean Energy Management, 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123–2394, (504) 736–2519 or (800) 200–GULF, or by visiting the BOEM Web site at *http://www.boem.gov/Sale-235/.*

Table of Contents

This Final NOS includes the following sections:

I. Lease Sale Area
II. Statutes And Regulations
III. Lease Terms And Economic Conditions
IV. Lease Stipulations
V. Information To Lessees
VI. Maps
VII. Bidding Instructions
VIII. Bidding Rules And Restrictions
IX. Forms
X. The Lease Sale
XI. Delay Of Sale

I. Lease Sale Area

Blocks Offered for Leasing

Note: Due to the expiration of a treaty prohibition on exploration and development within 1.4 nautical miles of the Continental Shelf Boundary (1.4-nautical mile buffer area) with Mexico, BOEM has decided to offer for lease in CPA Sale 235 all whole and partial blocks in the 1.4-nautical mile buffer area. The Agreement between the United States of America and the United Mexican States Concerning Transboundary Hydrocarbon Reservoirs in the Gulf of Mexico (Agreement) entered into force on July 18, 2014, and will apply to, among others, whole and partial blocks in the 1.4-nautical mile buffer area.

In CPA Sale 235, BOEM is offering for lease all blocks and partial blocks in the document ''List of Blocks Available for Leasing'' included in the Final NOS Package. All of these blocks are shown on the following leasing maps and Official Protraction Diagrams (OPDs):

Outer Continental Shelf Leasing Maps—Louisiana Map Numbers 1 through 12

LA1 West Cameron Area (Revised July 1, 2011)
LA1A West Cameron Area, West Addition (Revised February 28, 2007)
LA1B West Cameron Area, South Addition (Revised February 28, 2007)
LA2 East Cameron Area (Revised November 1, 2000)
LA2A East Cameron Area, South Addition (Revised November 1, 2000)
LA3 Vermilion Area (Revised November 1, 2000)
LA3A South Marsh Island Area (Revised November 1, 2000)
LA3B Vermilion Area, South Addition (Revised November 1, 2000)
LA3C South Marsh Island Area, South Addition (Revised November 1, 2000)
LA3D South Marsh Island Area, North Addition (Revised November 1, 2000)
LA4 Eugene Island Area (Revised November 1, 2000)
LA4A Eugene Island Area, South Addition (Revised November 1, 2000)
LA5 Ship Shoal Area (Revised November 1, 2000)
LA5A Ship Shoal Area, South Addition (Revised November 1, 2000)
LA6 South Timbalier Area (Revised November 1, 2000)
LA6A South Timbalier Area, South Addition (Revised November 1, 2000)
LA6B South Pelto Area (Revised November 1, 2000)
LA6C Bay Marchand Area (Revised November 1, 2000)
LA7 Grand Isle Area (Revised November 1, 2000)
LA7A Grand Isle Area, South Addition (Revised February 17, 2004)
LA8 West Delta Area (Revised November 1, 2000)
LA8A West Delta Area, South Addition (Revised November 1, 2000)
LA9 South Pass Area (Revised November 1, 2000)
LA9A South Pass Area, South and East Additions (Revised November 1, 2000)
LA10 Main Pass Area (Revised November 1, 2000)
LA10A Main Pass Area, South and East Additions (Revised November 1, 2000)
LA10B Breton Sound Area (Revised November 1, 2000)
LA11 Chandeleur Area (Revised November 1, 2000)
LA11A Chandeleur Area, East Addition (Revised November 1, 2000)
LA12 Sabine Pass Area (Revised July 1, 2011)

Outer Continental Shelf Official Protraction Diagrams

NG15–02 Garden Banks (Revised February 28, 2007)
NG15–03 Green Canyon (Revised November 1, 2000)
NG15–05 Keathley Canyon (Revised October 1, 2014)
NG15–06 Walker Ridge (Revised November 1, 2000)
NG15–08 Sigsbee Escarpment (Revised October 1, 2014)
NG15–09 Amery Terrace (Revised October 1, 2014)

NG16–01 Atwater Valley (Revised November 1, 2000)
NG16–02 Lloyd Ridge (Revised August 1, 2008)
NG16–04 Lund (Revised November 1, 2000)
NG16–05 Henderson (Revised August 1, 2008)
NG16–07 Lund South (Revised October 1, 2014)
NG16–08 Florida Plain (Revised February 28, 2007)
NH15–12 Ewing Bank (Revised November 1, 2000)
NH16–04 Mobile (Revised July 1, 2011)
NH16–05 Pensacola (Revised February 28, 2007)
NH16–07 Viosca Knoll (Revised November 1, 2000)
NH16–08 Destin Dome (Revised February 28, 2007)
NH16–10 Mississippi Canyon (Revised November 1, 2000)
NH16–11 De Soto Canyon (Revised August 1, 2008)

Please Note: A CD–ROM (in ArcInfo and Acrobat (.pdf) format) containing all of the GOM leasing maps and OPDs, is available from the BOEM Gulf of Mexico Region Public Information Office for a price of $15.00. These GOM leasing maps and OPDs also are available for free online in .pdf and .gra formats at *http://www.boem.gov/Oil-and-Gas-Energy-Program/Mapping-and-Data/Official-Protraction-Diagrams.aspx.*

For the current status of all CPA leasing maps and OPDs, please refer to 66 FR 28002 (May 21, 2001), 69 FR 23211 (April 28, 2004), 72 FR 27590 (May 16, 2007), 72 FR 35720 (June 29, 2007), 73 FR 63505 (October 24, 2008), 76 FR 54787 (September 2, 2011), 79 FR 32572 (June 5, 2014), and 80 FR 3251 (January 22, 2015). In addition, Supplemental Official OCS Block Diagrams (SOBDs) for blocks containing the U.S. 200-Nautical Mile Limit line and the U.S.-Mexico Maritime and Continental Shelf Boundary line are available. These SOBDs also are available from the BOEM Gulf of Mexico Region Public Information Office and on BOEM's Web site at *http://www.boem.gov/Oil-and-Gas-Energy-Program/Mapping-and-Data/Supplemental-Official-OCS-Block-Diagrams-SOBDs.aspx.* For additional information, or to order the above referenced maps or diagrams, please call the Mapping and Automation Section at (504) 736–5768.

All blocks being offered in the lease sale are shown on these leasing maps and OPDs. The available Federal acreage of all whole and partial blocks in this lease sale is shown in the document ''List of Blocks Available for Leasing'' included in the Final NOS Package. Some of these blocks may be partially leased or deferred, or transected by administrative lines such as the Federal/State jurisdictional line. A bid on a block must include all of the available Federal acreage of that block. Also, information on the unleased portions of such blocks is found in the document entitled ''Central Planning Area, Lease Sale 235, March 18, 2015—Unleased Split Blocks and Available Unleased Acreage of Blocks with Aliquots and Irregular Portions under Lease or Deferred,'' which is included in the Final NOS Package.

For additional information, please call Mr. Lenny Coats, Chief of the Mapping and Automation Section, at (504) 736–1457.

Blocks Not Offered for Leasing: The following whole and partial blocks are not offered for lease in this sale:

Whole and partial blocks deferred by the Gulf of Mexico Energy Security Act of 2006, Public Law. 109–432:

Pensacola (OPD NH 16–05)

Whole Blocks: 751 through 754, 793 through 798, 837 through 842, 881 through 886, 925 through 930, and 969 through 975

Destin Dome (OPD NH 16–08)

Whole Blocks: 1 through 7, 45 through 51, 89 through 96, 133 through 140, 177 through 184, 221 through 228, 265 through 273, 309 through 317, 353 through 361, 397 through 405, 441 through 450, 485 through 494, 529 through 538, 573 through 582, 617 through 627, 661 through 671, 705 through 715, 749 through 759, 793 through 804, 837 through 848, 881 through 892, 925 through 936, and 969 through 981

De Soto Canyon (OPD NH 16–11)

Whole Blocks: 1 through 15, 45 through 59, and 92 through 102
Partial Blocks: 16, 60, 61, 89 through 91, 103 through 105, and 135 through 147

Henderson (OPD NG 16–05)

Partial Blocks: 114, 158, 202, 246, 290, 334, 335, 378, 379, 422, and 423

Blocks that are adjacent to or beyond the United States Exclusive Economic Zone in the area known as the northern portion of the Eastern Gap:

Lund South (OPD NG 16–07)

Whole Blocks: 128, 129, 169 through 173, 208 through 217, 248 through 261, 293 through 305, and 349

Henderson (OPD NG 16–05)

Whole Blocks: 466, 508 through 510, 551 through 554, 594 through 599, 637 through 643, 679 through 687, 722 through 731, 764 through 775, 807 through 819, 849 through 862, 891 through 905, 933 through 949, and 975 through 992

Partial Blocks: 467, 511, 555, 556, 600, 644, 688, 732, 776, 777, 820, 821, 863, 864, 906, 907, 950, 993, and 994

Florida Plain (OPD NG 16–08)

Whole Blocks: 5 through 24, 46 through 67, 89 through 110, 133 through 154, 177 through 197, 221 through 240, 265 through 283, 309 through 327, and 363 through 370

The following block whose lease status is currently under appeal:

West Cameron (Leasing Map LA1) Block 171

II. Statutes and Regulations

Each lease is issued pursuant to OCSLA, and is subject to OCSLA, implementing regulations promulgated pursuant thereto, and other applicable statutes and regulations in existence upon the effective date of the lease, as well as those applicable statutes enacted and regulations promulgated thereafter, except to the extent that the after-enacted statutes and regulations explicitly conflict with an express provision of the lease. Each lease also is subject to amendments to statutes and regulations, including, but not limited to, OCSLA, that do not explicitly conflict with an express provision of the lease. The lessee expressly bears the risk that such new or amended statutes and regulations (*i.e.,* those that do not explicitly conflict with an express provision of the lease) may increase or decrease the lessee's obligations under the lease.

III. Lease Terms And Economic Conditions

Lease Terms

OCS Lease Form

BOEM will use Form BOEM–2005 (October 2011) to convey leases resulting from this sale. This lease form may be viewed on the BOEM Web site at *http://www.boem.gov/About-BOEM/Procurement-Business-Opportunities/BOEM–OCS-Operation-Forms/BOEM-2005.aspx.* The lease form will be amended to conform with the specific terms, conditions, and stipulations applicable to the individual lease. The terms, conditions, and stipulations applicable to this sale are set forth below.

Initial Periods

Initial periods are summarized in the following table:

Water depth (meters)	Initial period
0 to < 400	Standard initial period is 5 years; the lessee may earn an additional 3 years (i.e., for an 8-year extended initial period) if a well is spudded targeting hydrocarbons below 25,000 feet True Vertical Depth Subsea (TVD SS) during the first 5 years of the lease.
400 to < 800	Standard initial period is 5 years; the lessee will earn an additional 3 years (i.e., for an 8-year extended initial period) if a well is spudded during the first 5 years of the lease.
800 to < 1,600	Standard initial period is 7 years; the lessee will earn an additional 3 years (i.e., for a 10-year extended initial period) if a well is spudded during the first 7 years of the lease.
1,600 +	10 years.

(1) The standard initial period for a lease in water depths less than 400 meters issued as a result of this sale is 5 years. If the lessee spuds a well targeting hydrocarbons below 25,000 feet TVD SS within the first 5 years of the lease, then the lessee may earn an additional 3 years, resulting in an 8-year extended initial period. The lessee will earn the 8-year extended initial period when the well is drilled to a target below 25,000 feet TVD SS, or the lessee may earn the 8-year extended initial period in cases where the well targets, but does not reach, a depth below 25,000 feet TVD SS due to mechanical or safety reasons, where sufficient evidence is provided.

In order to earn the 8-year extended initial period, the lessee is required to submit to the Bureau of Safety and Environmental Enforcement (BSEE) Gulf of Mexico Regional Supervisor for Production and Development, within 30 days after completion of the drilling operation, a letter providing the well number, spud date, information demonstrating a target below 25,000 feet TVD SS and whether that target was reached, and if applicable, any safety, mechanical, or other problems encountered that prevented the well from reaching a depth below 25,000 feet TVD SS. The BSEE Gulf of Mexico Regional Supervisor for Production and Development must concur in writing that the conditions have been met for the lessee to earn the 8-year extended initial period. The BSEE Gulf of Mexico Regional Supervisor for Production and Development will provide a written response within 30 days of receipt of the lessee's letter.

A lessee that has earned the 8-year extended initial period by spudding a well with a hydrocarbon target below 25,000 feet TVD SS during the first 5 years of the lease, confirmed by BSEE, will not be granted a suspension for that same period under the regulations at 30 CFR 250.175 because the lease is not at risk of expiring.

(2) The standard initial period for a lease in water depths ranging from 400 to less than 800 meters issued as a result of this sale is 5 years. The lessee will earn an additional 3 years, resulting in an 8-year extended initial period, if the lessee spuds a well within the first 5 years of the lease.

In order to earn the 8-year extended initial period, the lessee is required to submit to the appropriate BSEE District Manager, within 30 days after spudding a well, a letter providing the well number and spud date, and requesting concurrence that the lessee has earned the 8-year extended initial period. The BSEE District Manager will review the request and make a written determination within 30 days of receipt of the request. The BSEE District Manager must concur in writing that the conditions have been met by the lessee to earn the 8-year extended initial period.

(3) The standard initial period for a lease in water depths ranging from 800 to less than 1,600 meters issued as a result of this sale will be 7 years. The lessee will earn an additional 3 years, resulting in a 10-year extended initial period, if the lessee spuds a well within the first 7 years of the lease.

In order to earn the 10-year extended initial period, the lessee is required to submit to the appropriate BSEE District Manager, within 30 days after spudding a well, a letter providing the well number and spud date, and requesting concurrence that the lessee has earned the 10-year extended initial period. The BSEE District Manager will review the request and make a written determination within 30 days of receipt of the request. The BSEE District Manager must concur in writing that the conditions have been met by the lessee to earn the 10-year extended initial period.

(4) The standard initial period for a lease in water depths 1,600 meters or greater issued as a result of this sale will be 10 years.

Economic Conditions

Minimum Bonus Bid Amounts

- $25.00 per acre or fraction thereof for blocks in water depths less than 400 meters
- $100.00 per acre or fraction thereof for blocks in water depths 400 meters or deeper

BOEM will not accept a bonus bid unless it provides for a cash bonus in the amount equal to, or exceeding, the specified minimum bid of $25.00 per acre or fraction thereof for blocks in water depths less than 400 meters, and $100.00 per acre or fraction thereof for blocks in water depths 400 meters or deeper.

Rental Rates

Annual rental rates are summarized in the following table:

RENTAL RATES PER ACRE OR FRACTION THEREOF

Water depth (meters)	Years 1–5	Years 6, 7, & 8 +
0 to < 200	$7.00	$14.00, $21.00, & $28.00
200 to < 400	11.00	22.00, 33.00, & 44.00
400 +	11.00	16.00

Escalating Rental Rates for Leases With an 8-Year Extended Initial Period in Water Depths Less Than 400 Meters

Any lessee with a lease in less than 400 meters water depth who earns an 8-year extended initial period will pay an escalating rental rate as shown above. The rental rates after the fifth year for blocks in less than 400 meters water depth will become fixed and no longer escalate, if another well is spudded targeting hydrocarbons below 25,000 feet TVD SS after the fifth year of the lease, and BSEE concurs that such a well has been spudded. In this case, the rental rate will become fixed at the rental rate in effect during the lease year in which the additional well was spudded.

Royalty Rate

- 18.75 percent.

Minimum Royalty Rate

- $7.00 per acre or fraction thereof per year for blocks in water depths less than 200 meters.
- $11.00 per acre or fraction thereof per year for blocks in water depths 200 meters or deeper.

Royalty Suspension Provisions

The issuance of leases with royalty suspension volumes (RSVs) or other forms of royalty relief is authorized under existing BOEM regulations at 30 CFR part 560. The specific details relating to eligibility and implementation of the various royalty relief programs, including those involving the use of RSVs, are codified in BSEE regulations at 30 CFR part 203. In this sale, the only royalty relief program being offered is the provision of RSVs, related to the drilling of ultra-deep wells in water depths less than 400 meters, as described below.

Royalty Suspension Volumes on Gas Production From Ultra-Deep Wells

Leases issued as a result of this sale may be eligible for RSV incentives on gas produced from ultra-deep wells pursuant to 30 CFR part 203. These regulations implement the requirements of the Energy Policy Act of 2005. Under this program, certain wells on leases in less than 400 meters water depth and completed to a drilling depth of 20,000 feet TVD SS or deeper may receive an RSV of 35 billion cubic feet on the production of natural gas. This RSV incentive is subject to applicable price thresholds set forth in the regulations at 30 CFR part 203.

IV. Lease Stipulations

One or more of the following stipulations may be applied to leases issued as a result of this sale. The detailed text of these stipulations is contained in the ''Lease Stipulations'' section of the Final NOS Package.

(1) Topographic Features
(2) Live Bottom
(3) Military Areas
(4) Evacuation
(5) Coordination
(6) Blocks South of Baldwin County, Alabama
(7) United Nations Convention on the Law of the Sea Royalty Payment
(8) Protected Species
(9) Below Seabed Operations
(10) Agreement between the United States of America and the United Mexican States Concerning Transboundary Hydrocarbon Reservoirs in the Gulf of Mexico

V. Information To Lessees

The Information to Lessees (ITL) clauses provide detailed information on certain issues pertaining to this oil and gas lease sale. The detailed text of these ITL clauses is contained in the ''Information to Lessees'' section of the Final NOS Package:

(1) Navigation Safety
(2) Ordnance Disposal Areas in the CPA
(3) Communications Towers
(4) Existing and Proposed Artificial Reefs/Rigs-to-Reefs
(5) Lightering Zones
(6) Indicated Hydrocarbons List
(7) Military Areas in the CPA
(8) Safety Zones for Certain Production Facilities
(9) Bureau of Safety and Environmental Enforcement (BSEE) Inspection and Enforcement of Certain Coast Guard Regulations
(10) Deepwater Port Applications for Offshore Liquefied Natural Gas Facilities
(11) Ocean Dredged Material Disposal Sites
(12) Potential Sand Dredging Activities in the CPA
(13) Below Seabed Operations
(14) Commercial Waste Disposal Areas
(15) Air Quality Permits
(16) Notice of Arrival on the Outer Continental Shelf
(17) Gulf Islands National Seashore
(18) Bidder/Lessee Notice of Obligations Related to Criminal/Civil Charges and Offenses, Suspension, or Debarment; Disqualification Due to a Conviction under the Clean Air Act or the Clean Water Act
(19) Protected Species

VI. Maps

The maps pertaining to this lease sale may be found on the BOEM Web site at *http://www.boem.gov/Sale-235.* The following maps also are included in the Final NOS Package:

Lease Terms and Economic Conditions Map

The lease terms and economic conditions and the blocks to which these terms and conditions apply are shown on the map entitled ''Final, Central Planning Area, Lease Sale 235, March 18, 2015, Lease Terms and Economic Conditions,'' which is included in the Final NOS Package.

Stipulations and Deferred Blocks Map

The blocks to which one or more lease stipulations may apply are shown on the map entitled ''Final, Central Planning Area, March 2015, Lease Sale 235, Stipulations and Deferred Blocks,'' which is included in the Final NOS Package.

VII. Bidding Instructions

Instructions on how to submit a bid, secure payment of the advance bonus bid deposit (if applicable), and what information must be included with the bid are as follows:

Bid Form

For each block bid upon, a separate sealed bid shall be submitted in a sealed envelope (as described below) and must include the following:

- Total amount of the bid in whole dollars only;
- sale number;
- sale date;
- each bidder's exact name;
- each bidder's proportionate interest, stated as a percentage, using a maximum of five decimal places (*e.g.,* 33.33333 percent);
- typed name, title, and signature of each bidder's authorized officer;
- each bidder's qualification number;
- map name and number or OPD name and number;
- block number; and
- statement acknowledging that the bidder(s) understand that this bid legally binds the bidder(s) to comply with all applicable regulations, including payment of one-fifth of the bonus bid amount on all apparent high bids.

The information required on the bid(s) will be specified in the document ''Bid Form'' to be contained in the Final NOS Package. A blank bid form will be provided therein for convenience and may be copied and completed with the necessary information described above.

Bid Envelope

Each bid must be submitted in a separate sealed envelope labeled as follows:

- ''Sealed Bid for Oil and Gas Lease Sale 235, not to be opened until 9 a.m. Wednesday, March 18, 2015'';

• map name and number or OPD name and number;
• block number for block bid upon; and
• the exact name and qualification number of the submitting bidder only.

The Final NOS Package will include a sample bid envelope for reference.

Mailed Bids

If bids are mailed, please address the envelope containing the sealed bid envelope(s) as follows: Attention: Leasing and Financial Responsibility Section, BOEM Gulf of Mexico Region, 1201 Elmwood Park Blvd., New Orleans, LA 70123–2394. Contains Sealed Bids for CPA Oil and Gas Lease Sale 235. Please Deliver to Ms. Cindy Thibodeaux or Mr. Chris Oos, 2nd Floor, Immediately.

Please Note: Bidders mailing bid(s) are advised to call Ms. Cindy Thibodeaux at (504) 736–2809, or Mr. Chris Oos at (504) 736–2862, immediately after putting their bid(s) in the mail. If BOEM receives bids later than the Bid Submission Deadline, the BOEM Gulf of Mexico Regional Director (RD) will return those bids unopened to bidders. Please see ''Section XI. Delay of Sale'' regarding BOEM's discretion to extend the Bid Submission Deadline in the case of an unexpected event (*e.g.,* flooding or travel restrictions) and how bidders can obtain more information on such extensions.

Advance Bonus Bid Deposit Guarantee

Bidders that are not currently an OCS oil and gas lease record title holder or designated operator, or those that ever have defaulted on a one-fifth bonus bid deposit, by Electronic Funds Transfer (EFT) or otherwise, must guarantee (secure) the payment of the one-fifth bonus bid deposit prior to bid submission using one of the following four methods:
• Provide a third-party guarantee;
• amend an areawide development bond via bond rider;
• provide a letter of credit; or
• provide a lump sum payment in advance via EFT.

For more information on EFT procedures, see Section X of this document entitled ''The Lease Sale.''

Affirmative Action

Prior to bidding, each bidder should file Equal Opportunity Affirmative Action Representation Form BOEM–2032 (October 2011) and Equal Opportunity Compliance Report Certification Form BOEM–2033 (October 2011) with the BOEM Gulf of Mexico Region Adjudication Section. This certification is required by 41 CFR part 60 and Executive Order No. 11246, issued September 24, 1965, as amended by Executive Order No. 11375, issued October 13, 1967. Both forms must be on file for the bidder(s) in the GOM Region Adjudication Section prior to the execution of any lease contract.

Geophysical Data and Information Statement (GDIS)

The GDIS is composed of three parts:

(1) The ''Statement'' page includes the company representatives' information and lists of blocks bid on that used proprietary data and those blocks bid on that did not use proprietary data;

(2) the ''Table'' listing the required data about each proprietary survey used (see below); and

(3) the ''Maps'' being the live trace maps for each survey that are identified in the GDIS statement and table.

Every bidder submitting a bid on a block in CPA Sale 235, or participating as a joint bidder in such a bid, must submit at the time of bid submission all three parts of the GDIS. A bidder must submit the GDIS *even if a joint bidder or bidders on a specific block also have submitted a GDIS.* Any speculative data that has been reprocessed externally or ''in-house'' is considered proprietary due to the proprietary processing and is no longer considered to be speculative.

The GDIS must be submitted in a separate and sealed envelope, and identify all proprietary data; reprocessed speculative data, and/or any Controlled Source Electromagnetic surveys, Amplitude Versus Offset, Gravity, or Magnetic data; or other information used as part of the decision to bid or participate in a bid on the block. The bidder and joint bidder must also include a live trace map (*e.g.,* .pdf and ArcGIS shape file) for each *proprietary* survey that they identify in the GDIS illustrating the actual areal extent of the *proprietary* geophysical data in the survey (see the ''Example of Preferred Format'' in the Final NOS Package for additional information).

The GDIS statement must include the name, phone number, and full address of a contact person and an alternate who are both *knowledgeable about the information and data listed and who are available for 30 days after the sale date.* The GDIS statement also must include entries for all blocks bid upon that did not use proprietary or reprocessed pre- or post-stack geophysical data and information as part of the decision to bid or to participate as a joint bidder in the bid. The GDIS statement must be submitted even if no proprietary geophysical data and information were used in bid preparation for the block.

The GDIS table should have columns that clearly state the sale number; the bidder company's name; the block area and block number bid on; the owner of the original data set (*i.e.,* who initially acquired the data); the industry's original name of the survey (*e.g.,* E Octopus); the BOEM permit number for the survey; whether the data set is a fast track version; whether the data is speculative or proprietary; the data type (*e.g.,* 2–D, 3–D, or 4–D; pre-stack or post-stack; and time or depth); migration algorithm (*e.g.,* Kirchhoff Migration, Wave Equation Migration, Reverse Migration, Reverse Time Migration) of the data and areal extent of bidder survey (*i.e.,* number of line miles for 2–D or number of blocks for 3–D). Provide the computer storage size, to the nearest gigabyte, of each seismic data and velocity volume used to evaluate the lease block in question. This will be used in estimating the reproduction costs for each data set, if applicable. The availability of reimbursement of production costs will be determined consistent with 30 CFR 551.13. The next column should state who reprocessed the data (*e.g.,* external company name or ''in-house'') and when the date of final reprocessing was completed (month and year). If the data was sent to BOEM for bidding in a previous lease sale, list the date the data was processed (month and year) and indicate if AVO data was used in the evaluation. BOEM reserves the right to query about alternate data sets, to quality check, and to compare the listed and alternative data sets to determine which data set most closely meets the needs of the fair market value determination process. An example of the preferred format of the table may be found in the Final NOS Package, and a blank digital version of the preferred table may be accessed on the CPA Sale 235 page at *http://www.boem.gov/Sale-235/.*

The GDIS maps are live trace maps (in .pdf and ArcGIS shape files) that should be submitted for each *proprietary* survey that is identified in the GDIS table. They should illustrate the actual areal extent of the proprietary geophysical data in the survey (see the ''Example of Preferred Format'' in the Final NOS Package for additional information).

Pursuant to 30 CFR 551.12 and 30 CFR 556.32, as a condition of the sale, the BOEM Gulf of Mexico RD requests that all bidders and joint bidders submit the proprietary data identified on their GDIS within 30 days after the lease sale (unless they are notified after the lease sale that BOEM has withdrawn the request). This request only pertains to proprietary data that is not commercially available. Commercially available data is not required to be submitted to BOEM, and reimbursement will not be provided if such data is

submitted by a bidder. The BOEM Gulf of Mexico RD will notify bidders and joint bidders of any withdrawal of the request, for all or some of the proprietary data identified on the GDIS, within 15 days of the lease sale. Pursuant to 30 CFR part 551 and as a condition of this sale, all bidders required to submit data must ensure that the data is received by BOEM no later than the 30th day following the lease sale, or the next business day if the submission deadline falls on a weekend or Federal holiday. The data must be submitted to BOEM at the following address:

Bureau of Ocean Energy Management, Resource Studies, GM 881A, 1201 Elmwood Park Blvd., New Orleans, LA 70123–2304.

BOEM recommends that bidders mark the submission's external envelope as ''Deliver Immediately to DASPU.'' BOEM also recommends that the data be submitted in an internal envelope, or otherwise marked, with the following designation: ''Proprietary Geophysical Data Submitted Pursuant to Lease Sale 235 and Used During <Bidder Name's> Evaluation of Block <Block Number>.''

In the event a person supplies any type of data to BOEM, that person must meet the following requirements to qualify for reimbursement:

(1) Persons must be registered with the System for Award Management (SAM), formerly known as the Central Contractor Registration (CCR). CCR usernames will not work in SAM. A new SAM User Account is needed to register or update an entity's records. The Web site for registering is *https://www.sam.gov.*

(2) Persons must be enrolled in the Department of Treasury's Internet Payment Platform (IPP) for electronic invoicing. The person must enroll in the IPP at *https://www.ipp.gov/.* Access then will be granted to use the IPP for submitting requests for payment. When a request for payment is submitted, it must include the assigned Purchase Order Number on the request.

(3) Persons must have a current On-line Representations and Certifications Application at *https://www.sam.gov.*

Please Note: The GDIS Information Table must be submitted digitally, preferably as an Excel spreadsheet, on a CD or DVD along with the seismic data map(s). If bidders have any questions, they should contact Ms. Dee Smith at (504) 736–2706, or Mr. John Johnson at (504) 736–2455. Bidders should refer to Section X of this document, ''The Lease Sale: Acceptance, Rejection, or Return of Bids,'' regarding a bidder's failure to comply with the requirements of the Final NOS, including any failure to submit information as required in the Final NOS or Final NOS Package.

Telephone Numbers/Addresses of Bidders

BOEM requests that bidders provide this information in the suggested format prior to or at the time of bid submission. The suggested format is included in the Final NOS Package. The form must not be enclosed inside the sealed bid envelope.

Additional Documentation

BOEM may require bidders to submit other documents in accordance with 30 CFR 556.46.

VIII. Bidding Rules and Restrictions

Restricted Joint Bidders

On October 29, 2014, BOEM published the most recent List of Restricted Joint Bidders in the **Federal Register** at 79 FR 64404. Potential bidders are advised to refer to the **Federal Register,** prior to bidding, for the most current List of Restricted Joint Bidders in place at the time of the lease sale. Please refer to joint bidding provisions at 30 CFR 556.41 for additional restrictions.

Authorized Signatures

All signatories executing documents on behalf of bidder(s) must execute the same in conformance with the BOEM qualification records. Bidders are advised that BOEM considers the signed bid to be a legally binding obligation on the part of the bidder(s) to comply with all applicable regulations, including payment of one-fifth of the bonus bid on all high bids. A statement to this effect must be included on each bid form (see the document ''Bid Form'' to be contained in the Final NOS Package).

Unlawful Combination or Intimidation

BOEM warns bidders against violation of 18 U.S.C. 1860, prohibiting unlawful combination or intimidation of bidders.

Bid Withdrawal

Bids may be withdrawn only by written request delivered to BOEM prior to the Bid Submission Deadline. The withdrawal request must be on company letterhead and must contain the bidder's name, its BOEM qualification number, the map name/number, and the block number(s) of the bid(s) to be withdrawn. The withdrawal request must be executed in conformance with the BOEM qualification records. Signatories must be authorized to bind their respective legal business entities (*e.g.,* a corporation, partnership, or LLC) and documentation must be on file with BOEM setting forth this authority to act on the business entity's behalf for purposes of bidding and lease execution under OCSLA (*e.g.,* business charter or articles, incumbency certificate, or power of attorney). The name and title of the authorized signatory must be typed under the signature block on the withdrawal request. The BOEM Gulf of Mexico RD, or the RD's designee, will indicate any approval by signing and dating the withdrawal request.

Bid Rounding

The bonus bid amount must be stated in whole dollars. Minimum bonus bid calculations, including all rounding, for all blocks are shown in the document entitled ''List of Blocks Available for Leasing,'' which is included in the Final NOS Package. If the acreage of a block contains a decimal figure, then prior to calculating the minimum bonus bid, BOEM has rounded up to the next whole acre. The appropriate minimum rate per acre then was applied to the whole (rounded up) acreage. If this calculation resulted in a fractional dollar amount, the minimum bonus bid was rounded up to the next whole dollar amount. The bonus bid amount must be greater than or equal to the minimum bonus bid in whole dollars.

IX. Forms

The Final NOS Package includes instructions, samples, and/or the preferred format for the following items. BOEM strongly encourages bidders to use these formats; should bidders use another format, they are responsible for including all the information specified for each item in the Final NOS Package.

(1) Bid Form
(2) Sample Completed Bid
(3) Sample Bid Envelope
(4) Sample Bid Mailing Envelope
(5) Telephone Numbers/Addresses of Bidders Form
(6) GDIS Form
(7) GDIS Envelope Form

X. The Lease Sale

Bid Opening and Reading

Sealed bids received in response to the Final NOS will be opened at the place, date, and hour specified in the ''DATES'' section of this document. The opening of the bids is for the sole purpose of publicly announcing and recording the bids received; no bids will be accepted or rejected at that time.

Bonus Bid Deposit for Apparent High Bids

Each bidder submitting an apparent high bid must submit a bonus bid deposit to the Office of Natural Resources Revenue (ONRR) equal to one-fifth of the bonus bid amount for each such bid. A copy of the notification

of the high bidder's one-fifth bonus bid requirement deposit may be obtained at the EFT Area outside the Bid Reading Room on the day of the bid opening, or it may be obtained on the BOEM Web site at *http://www.boem.gov/Sale-235/* under the heading ''Notification of EFT 1/5 Bonus Liability.'' All payments must be deposited electronically into an interest-bearing account in the U.S. Treasury by 11:00 a.m. Eastern Time the day following the bid reading (no exceptions). Account information is provided in the ''Instructions for Making Electronic Funds Transfer Bonus Payments'' found on the BOEM Web site identified above. BOEM requires bidders to use EFT procedures for payment of one-fifth bonus bid deposits for CPA Sale 235, following the detailed instructions contained on the ONRR Payment Information Web page at *http://www.onrr.gov/FM/PayInfo.htm.* Acceptance of a deposit does not constitute and shall not be construed as acceptance of any bid on behalf of the United States.

Withdrawal of Blocks

The United States reserves the right to withdraw any block from this lease sale prior to issuance of a written acceptance of a bid for the block.

Acceptance, Rejection, or Return of Bids

The United States reserves the right to reject any and all bids. No bid will be accepted, and no lease for any block will be awarded to any bidder, unless: (1) The bidder has complied with all requirements of the Final NOS, including those set forth in the documents contained in the Final NOS Package and applicable regulations; (2) the bid is the highest valid bid; and (3) the amount of the bid has been determined to be adequate by the authorized officer. Any bid submitted that does not conform to the requirements of the Final NOS and Final NOS Package, OCSLA, or other applicable statute or regulation may be rejected and returned to the bidder. The U.S. Department of Justice and the Federal Trade Commission will review the results of the lease sale for antitrust issues prior to the acceptance of bids and issuance of leases.

To ensure that the Government receives a fair return for the conveyance of leases from this sale, high bids will be evaluated in accordance with BOEM's bid adequacy procedures. A copy of current procedures, ''Modifications to the Bid Adequacy Procedures,'' published at 64 FR 37560 on July 12, 1999, can be obtained from the BOEM Gulf of Mexico Region Public Information Office, or via the BOEM Gulf of Mexico Region Web site at *http://www.boem.gov/Oil-and-Gas-Energy-Program/Leasing/Regional-Leasing/Gulf-of-Mexico-Region/Bid-Adequacy-Procedures.aspx.*

Bid Adequacy Review Procedures for CPA Sale 235

BOEM published a notification in the **Federal Register,** Volume 79, No. 201, October 17, 2014, 62461–62463, at *http://www.gpo.gov/fdsys/pkg/FR-2014-10-17/pdf/2014-24727.pdf,* proposing the elimination of one of its acceptance rules, the Number of Bids Rule, from its bid adequacy procedures. However, BOEM has decided not to eliminate the rule for CPA Sale 235 and will continue using the existing bid adequacy procedures, referenced above. If the proposed change in the bid adequacy procedures is finalized and applicable to future lease sales, bidders will be notified in the Final NOS, and BOEM will publish the revised procedures no later than the time the Final NOS for that sale is published.

Lease Award

BOEM requires each bidder awarded a lease to: (1) Execute all copies of the lease (Form BOEM–2005 (October 2011), as amended); (2) pay by EFT the balance of the bonus bid amount and the first year's rental for each lease issued in accordance with the requirements of 30 CFR 218.155 and 556.47(f); and (3) satisfy the bonding requirements of 30 CFR part 556, subpart I, as amended. ONRR requests that only one transaction be used for payment of the four-fifths bonus bid amount and the first year's rental.

XI. Delay of Sale

The BOEM Gulf of Mexico RD has the discretion to change any date, time, and/or location specified in the Final NOS Package in case of an event that the BOEM Gulf of Mexico RD deems may interfere with the carrying out of a fair and orderly lease sale process. Such events could include, but are not limited to, natural disasters (*e.g.,* earthquakes, hurricanes, and floods), wars, riots, acts of terrorism, fires, strikes, civil disorder, or other events of a similar nature. In case of such events, bidders should call (504) 736–0557, or access the BOEM Web site at *www.boem.gov,* for information regarding any changes.

Dated: January 22, 2015.

Abigail Ross Hopper,

Director, Bureau of Ocean Energy Management.

[FR Doc. 2015–02273 Filed 2–5–15; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[MMAA 104000]

Gulf of Mexico, Outer Continental Shelf (OCS), Central Planning Area (CPA) Oil and Gas Lease Sales 235, 241, and 247

AGENCY: Bureau of Ocean Energy Management (BOEM), Interior.

ACTION: Notice of Availability (NOA) of a Record of Decision (ROD) for CPA Lease Sale 235 in the *Gulf of Mexico OCS Oil and Gas Lease Sales: 2015–2017; Central Planning Area Lease Sales 235, 241, and 247; Final Supplemental Environmental Impact Statement* (CPA 235, 241, and 247 Supplemental EIS).

SUMMARY: BOEM has prepared a ROD for proposed oil and gas CPA Lease Sale 235, which is scheduled for March 18, 2015. The proposed lease sale is in the Gulf of Mexico's CPA off the States of Louisiana, Mississippi, and Alabama. Proposed CPA Lease Sale 235 is the third CPA lease sale scheduled in the OCS Oil & Gas Leasing Program for 2012–2017 (Five-Year Program). The CPA 235, 241, and 247 Supplemental EIS evaluated the environmental and socioeconomic impacts for proposed CPA Lease Sale 235. In making its decision, BOEM considered two alternatives to the proposed action, the potential impacts as presented in the CPA 235, 241, and 247 Supplemental EIS, and all comments received throughout the National Environmental Policy Act (NEPA) process.

SUPPLEMENTARY INFORMATION: In the CPA 235, 241, and 247 Supplemental EIS, BOEM evaluated the three alternatives that are summarized below:

Alternative A—The Proposed Action: This is BOEM's preferred alternative. This alternative would offer for lease all unleased blocks within the proposed CPA lease sale area for oil and gas operations with the following exceptions: Whole and partial blocks deferred by the Gulf of Mexico Energy Security Act of 2006; and, blocks that are adjacent to or beyond the United States Exclusive Economic Zone in the area known as the northern portion of the Eastern Gap.

All unleased whole and partial blocks in the CPA that BOEM will offer for leasing in proposed CPA Lease Sale 235 are listed in the document ''List of Blocks Available for Leasing,'' which is included in the Final Notice of Sale 235 Package. The proposed CPA lease sale area encompasses about 63 million acres of the total CPA area of 66.45 million acres. As of January 2015, approximately 41 million acres of the

proposed CPA lease sale area are currently unleased. The estimated amount of resources projected to be developed as a result of the proposed CPA lease sale is 0.460–0.894 billion barrels of oil (BBO) and 1.939–3.903 trillion cubic feet (Tcf) of gas.

Alternative B—Exclude the Unleased Blocks Near the Biologically Sensitive Topographic Features: This alternative would offer for lease all unleased blocks within the proposed CPA lease sale area, as described for the proposed action (Alternative A), but it would exclude from leasing any unleased blocks subject to the Topographic Features Stipulation. The estimated amount of resources projected to be developed under Alternative B is 0.460–0.894 BBO and 1.939–3.903 Tcf of gas. The number of blocks that would not be offered under Alternative B represents only a small percentage of the total number of blocks to be offered under Alternative A; therefore, it is estimated that the levels of activity for Alternative B would be essentially the same as those projected for a CPA proposed action.

Alternative C—No Action: This alternative is the cancellation of proposed CPA Lease Sale 235 and is identified as the environmentally preferred alternative.

After careful consideration, the Assistant Secretary—Land and Minerals Management has selected the proposed action, identified as BOEM's preferred alternative (Alternative A) in the CPA 235, 241, and 247 Supplemental EIS. BOEM's selection of the preferred alternative meets the purpose and need for the proposed action, as identified in the CPA 235, 241, and 247 Supplemental EIS, and reflects an orderly resource development with appropriate protection of the human, marine, and coastal environments while also ensuring that the public receives an equitable return for these resources and that free-market competition is maintained.

Record of Decision Availability: To obtain a single printed or CD copy of the ROD for proposed CPA Lease Sale 235, you may contact BOEM, Gulf of Mexico OCS Region, Public Information Office (GM 335A), 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123–2394 (1–800–200–GULF). An electronic copy of the ROD is available on BOEM's Internet Web site at *http://www.boem.gov/nepaprocess/.*

FOR FURTHER INFORMATION CONTACT: For more information on the ROD, you may contact Mr. Gary D. Goeke, Bureau of Ocean Energy Management, Gulf of Mexico OCS Region, 1201 Elmwood Park Boulevard (GM 623E), New Orleans, Louisiana 70123–2394. You may also contact Mr. Goeke by telephone at 504–736–3233.

Authority: This NOA is published pursuant to the regulations (40 CFR part 1503) implementing the provisions of the National Environmental Policy Act (NEPA) of 1969, as amended (42 U.S.C. 4321 *et seq.*).

Dated: January 22, 2015.

Abigail Ross Hopper,

Director, Bureau of Ocean Energy Management.

[FR Doc. 2015–02272 Filed 2–5–15; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR03510000, XXXR0680A1, RX.20116000.0019400]

Notice of Intent To Prepare an Environmental Impact Statement/Environmental Impact Report for the Clean Water Factory Project, San Bernardino County, California

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Reclamation and the City of San Bernardino Municipal Water Department will prepare a joint Environmental Impact Statement/Environmental Impact Report (EIS/EIR) to evaluate the effects of the Clean Water Factory project. The proposed Clean Water Factory is a water reclamation project to treat and reuse municipal wastewater that is currently discharged to the Santa Ana River. The reclaimed water will be used for groundwater recharge and landscape irrigation. The purpose of the project is to reduce dependence on imported water and establish a reliable, sustainable source of clean water. The public and agencies are invited to comment on the scope of the EIS/EIR and the proposed alternatives.

DATES: Submit written comments on the scope of the EIS/EIR on or before March 9, 2015.

ADDRESSES: Please send written comments to Doug McPherson, Southern California Area Office, Bureau of Reclamation, 27708 Jefferson Avenue, Suite 202, Temecula, CA 92590; or email to *dmcpherson@usbr.gov.*

FOR FURTHER INFORMATION CONTACT: Doug McPherson, Southern California Area Office general telephone number 951–695–5310; or email *dmcpherson@usbr.gov.*

SUPPLEMENTARY INFORMATION: This notice is provided pursuant to the National Environmental Policy Act (NEPA) (42 U.S.C. 4332(2)(c)), and Department of the Interior regulations for implementation of NEPA (43 CFR part 46).

Background

The San Bernardino Municipal Water Department (SBMWD) is preparing a feasibility study report for approval under the Reclamation Wastewater and Groundwater Study and Facilities Act of 1992 (Title XVI of Pub. L. 102–575, as amended). If the Bureau of Reclamation determines that the feasibility study report meets the requirements defined at 43 U.S.C. 390h–2, and Congress amends Title XVI to specifically authorize Federal appropriations for the project, it will be eligible for construction funding under the Title XVI program.

The proposed project will install treatment improvements within the existing San Bernardino Water Reclamation Plant (SBWRP) to achieve product water quality approved for groundwater recharge by the California Department of Public Health and the Santa Ana Regional Water Quality Control Board. New pipelines will convey treated effluent to the existing Waterman Basins and East Twin Creek Spreading Grounds for recharge into the Bunker Hill Groundwater Basin. Recycled water will be delivered for non-potable irrigation uses along the pipeline alignment. The project may also include a pipeline to convey recycled water from the existing Rapid Infiltration and Extraction (RIX) facility to the Inland Empire Utilities Agency service area.

SBWRP effluent is currently discharged to the Santa Ana River through the RIX facility, under National Pollutant Discharge Elimination System permit no. CA8000304. The Santa Ana River is designated critical habitat for the Santa Ana sucker (*Catostomus santaanae*), a fish species listed as threatened under the Endangered Species Act. The existing RIX discharge contributes to dry season baseflows that support the Santa Ana sucker.

Pursuant to California Water Code section 1211, SBMWD filed Wastewater Change Petition WW0059 with the California State Water Resources Control Board to reduce recycled water discharge from the RIX facility to the Santa Ana River by up to 31,500 acre-feet per year. Reductions in RIX discharge will be phased over time through an Adaptive Management Plan to monitor and manage downstream flows, to comply with the requirements of the Endangered Species Act.

Scoping Process

SBMWD filed a Notice of Preparation (California State Clearinghouse no. 2014111012) on November 6, 2014, pursuant to the California Environmental Quality Act (CEQA) (P.R.C. section 21092, C.C.R. section 15082) and held two public scoping meetings on November 19, 2014. To avoid duplication with State and local procedures, we plan to use the scoping process initiated by SBMWD under CEQA. No additional public scoping meetings are planned at this time. The CEQA Notice of Preparation is available at *http://www.usbr.gov/lc/socal/envdocs.html.*

No known Indian trust assets or environmental justice issues are associated with the proposed action, although the pipeline alignments may include areas of low income and minority populations.

Written comments are requested to help identify alternatives and issues that should be analyzed in the EIS/EIR. Federal, State and local agencies, tribes, and the general public are invited to participate in the environmental review process.

Public Disclosure

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.

Dated: January 27, 2015.

Terrance J. Fulp,

Regional Director, Lower Colorado Region.

[FR Doc. 2015–01942 Filed 2–5–15; 8:45 am]

BILLING CODE 4332–90–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1020 (Second Review)]

Barium Carbonate From China

Determination

On the basis of the record [1] developed in the subject five-year review, the United States International Trade Commission (''Commission'') determines, pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)), that revocation of the antidumping duty order on barium carbonate from China would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission instituted this review on February 3, 2014 (79 FR 6219) and determined on May 9, 2014 that it would conduct a full review (79 FR 29454, May 22, 2014). Notice of the scheduling of the Commission's review and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on August 1, 2014 (79 FR 44864). The hearing was cancelled at the request of the domestic interested party.

The Commission completed and filed its determination in this review on February 2, 2015. The views of the Commission are contained in USITC Publication 4518 (February 2015), entitled *Barium Carbonate from China: Investigation No. 731–TA–1020 (Second Review).*

By order of the Commission.

Issued: February 2, 2015.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015–02341 Filed 2–5–15; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

DEPARTMENT OF JUSTICE

[OMB Number 1117–0024]

Agency Information Collection Activities; Proposed eCollection, eComments Requested; Extension Without Change of a Previously Approved Collection Reports of Regulated Transactions Involving Extraordinary Quantities, Uncommon Methods of Payment, and Unusual/Excessive Loss or Disappearance, and Regulated Transactions in Tableting/Encapsulating Machines

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Drug Enforcement Administration (DEA), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until April 7, 2015.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information proposed to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *Title of the Form/Collection:* Reports of Regulated Transactions Involving Extraordinary Quantities, Uncommon Methods of Payment, and Unusual/Excessive Loss or Disappearance, and Regulated Transactions in Tableting/Encapsulating Machines.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Notification of extraordinary quantities, uncommon methods of payment, and unusual/excessive loss or disappearance of listed chemicals and regulated transactions in tableting/encapsulating machines is provided in writing on an as needed basis and does not require use of a form. The applicable component within the Department of Justice is the Drug Enforcement Administration, Office of Diversion Control.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Affected public (Primary): Business or other for-profit.

Affected public (Other): Not-for-profit institutions; Federal, State, local, and tribal governments.

Abstract: Each regulated person is required to report any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, any unusual or excessive loss or disappearance of a listed chemical, and any regulated transaction in a tableting or encapsulating machine, to include any domestic regulated transaction in a tableting or encapsulating machine and any import or export of a tableting or encapsulating machine. 21 U.S.C. 830 (b)(1)(A), (C) and (D); 21 CFR 1310.05(a)(1), (3)–(4); 21 CFR 1310.05(c). Regulated persons include manufacturers, distributors, importers, and exporters of listed chemicals, tableting machines, or encapsulating machines, or persons who serve as brokers or traders for international transactions involving a listed chemical, tableting machine, or encapsulating machine. 21 CFR 1300.02(b).

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The DEA estimates that 63 persons respond as needed to this collection. Responses take 20 minutes.

6. *An estimate of the total public burden (in hours) associated with the proposed collection:* The DEA estimates that this collection takes 21 annual burden hours.

If additional information is required please contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Suite 3E.405B, Washington, DC 20530.

Dated: February 3, 2015.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2015–02391 Filed 2–5–15; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Community Oriented Policing Services; Public Meeting With the President's Task Force on 21st Century Policing Discussing Best Practices and Recommendations

AGENCY: Community Oriented Policing Services, Justice.

ACTION: Notice of meeting.

SUMMARY: On December 18, 2014, President Barack Obama signed an Executive Order titled ''Establishment of the President's Task Force on 21st Century Policing'' establishing the President's Task Force on 21st Century Policing (''Task Force''). The Task Force seeks to identify best practices and make recommendations to the President on how policing practices can promote effective crime reduction while building public trust and examine, among other issues, how to foster strong, collaborative relationships between local law enforcement and the communities they protect. The Task Force will be holding a public teleconference.

The meeting agenda is as follows:

Call to Order

Discussion of best practices and recommendations

Conclusion

DATES: The teleconference will be held Tuesday, February 24, 2015 from 9:00 a.m. to 5:00 p.m. Eastern Standard Time.

For disability access please call 1–800–888–8888 (TTY users call via Relay).

ADDRESSES: The meeting will be held by teleconference only. To access the conference line, please call 1–866–906–7447 and, when prompted, enter access code 8072024#.

FOR FURTHER INFORMATION CONTACT: Director, Ronald L. Davis, 202–514–4229 or *PolicingTaskForce@usdoj.gov.*

Address all comments concerning this notice to *PolicingTaskForce@usdoj.gov.*

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing Addresses

The Task Force is interested in receiving written comments including proposed recommendations from individuals, groups, advocacy organizations, and professional communities. Additional information on how to provide your comments will be posted to *www.cops.usdoj.gov/PolicingTaskForce.*

Availability of Meeting Materials: The agenda and other materials in support of the teleconference will be available on the Task Force Web site at *www.cops.usdoj.gov/PolicingTaskForce* in advance of the teleconference.

Ronald L. Davis,

Director.

[FR Doc. 2015–02463 Filed 2–5–15; 8:45 am]

BILLING CODE 4410–AT–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to The National Cooperative Research and Production Act of 1993—Open Platform for NVF Project, Inc.

Notice is hereby given that, on January 12, 2015, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Open Platform for NVF Project, Inc. (''Open Platform for NVF Project'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Array Networks, Inc., Milpitas, CA; ENEA Software AB, Kista, SWEDEN; KT, Seongnam City, GyeongGi-do, REPUBLIC OF KOREA; Midokura USA Inc., San Francisco, CA; Sonus Networks, Westford, MA; Xilinx, Inc., San Jose, CA; and ZTE Corporation, Shenzhen PEOPLE'S REPUBLIC OF CHINA, have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Open Platform for NVF Project intends to file additional written notifications disclosing all changes in membership.

On October 17, 2014, Open Platform for NVF Project filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on November 14, 2014 (79 FR 68301).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2015–02360 Filed 2–5–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—U.S. Photovoltaic Manufacturing Consortium, Inc.

Notice is hereby given that, on January 6, 2015, pursuant to Section 6(a)

of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), U.S. Photovoltaic Manufacturing Consortium, Inc. (''USPVMC'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Akrion Systems LLC, Allentown, PA, has been added as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and USPVMC intends to file additional written notifications disclosing all changes in membership.

On November 14, 2011, USPVMC filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on December 21, 2011 (76 FR 79218).

The last notification was filed with the Department on August 1, 2014. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on September 3, 2014 (79 FR 52364).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2015–02359 Filed 2–5–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Heterogeneous System Architecture Foundation

Notice is hereby given that, on December 19, 2014, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Heterogeneous System Architecture Foundation (''HSA Foundation'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, National Taiwan University, Taipei, TAIWAN, has been added as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and HSA Foundation intends to file additional written notifications disclosing all changes in membership.

On August 31, 2012, HSA Foundation filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on October 11, 2012 (77 FR 61786).

The last notification was filed with the Department on September 29, 2014. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on October 22, 2014 (79 FR 63169).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2015–02460 Filed 2–5–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Advanced Media Workflow Association, Inc.

Notice is hereby given that, on December 23, 2014, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Advanced Media Workflow Association, Inc. has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, TF1, Paris, FRANCE; and Digital Media Centre, B.V., Amsterdam, THE NETHERLANDS, have been added as parties to this venture.

Also, Chellomedia Direct Programing, B.V., Amsterdam, THE NETHERLANDS; Front Porch Digital, Louisville, CO; Red Bee Media, London, UNITED KINGDOM; Snell, Reading, Berkshire, UNITED KINGDOM; George Blood (individual member), Philadelphia, PA; Chris Dee (individual member), Babylon, NY; Stefan Riediger (individual member), Munich, GERMANY; and Robert Rutherford (individual member), Lidcombe, AUSTRALIA, have withdrawn as parties to this venture. No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Advanced Media Workflow Association, Inc. intends to file additional written notifications disclosing all changes in membership.

On March 28, 2000, Advanced Media Workflow Association, Inc. filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on June 29, 2000 (65 FR 40127).

The last notification was filed with the Department on September 24, 2014. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on October 22, 2014 (79 FR 63168).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2015–02471 Filed 2–5–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—OpenDaylight Project, Inc.

Notice is hereby given that, on December 24, 2014 pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), OpenDaylight Project, Inc. (''OpenDaylight'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Intracom S.A. Telecom Solutions, Athens, Greece; Compass Electro Optical System, Netanya, Israel; and Megaport, Queensland, Australia, have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and OpenDaylight intends to file additional written notifications disclosing all changes in membership.

On May 23, 2013, OpenDaylight filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on July 1, 2013 (78 FR 39326).

The last notification was filed with the Department on October 1, 2014. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on November 4, 2014 (79 FR 65425).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2015–02474 Filed 2–5–15; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act Of 1993—Cable Television Laboratories, Inc.

Notice is hereby given that, on December 11, 2014, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Cable Television Laboratories, Inc. (''CableLabs'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, TDS Baja Broadband, Alamogordo, NM, has been added as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and CableLabs intends to file additional written notifications disclosing all changes in membership.

On August 8, 1988, CableLabs filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on September 7, 1988 (53 FR 34593).

The last notification was filed with the Department on August 14, 2014. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on September 19, 2014 (79 FR 56404).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2015–02476 Filed 2–5–15; 8:45 am]

BILLING CODE P

FOREIGN CLAIMS SETTLEMENT COMMISSION

[F.C.S.C. Meeting and Hearing Notice No. 02–15]

Sunshine Act Meeting

The Foreign Claims Settlement Commission, pursuant to its regulations (45 CFR part 503.25) and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of open meetings as follows:

Thursday, February 12, 2015: 10:00 a.m.—Oral hearing on Objection to Commission's Proposed Decision in Claim No. IRQ–I–021.

11:30 a.m.—Issuance of Proposed Decisions in claims against Libya.

STATUS: Open.

All meetings are held at the Foreign Claims Settlement Commission, 600 E Street NW., Washington, DC. Requests for information, or advance notices of intention to observe an open meeting, may be directed to: Patricia M. Hall, Foreign Claims Settlement Commission, 600 E Street NW., Suite 6002, Washington, DC 20579. Telephone: (202) 616–6975.

Brian M. Simkin,

Chief Counsel.

[FR Doc. 2015–02575 Filed 2–4–15; 4:15 pm]

BILLING CODE 4410–BA–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Cognitive and Psychological Research

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Bureau of Labor Statistics (BLS) sponsored information collection request (ICR) titled, ''Cognitive and Psychological Research,'' to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.* Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before March 9, 2015.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=* 201408–1220–002 (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–BLS, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the Cognitive and Psychological Research information collection. The BLS Behavioral Science Research Center (BSRC) conducts psychological research focusing on the design and execution of the data collection process in order to improve the quality of data collected by the Bureau. The BSRC conducts research aimed at improving data collection quality by assessing questionnaire/form management and administration, as well as issues that relate to interviewer training and interaction with respondents during the interview process. BSRC staff work closely with economists and/or program specialists responsible for defining the concepts to be measured by BLS collection programs. This laboratory

research enhances BLS survey data quality. Improvements are made by examining psychological and cognitive aspects of BLS data collection procedures, including questionnaire design, interviewing procedures, collection modalities, and administrative technology. The BLS Authorizing Statute authorizes this information collection. *See* 29 U.S.C. 1 and 2.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1220–0141.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on February 28, 2015. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on August 29, 2014 (79 FR 51614).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1220–0141. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–BLS.

Title of Collection: Cognitive and Psychological Research.

OMB Control Number: 1220–0141.

Affected Public: Individuals or Households.

Total Estimated Number of Respondents: 6,140.

Total Estimated Number of Responses: 6,606.

Total Estimated Annual Time Burden: 6,606 hours.

Total Estimated Annual Other Costs Burden: $0.

Dated: February 2, 2015.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2015–02389 Filed 2–5–15; 8:45 am]

BILLING CODE 4510–24–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2015–021]

Office of Presidential Libraries; Disposal of Presidential Records

AGENCY: National Archives and Records Administration (NARA).

ACTION: Presidential Records Act notice of proposed disposal of Reagan and George H.W. Bush administration disaster recovery backup tapes; request for public comment.

SUMMARY: NARA has identified several collections of disaster recovery backup tapes, and subsequently-created preservation copies, from the Ronald Reagan and George H.W. Bush (GHW Bush) administrations, maintained for the Professional/Office Vision software (PROFS), the Sperry/VAX All-in-One (All-in-One), and for systems maintained by the White House Situation Support Staff (WHSSS) and the White House Situation Room (WHSR), as appropriate for disposal under the Presidential Records Act, 44 U.S.C. 2203(g)(3). This notice describes our reasons for determining that further retention of these disaster recovery backup tapes is not warranted. Because the administrations made these backup tapes for disaster recovery purposes, all required backup restoration projects have taken place, and NARA is preserving the restored records, we have identified no further need to preserve and maintain these backup tapes. Accordingly, we are following a disposal procedure similar to that in General Records Schedule (GRS) 24 for the routine disposal of backup tapes used by Federal agencies.

This notice does not constitute a final agency action, as described in 44 U.S.C. 2203(g)(3), and no Presidential records will be disposed of following this notice. NARA will publish a second notice only after we have considered any comments received following this 45-day notice period. If NARA proceeds with disposal, we will publish a second notice, with a 60-day notice period, that will constitute a final agency action.

DATES: Please submit any comments by March 23, 2015 for NARA's consideration.

ADDRESSES: Comments regarding the proposed disposal of these Presidential records must be sent in writing to Susan K. Donius, by mail to National Archives and Records Administration, Suite 2200; 8601 Adelphi Road; College Park, MD 20740–6001; by fax to 301–837–3199; or by email to *beth.fidler@nara.gov.*

FOR FURTHER INFORMATION CONTACT: Director of Presidential Libraries Susan K. Donius, by telephone at 301–837–3250; or by email at *beth.fidler@nara.gov.*

SUPPLEMENTARY INFORMATION: NARA proposes to dispose of 3,071 original disaster recovery backup tapes created during the Reagan and GHW Bush administrations, along with subsequent preservation copies of those media. A Stipulation and Order entered in the case of *Armstrong* v. *Executive Office of the President,* Civ. No. 89–0142 (D.D.C.), on January 27, 1994, allows NARA to dispose of preserved disaster recovery backup tapes from the Reagan and GHW Bush administrations, provided that NARA issues a public notice in the **Federal Register**. On June 28, 2013, NARA published a **Federal Register** notice proposing the disposal of over 22,000 unclassified backup tapes from the Reagan and GHW Bush administrations that were used to restore emails and related records pursuant to court orders entered in the *Armstrong* case. NARA received no comments concerning that proposed disposal.

Similarly, NARA now proposes to dispose of 3,039 classified backup tapes from the Reagan and GHW Bush administrations that were transferred to

NARA at the end of the GHW Bush administration in 1993 and were used to restore emails and related records pursuant to the *Armstrong* case, along with 32 additional unclassified *Armstrong* backup tapes. NARA will permanently retain the restored Presidential and Federal records from these media, including PROFS notes, documents, and calendars, as well as email and cables from the All-in-One electronic system and the WHSSS and the WHSR electronic systems, on different electronic media.

Details About the Records

These backups were maintained for the PROFS, the All-in-One, and on systems maintained by WHSSS and WHSR. Four White House entities maintained these backups—the White House Communications Agency (WHCA), WHSSS, and WHSR, on behalf of the National Security Council (NSC), and the Office of Administration (OA) on behalf of components of the Executive Office of the President.

These tapes include 3,039 original classified backup tapes originally preserved under court orders entered in the *Armstrong* case and transferred to NARA at the end of the GHW Bush administration in 1993. These backup tapes were created by WHCA and WHSSS staff, on behalf of the NSC, during the Reagan and GHW Bush administrations, and by WHSR staff during the Bush administration. The original backup media consist of a variety of formats, including, but not limited to, open-reel tapes, 3480-class cartridge tapes, hard drives, 8mm tapes, 4mm tapes, DEC cartridges, removable disc packs, and a floppy disk. During the Clinton administration, WHCA, WHSSS, and WHSR administrative staff, on behalf of the NSC, conducted tape restoration projects to restore records from these backup tapes. All of these backup media have been duplicated in two or more preservation copy sets (not necessarily using the same media) created subsequently. NARA will permanently retain the restored Presidential and Federal records from these media, including PROFS notes, documents, and calendars, as well as email and cables from the All-in-One electronic system and the WHSSS and WHSR electronic systems, in an electronic format as part of the permanent record collections of the Reagan and GHW Bush administrations.

Tape Restoration Projects and Retained Records

During the Reagan and GHW Bush administrations, NSC staff conducted business using two electronic communication systems. The first system was known as PROFS, which was an IBM proprietary office management tool available to NSC staff and supported by WHCA. WHCA captured stored electronic information on open reel tapes, created to sustain disaster recovery ability, during scheduled backup periods. During the Clinton administration, WHCA used copies of PROFS system backup tapes to conduct a tape restoration project (WHCA TRP) of all PROFS notes, documents, calendars, and other partial or residual data on the tapes from the Reagan and GHW Bush administrations, in response to stipulations and orders entered in the *Armstrong* case. We will continue to retain these restored records.

The second system used by NSC staff during the Reagan administration, and increasingly during the GHW Bush administration, was the All-in-One system, which also allowed for transmission of electronic mail, calendars, and cables. The All-in-One system maintained by WHCA and WHSSS was connected to the IBM PROFS system so that mail could be sent and received between NSC staff. After September 1992, WHSR staff began using a new system for electronic mail (CCMail) instead of All-in-One.

WHSSS staff conducted a second tape restoration project (WHSSS TRP) on the backup media from each of the above systems, also in response to stipulations and orders entered in the *Armstrong* case. From the Reagan administration, all WHCA All-in-One email and cables, and WHSSS All-in-One email, calendars, and cables, were restored as part of the WHSSS TRP. From the GHW Bush administration, all WHCA All-in-One email, calendars, and cables, WHSSS All-in-One email, calendars, and cables, and WHSR CCMail email, calendars, and cables, were restored as part of the WHSSS TRP. We will continue to retain these records.

The records restored pursuant to the WHCA and WHSSS TRPs are currently classified and are otherwise subject to access restrictions imposed by the Presidential Records Act (44 U.S.C. 2204(a)). NARA will be able to respond to future access requests for the PROFS notes, documents, and calendars, as well as All-in-One and CCMail electronic mail, calendars, and cables. In light of the extensive past restoration efforts to obtain these records, we believe the original backup media and subsequent preservation copies do not warrant permanent retention and are disposable.

Staff in OA conducted a third tape restoration project to restore unclassified Reagan-era PROFS notes, documents, and calendars residing on OA's separate unclassified PROFS system for components of the Executive Office of the President, also in response to stipulations and orders entered in the *Armstrong* case. NARA now proposes to dispose of 32 unclassified open-reel backup tapes created during the Reagan administration and used by OA staff for this third TRP. OA created separate sets of output tapes, labeled the ''Presidential Tape Set,'' and the ''Federal Tape Set,'' containing PROFS notes, documents, and calendars covered under the Presidential Records Act and the Federal Records Act, respectively. We will continue to retain these records. In light of OA's restoration efforts, we believe that these 32 original backup media and subsequent preservation copies also do not warrant permanent retention and are disposable.

Dated: January 30, 2015.

Susan K. Donius,

Director, Office of Presidential Libraries.

[FR Doc. 2015–02454 Filed 2–5–15; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL FOUNDATION FOR THE ARTS AND HUMANITIES

Notice of Continuance for General Clearance for Guidelines, Applications and Reporting Forms

AGENCY: Institute of Museum and Library Services, National Foundation for the Arts and Humanities.

ACTION: Notice, request for comments, collection of information.

SUMMARY: The Institute of Museum and Library Services (IMLS), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). This pre-clearance consultation program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. By this notice, IMLS is soliciting comments on IMLS program guidelines and reporting requirements.

A copy of the proposed information collection request can be obtained by

contacting the individual listed below in the **ADDRESSES** section of this notice.

DATES: Written comments must be submitted to the office listed in the **ADDRESSES** section below on or before April 6, 2015.

The IMLS is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

ADDRESSES: For a copy of the documents contact: Kim A. Miller, Management Analyst, Institute of Museum and Library Services, 1800 M Street NW., 9th Floor, Washington, DC 20036. Ms. Miller can be reached by telephone: 202–653–4762; fax: 202–653–4600; email: *kmiller@imls.gov* or by *teletype* (TTY/TDD) for persons with hearing difficulty at 202–653–4614.

SUPPLEMENTARY INFORMATION:

I. Background

The Institute of Museum and Library Services is the primary source of federal support for the Nation's 123,000 libraries and 35,000 museums. The Institute's mission is to inspire libraries and museums to advance innovation, learning and civic engagement. We provide leadership through research, policy development, and grant making. IMLS provides a variety of grant programs to assist the Nation's museums and libraries in improving their operations and enhancing their services to the public. (20 U.S.C. 9101 *et seq.*).

II. Current Actions

To administer these programs of grants, cooperative agreements and contracts, IMLS must develop application guidelines and reporting forms.

Agency: Institute of Museum and Library Services.

Title: IMLS Guidelines, and Applications and Reporting Forms.

OMB Number: 3137–0029, 3137–0071.

Agency Number: 3137.

Frequency: Annually, Semi-annually.

Affected Public: State Library Administrative Agencies, museums, libraries, institutions of higher education, library and museum professional associations, and museum and library professionals, Indian tribes (including any Alaska native village, regional corporation, or village corporation), and organizations that primarily serve and represent Native Hawaiians.

Number of Respondents: 10,037.

Estimated Time per Respondent: .08–90 hours.

Total Burden Hours: 63,085.

Total Annualized capital/startup costs: 0.

Total Annual Costs: $1,745,562.

Public Comments Invited: Comments submitted in response to this notice will be summarized and/or included in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Kim Miller, Management Analyst, Institute of Museum and Library Services, 1800 M Street NW., 9th Floor, Washington, DC 20036. Ms. Miller can be reached by telephone: 202–653–4762; fax: 202–653–4600; or email: *kmiller@imls.gov*.

Dated: February 3, 2015.

Kim A. Miller,

Management Analyst, Office of Planning, Research and Evaluation.

[FR Doc. 2015–02390 Filed 2–5–15; 8:45 am]

BILLING CODE 7036–01–P

NATIONAL SCIENCE FOUNDATION

Comment Request: National Science Foundation Proposal & Award Policies & Procedures Guide

AGENCY: National Science Foundation.

ACTION: Notice.

SUMMARY: The National Science Foundation (NSF) is announcing plans to request renewed clearance of this collection. In accordance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we are providing opportunity for public comment on this action.

After obtaining and considering public comment, NSF will prepare the submission requesting OMB clearance of this collection for no longer than 3 years.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information on respondents, including through the use of automated collection techniques or other forms of information technology; 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.

DATES: Written comments should be received by April 7, 2015 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Written comments regarding the information collection and requests for copies of the proposed information collection request should be addressed to Suzanne Plimpton, Reports Clearance Officer, National Science Foundation, 4201 Wilson Blvd., Rm. 1265, Arlington, VA 22230, or by email to *splimpto@nsf.gov.*

FOR FURTHER INFORMATION CONTACT: Suzanne Plimpton on (703) 292–7556 or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays).

SUPPLEMENTARY INFORMATION:

Title of Collection: ''National Sciences Foundation Proposal & Award Policies & Procedures Guide.''

OMB Approval Number: 3145–0058.

Expiration Date of Approval: November 30, 2017.

Type of Request: Intent to seek approval to extend with revision an information collection for three years.

Proposed Project: The National Science Foundation Act of 1950 (Pub. L. 81–507) set forth NSF's mission and purpose:

> ''To promote the progress of science; to advance the national health, prosperity, and welfare; to secure the national defense. . . .''

The Act authorized and directed NSF to initiate and support:

- Basic scientific research and research fundamental to the engineering process;
- Programs to strengthen scientific and engineering research potential;
- Science and engineering education programs at all levels and in all the various fields of science and engineering;

• Programs that provide a source of information for policy formulation; and

• Other activities to promote these ends.

Over the years, NSF's statutory authority has been modified in a number of significant ways. In 1968, authority to support applied research was added to the Organic Act. In 1980, The Science and Engineering Equal Opportunities Act gave NSF standing authority to support activities to improve the participation of women and minorities in science and engineering.

Another major change occurred in 1986, when engineering was accorded equal status with science in the Organic Act. NSF has always dedicated itself to providing the leadership and vision needed to keep the words and ideas embedded in its mission statement fresh and up-to-date. Even in today's rapidly changing environment, NSF's core purpose resonates clearly in everything it does: Promoting achievement and progress in science and engineering and enhancing the potential for research and education to contribute to the Nation. While NSF's vision of the future and the mechanisms it uses to carry out its charges have evolved significantly over the last four decades, its ultimate mission remains the same.

Use of the Information: The regular submission of proposals to the Foundation is part of the collection of information and is used to help NSF fulfill this responsibility by initiating and supporting merit-selected research and education projects in all the scientific and engineering disciplines. NSF receives more than 50,000 proposals annually for new projects, and makes approximately 11,000 new awards.

Support is made primarily through grants, contracts, and other agreements awarded to more than 2,000 colleges, universities, academic consortia, nonprofit institutions, and small businesses. The awards are based mainly on evaluations of proposal merit submitted to the Foundation.

The Foundation has a continuing commitment to monitor the operations of its information collection to identify and address excessive reporting burdens as well as to identify any real or apparent inequities based on gender, race, ethnicity, or disability of the proposed principal investigator(s)/project director(s) or the co-principal investigator(s)/co-project director(s).

Burden on the Public: The Foundation estimates that an average of 120 hours is expended for each proposal submitted. An estimated 50,000 proposals are expected during the course of one year for a total of 6,000,000 public burden hours annually.

Dated: February 3, 2015.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2015–02386 Filed 2–5–15; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request; Engineering IIP Program Monitoring Clearance

AGENCY: National Science Foundation.

ACTION: Notice.

SUMMARY: Under the Paperwork Reduction Act of 1995, Pub. L. 104–13 (44 U.S.C. U.S.C. 3506(c)(2)(A)), and as part of its continuing effort to reduce paperwork and respondent burden, the National Science Foundation invites the general public and other Federal agencies to take this opportunity to comment on this information collection. This is the second notice for public comment; the first was published in the **Federal Register** at 79 FR 9485 and no comments were received. NSF is forwarding the proposed submission to the Office of Management and Budget (OMB) for clearance simultaneously with the publication of this second notice. The full submission may be found at: *http://www.reginfo.gov/public/do/PRAMain*.

DATES: Comments regarding these information collections are best assured of having their full effect if received by OMB within March 9, 2015.

ADDRESSES: Written comments regarding the information collection and requests for copies of the proposed information collection request should be addressed to Suzanne Plimpton, Reports Clearance Officer, National Science Foundation, 4201 Wilson Blvd., Rm. 1265, Arlington, VA 22230, or by email to *splimpto@nsf.gov*. Copies of the submission may be obtained by calling (703) 292–7556.

FOR ADDITIONAL INFORMATION: Contact Suzanne Plimpton, the NSF Reports Clearance Officer, phone (703) 292–7556, or send email to *splimpto@nsf.gov*. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays).

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

SUPPLEMENTARY INFORMATION:

Title of Collection: Engineering IIP Program; Monitoring Data Collections.

OMB Number: 3145–NEW.

Type of Request: Intent to seek approval to establish specific collections for 5 IIP programs for post-award output and outcome monitoring.

Abstract

Proposed Project: NSF provides nearly 20 percent of federal funding for basic research to academic institutions.[1] Within NSF, the Directorate for Engineering (ENG) has primary responsibility for promoting the progress of engineering in the United States in order to enable the Nation's capacity to perform. Its investments in engineering research and education aim to build and strengthen a national capacity for innovation that can lead over time to the creation of new shared wealth and a better quality of life. Most NSF programs in engineering are funded through the Directorate for Engineering, which also sponsors the NSF's Industrial Innovation and Partnerships (IIP) Division. To these ends, ENG provides support for research and implementation activities that may meet national needs. While scientists seek to discover what is not yet known, engineers apply fundamental science to design and develop new devices and engineered systems to solve societal problems. ENG also focuses on broadening participation in engineering research and careers, particularly among those individuals traditionally underrepresented and underemployed in the STEM workforce, including but not limited to, women, persons with disabilities, and racial and ethnic minorities.

This request seeks approval for a group of information collections intended to monitor outputs, short-term, intermediate and long-term outcomes of NSF–ENG investments in research and innovation in the Division of Industrial Innovation and Partnerships (IIP). IIP programs serve the entire foundation by fostering partnerships to advance technological innovation and plays an important role in the public-private

[1] National Science Foundation. (2012). *NSF at a glance.* Retrieved from *http://www.nsf.gov/about/glance.jsp.*

innovation partnership enterprise by investing in science and engineering research across all disciplines that have the potential for high impact in meeting national and societal needs. IIP focuses on leveraging federal, small business, industrial, university, state and community college resources.

Genuine partnerships between academe and industry are an important aspect of IIP programs and should facilitate the types of infrastructure that can sustain and nurture the spread of innovative activity.

Innovation infrastructures educate and train human capital for the research enterprise and the entrepreneurial aspects of innovation; develop social networks characterized by shared commitment and trust; and build a base of operational support without which sustainable partnerships cannot exist. This support includes a diversified base of private investment, a physical place to provide a context for incubation, technical, management, and administrative support, laboratories, communications services, and reliable sources of capital. One end of the innovation spectrum within the division includes unsolicited research proposals generated by the academic community. On the other end of the innovation spectrum, IIP supports small business research proposals aimed at pursuing opportunities to commercialize products and services.

IIP is home to the two Congressionally mandated small business research programs, the *Small Business Innovation Research (SBIR) program* and the *Small Business Technology Transfer (STTR) program*. IIP also manages the *Partnerships for Innovation: Accelerating Innovation Research (PFI:AIR)* as well as the *Partnerships for Innovation: Building Innovation Capacity (PFI:BIC)* program, which stimulate innovation by building partnerships across the scientific, engineering, and business community. In addition, the IIP leverages industrial support through the *Industry/University Cooperative Research Centers (I/UCRC)* program. The division also actively participates in NSF-wide programs, such as the *Grants Opportunities for Academic Liaison with Industry (GOALI)* program. Another NSF-wide program in which IIP actively participates is the Innovation Corps program (*I-Corps*), which equips scientists with the entrepreneurial tools needed to transform discoveries with commercial realization potential into innovative technologies.[2] ENG-funded projects could include research opportunities and mentoring for educators, scholars, small businesses and university students.

These survey questionnaires, individually tailored to measure outputs and outcomes for different programs, will provide essential information for program monitoring purposes. Data collected by ENG IIP program monitoring collections will be used for program planning, management, and evaluation. Summaries of monitoring data are used to respond to queries from Congress, the public, NSF's external merit reviewers who serve as advisors, including Committees of Visitors (COVs), and NSF's Office of the Inspector General. These data are needed for effective administration, program and project monitoring, evaluation, and for measuring attainment of NSF's program and strategic goals, as identified by the President's Accountable Government Initiative, the Government Performance and Results Act (GPRA) Modernization Act of 2010, and NSF's Strategic Plan.

The seven (7) program-specific collections included in this request are designed to assist in management of specific programs and to serve as data resources for current and future program evaluations. As such, expected outcomes could vary according to the nature of the program funding, field of study, and other program characteristics.

Office	Programs
Industrial Innovation and Partnerships (IIP)	Grant Opportunities for Academic Liaison with Industry (GOALI). Innovation Corps (I-Corps). Partnerships For Innovation: Accelerating Innovation Research (PFI:AIR). Partnerships For Innovation: building Innovation Capacity (PFI:BIC). Small Business Innovation Research (SBIR).

This data collection effort will enable program officers to longitudinally monitor outputs and outcomes given the unique goals and purpose of their programs. This is very important to enable appropriate and accurate evidence-based management of the programs and to determine whether or not the specific goals of the programs are being met.

Grantees will be invited to submit this information on a periodic basis via data collection methods that include but are not limited to online surveys, interviews, phone interviews, etc. These indicators are both quantitative and descriptive and may include, for example, the characteristics of project personnel and students; sources of complementary cash and in-kind support to the ENG project; characteristics of industrial and/or other sector participation; research activities; education activities; knowledge transfer activities; patents, licenses; publications; descriptions of significant advances and other outcomes of the ENG-funded effort.

Use of the Information: The data collected will be used for NSF internal reports, historical data, program level studies and evaluations, and for securing future funding for the ENG program maintenance and growth. These data could be used for program evaluation purposes if deemed necessary for a particular program. Evaluation designs could make use of metadata associated with the award, and other characteristics to identify a comparison group to evaluate the impact of the program funding and other interesting research questions.

[2] National Science Foundation. (2014) *About IIP*. Retrieved from *http://www.nsf.gov/eng/iip/about.jsp*.

ESTIMATE OF BURDEN

Collection title	Number of respondents	Annual number of hours/ respondents	Annual hour burden
Grant Opportunities for Academic Liaison with Industry (GOALI)	200	2	400
Innovation Corps (I-Corps) Longitudinal Collection	800	.25	200
Innovation Corps (I-Corps) Pre-Course Survey Questionnaire	150	.25	37.5
Innovation Corps (I-Corps) Post-Course Survey Questionnaire	150	.25	37.5
Partnerships for Innovation: Accelerating Innovation Research (PFI:AIR)	200	2	400
Partnerships for Innovation: Building Innovation Capacity (PFI:BIC)	30	2	60
Small Business Innovation Research (SBIR)	1,100	2	2,200
Total	2,630	8.75	3,335

Below is an example that shows how the hour burden was estimated for the monitoring system.

The estimated average number of annual respondents is 2,630, with an estimated annual response burden of 3,335 hours. For post-award monitoring systems, IIP expects to collect data at 1, 2, 5, and 10 years post-award, in order to have the best chance of capturing the more immediate outcomes expected by 1–2 years post-award, intermediate outcomes at 5 years post-award, and long-term outcomes/impacts at 10 years post award. These seven (7) data collections spread over the span of 10 years; this averages to 0.25 data collections/year. For the IIP division, many awards are made in translational research, such that we might expect a shorter and more condensed timeline of outcomes and impacts. Thus, some programs may wish to collect data quarterly for the first two years of the award, and then once annually at 5 and 10 years post-award. The annual number of responses for the first 2 years post award is included in this table.

For life-of-award monitoring, the data collection burden to awardees will be limited to no more than 2 hours of the respondents' time in each instance.

Respondents: The respondents are PIs, partners or students. For some programs (I-Corps) the burden already includes a response from 3 members of the team in the pre and post surveys. For all others, one PI or assignee per award completes the questionnaire.

Estimates of Annualized Cost to Respondents for the Hour

Burdens: The overall annualized cost to the respondents is estimated to be $215,660. The following table shows the annualized estimate of costs to PI/program coordinator respondents, who are generally university professors. This estimated hourly rate is based on a report from the American Association of University Professors, ''Annual Report on the Economic Status of the Profession, 2011–12,'' *Academe,* March–April 2012, Survey Report Table 4. According to this *report,* the average salary of an associate professor across all types of doctoral-granting institutions (public, private-independent, religiously affiliated) was $86,319. When divided by the number of standard annual work hours (2,080), this calculates to approximately $41 per hour.

Respondent	Number of respondents	Burden hours per respondent	Average hourly rate	Estimated annual cost
PIs, Assignees, Partners or Students	2,630	2	$41	$215,660

Estimated Number of Responses per Report

Data collection for the collections involves all awardees in the programs involved. The table below shows the total universe and sample size for each of the collections.

RESPONDENT UNIVERSE AND SAMPLE SIZE OF ENG PROGRAM MONITORING CLEARANCE COLLECTIONS

Collection title	Universe of respondents	Sample size
Grant Opportunities for Academic Liaison with Industry (GOALI)	200	200
Innovation Corps (I-Corps) Longitudinal Collection	800	800
Innovation Corps (I-Corps) Pre-Course Survey Questionnaire	150	150
Innovation Corps (I-Corps) Post-Course Survey Questionnaire	150	150
Partnerships for Innovation: Accelerating Innovation Research (PFI:AIR)	200	200
Partnerships for Innovation: Building Innovation Capacity (PFI:BIC)	30	30
Small Business Innovation Research (SBIR)	1,100	1,100

Dated: February 3, 2015.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2015–02385 Filed 2–5–15; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Proposal Review Panel for Materials Research; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463 as amended), the National Science Foundation announces the following meeting:

NAME: Site visit review of the Materials Research Science and Engineering Center (MRSEC) at the University of Wisconsin—Madison by the Division of Materials Research (DMR) #1203

DATES AND TIMES: April 26, 2015; 7:00 p.m. to 9:00 p.m.
April 27, 2015; 7:00 a.m.–8:30 p.m.
April 28, 2015; 7:15 a.m.–4:30 p.m.

PLACE: University of Wisconsin, Madison, WI.

TYPE OF MEETING: Part Open.

CONTACT PERSON: Dr. Thomas Rieker, Program Director, Division of Materials Research, Room 1065, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230, Telephone (703) 292–4914.

PURPOSE OF MEETING: To provide advice and recommendations concerning further support of the MRSEC at the University of Wisconsin.

AGENDA:

Sunday, April 26, 2015

7:00 p.m.–9:00 p.m. Closed—Briefing of panel

Monday, April 27, 2015

7:00 a.m.–5:00 p.m. Open—Review of the MRSEC
5:00 p.m.–6:30 p.m. Closed—Executive Session
7:00 p.m.–8:30 p.m. Open—Dinner

Tuesday, April 28, 2015

7:30 a.m.–10:10 a.m. Open—Review of the MRSEC
10:10 a.m.–4:30 p.m. Closed—Executive Session, Draft and Review Report

REASON FOR CLOSING: The work being reviewed may include information of a proprietary or confidential nature, including technical information; financial data, such as salaries and personal information concerning individuals associated with the MRSEC. These matters are exempt under 5 U.S.C. 552 b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: February 3, 2015.

Suzanne Plimpton,

Acting Committee Management Officer.

[FR Doc. 2015–02384 Filed 2–5–15; 8:45 am]

BILLING CODE 7555–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2015–25 and CP2015–34; Order No. 2343]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning an addition of Priority Mail Contract 106 to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* February 10, 2015.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Notice of Commission Action
III. Ordering Paragraphs

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.,* the Postal Service filed a formal request and associated supporting information to add Priority Mail Contract 106 to the competitive product list.[1]

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. *Id.* Attachment B.

To support its Request, the Postal Service filed a copy of the contract, a copy of the Governors' Decision authorizing the product, proposed changes to the Mail Classification Schedule, a Statement of Supporting Justification, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket Nos. MC2015–25 and CP2015–34 to consider the Request pertaining to the proposed Priority Mail Contract 106 product and the related contract, respectively.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than February 10, 2015. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Kenneth R. Moeller to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2015–25 and CP2015–34 to consider the matters raised in each docket.
2. Pursuant to 39 U.S.C. 505, Kenneth R. Moeller is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).
3. Comments are due no later than February 10, 2015.
4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2015–02422 Filed 2–5–15; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2015–30 and CP2015–39; Order No. 2338]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the addition of Priority Mail Contract 111 negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* February 9, 2015.

[1] Request of the United States Postal Service to Add Priority Mail Contract 106 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, January 30, 2014 (Request).

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Notice of Commission Action
III. Ordering Paragraphs

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.*, the Postal Service filed a formal request and associated supporting information to add Priority Mail Contract 111 to the competitive product list.[1]

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. *Id.* Attachment B.

To support its Request, the Postal Service filed a copy of the contract, a copy of the Governors' Decision authorizing the product, proposed changes to the Mail Classification Schedule, a Statement of Supporting Justification, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket Nos. MC2015–30 and CP2015–39 to consider the Request pertaining to the proposed Priority Mail Contract 111 product and the related contract, respectively.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than February 9, 2015. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Kenneth R. Moeller to serve as Public Representative in these dockets.

[1] Request of the United States Postal Service to Add Priority Mail Contract 111 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, January 30, 2015 (Request).

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2015–30 and CP2015–39 to consider the matters raised in each docket.
2. Pursuant to 39 U.S.C. 505, Kenneth R. Moeller is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).
3. Comments are due no later than February 9, 2015.
4. The Secretary shall arrange for publication of this Order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2015–02315 Filed 2–5–15; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2015–27 and CP2015–36; Order No. 2341]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning an addition of Priority Mail Contract 108 to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* February 10, 2015.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Notice of Commission Action
III. Ordering Paragraphs

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.,* the Postal Service filed a formal request and associated supporting information to add Priority Mail Contract 108 to the competitive product list.[1]

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. *Id.* Attachment B.

To support its Request, the Postal Service filed a copy of the contract, a copy of the Governors' Decision authorizing the product, proposed changes to the Mail Classification Schedule, a Statement of Supporting Justification, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket Nos. MC2015–27 and CP2015–36 to consider the Request pertaining to the proposed Priority Mail Contract 108 product and the related contract, respectively.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than February 10, 2015. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Lyudmila Y. Bzhilyanskaya to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2015–27 and CP2015–36 to consider the matters raised in each docket.
2. Pursuant to 39 U.S.C. 505, Lyudmila Y. Bzhilyanskaya is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).
3. Comments are due no later than February 10, 2015.
4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2015–02418 Filed 2–5–15; 8:45 am]

BILLING CODE 7710–FW–P

[1] Request of the United States Postal Service to Add Priority Mail Contract 108 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, January 30, 2015 (Request).

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2015–28 and CP2015–37; Order No. 2339]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning an addition of Priority Mail Contract 109 to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* February 9, 2015.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Notice of Commission Action
III. Ordering Paragraphs

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.,* the Postal Service filed a formal request and associated supporting information to add Priority Mail Contract 109 to the competitive product list.[1]

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. *Id.* Attachment B.

To support its Request, the Postal Service filed a copy of the contract, a copy of the Governors' Decision authorizing the product, proposed changes to the Mail Classification Schedule, a Statement of Supporting Justification, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

[1] Request of the United States Postal Service to Add Priority Mail Contract 109 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, January 30, 2015 (Request).

II. Notice of Commission Action

The Commission establishes Docket Nos. MC2015–28 and CP2015–37 to consider the Request pertaining to the proposed Priority Mail Contract 109 product and the related contract, respectively.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than February 9, 2015. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Curtis E. Kidd to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2015–28 and CP2015–37 to consider the matters raised in each docket.
2. Pursuant to 39 U.S.C. 505, Curtis E. Kidd is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).
3. Comments are due no later than February 9, 2015.
4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2015–02343 Filed 2–5–15; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. ACR2014; Order No. 2342]

Postal Service Performance Report and Performance Plan

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: On December 29, 2014, the Postal Service filed the FY 2014 Performance Report and FY 2015 Performance Plan with its FY 2014 Annual Compliance Report. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* February 25, 2015. *Reply Comments are due:* March 4, 2015.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Background
III. Request for Comments
IV. Ordering Paragraphs

I. Introduction

Each fiscal year, the Postal Service prepares an annual performance plan (Performance Plan) and a report on program performance (Performance Report) as required under 39 U.S.C. 2803 and 2804. Pursuant to 39 U.S.C. 3652(g), on December 29, 2014, the Postal Service filed the FY 2014 Performance Report and FY 2015 Performance Plan with the Commission along with its FY 2014 Annual Compliance Report.[1]

The Commission is required to evaluate whether the Postal Service has met the goals established in the FY 2014 Performance Report and FY 2015 Performance Plan. See 39 U.S.C. 3653(d). It may also provide recommendations to the Postal Service related to the protection or promotion of public policy objectives set out in title 39. *Id.*

II. Background

In past years, the Commission included its analysis of Performance Reports and Performance Plans in its Annual Compliance Determination (ACD).[2] In FY 2014, the Commission determined that its obligations under section 3653(d) are distinguishable from its ACD obligations under section 3653(b).[3] Thus, in FY 2014, the Commission issued a separate report analyzing the Postal Service's FY 2013 Performance Report and FY 2014 Performance Plan. See *id.* That report provided an in-depth analysis of legal

[1] The FY 2014 Performance Report and FY 2015 Performance Plan are included in the Postal Service's 2014 Annual Report to Congress. United States Postal Service, United States Postal Service 2014 Annual Report to Congress, at 37–45; see Library Reference USPS–FY14–17, December 29, 2014.

[2] See, *e.g.,* Docket No. ACR2012, Postal Regulatory Commission, Annual Compliance Determination Report Fiscal Year 2012 (Revised May 7, 2013), May 7, 2013, at 35–46.

[3] Docket No. ACR2013, Postal Regulatory Commission, Review of Postal Service FY 2013 Performance Report and FY 2014 Performance Plan, July 7, 2014, at 3.

requirements, performance goals, and strategic initiatives.

In FY 2015, the Commission will also analyze the FY 2014 Performance Report and FY 2015 Performance Plan in a separate report. To facilitate its review, the Commission is establishing a separate comment period for the FY 2014 Performance Report and FY 2015 Performance Plan. The Commission invites public comment to consider the following issues related to the FY 2014 Performance Report and FY 2015 Performance Plan:

- Did the Postal Service meet the goals established in the FY 2014 Performance Report and FY 2015 Performance Plan?
- Do the FY 2014 Performance Report and FY 2015 Performance Plan meet applicable statutory requirements, including 39 U.S.C. 2803 and 2804?
- What recommendations should the Commission provide to the Postal Service that relate to protecting or promoting public policy objectives in title 39?
- What is the role of strategic initiatives in the FY 2014 Performance Report and FY 2015 Performance Plan?
- What other matters are relevant to the Commission's analysis of the FY 2014 Performance Report and FY 2015 Performance Plan under 39 U.S.C. 3653(d)?

III. Request for Comments

Comments by interested persons are due no later than February 25, 2015. Reply comments are due no later than March 4, 2015. Pursuant to 39 U.S.C. 505, Kenneth R. Moeller is appointed to serve as Public Representative to represent the interests of the general public in this docket with respect to issues related to the Commission's analysis of the FY 2014 Performance Report and FY 2015 Performance Plan.

IV. Ordering Paragraphs

It is ordered:

1. The Commission invites public comment on the Postal Service's FY 2014 Performance Report and FY 2015 Performance Plan.

2. Pursuant to 39 U.S.C. 505, the Commission appoints Kenneth R. Moeller to serve as Public Representative to represent the interests of the general public in this proceeding with respect to issues related to the Commission's analysis of the FY 2014 Performance Report and FY 2015 Performance Plan.

3. Comments on the Postal Service's FY 2014 Performance Report and FY 2015 Performance Plan are due no later than February 25, 2015.

4. Reply comments are due no later than March 4, 2015.

5. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2015–02420 Filed 2–5–15; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* February 6, 2015.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 30, 2015, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Contract 107 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2015–26, CP2015–35.

Stanley F. Mires,

Attorney, Federal Requirements.

[FR Doc. 2015–02355 Filed 2–5–15; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* February 6, 2015.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 30, 2015, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Contract 108 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2015–27, CP2015–36.

Stanley F. Mires,

Attorney, Federal Requirements.

[FR Doc. 2015–02353 Filed 2–5–15; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service ™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* February 6, 2015.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service ® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 30, 2015, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Contract 109 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2015–28, CP2015–37.

Stanley F. Mires,

Attorney, Federal Requirements.

[FR Doc. 2015–02365 Filed 2–5–15; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service ™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* February 6, 2015.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 30, 2015, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Contract 111 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2015–30, CP2015–39.

Stanley F. Mires,

Attorney, Federal Requirements.

[FR Doc. 2015–02363 Filed 2–5–15; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* February 6, 2015.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 30, 2015, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Contract 106 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2015–25, CP2015–34.

Stanley F. Mires,

Attorney, Federal Requirements.

[FR Doc. 2015–02356 Filed 2–5–15; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* February 6, 2015.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 30, 2015, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Contract 110 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2015–29, CP2015–38.

Stanley F. Mires,

Attorney, Federal Requirements.

[FR Doc. 2015–02364 Filed 2–5–15; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 31441; 812–14338]

Capital Group ETF Trust, *et al.;* Notice of Application

February 2, 2015.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from sections 2(a)(32), 5(a)(1), 22(d) and 22(e) of the Act and rule 22c–1 under the Act, under section 12(d)(1)(J) of the Act for an exemption from sections 12(d)(1)(A) and (B) of the Act, and under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and (a)(2) of the Act.

APPLICANTS: Capital Group ETF Trust (the ''Trust''); Capital Research and Management Company (the ''Initial Adviser''); and American Funds Distributors, Inc. (the ''Distributor'').

SUMMARY OF APPLICATION: Applicants request an order that permits: (a) Actively-managed series of certain open-end management investment companies to issue shares (''Shares'') redeemable in large aggregations only (''Creation Units''); (b) secondary market transactions in Shares to occur at negotiated market prices; (c) certain series to pay redemption proceeds, under certain circumstances, more than seven days from the tender of Shares for redemption; (d) certain affiliated persons of the series to deposit securities into, and receive securities from, the series in connection with the purchase and redemption of Creation Units; (e) certain registered management investment companies and unit investment trusts outside of the same group of investment companies as the series to acquire Shares; and (f) certain series to perform creations and redemptions of Creation Units in-kind in a master-feeder structure.

FILING DATES: The application was filed on July 28, 2014, and amended on October 17, 2014 and January 26, 2015.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on February 27, 2015, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549. Applicants: 333 South Hope Street, Los Angeles, California 90071.

FOR FURTHER INFORMATION CONTACT: Mark N. Zaruba, Senior Counsel, at (202) 551–6878 or Mary Kay Frech, Branch Chief, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. The Trust, which is organized as a Delaware statutory trust, will be registered under the Act as an open-end management investment company. The Trust will consist of multiple series. The Trust will initially offer one series (the ''Initial Fund'') that will rely on the order. The Initial Fund's investment objective will be to seek to provide long-term growth of capital, with income as a secondary objective.

2. The Initial Adviser is, and any other Adviser (as defined below), will be registered as an investment adviser under the Investment Advisers Act of

1940 (''Advisers Act''). An Adviser will serve as investment adviser to each of the Funds (as defined below). The Adviser may enter into sub-advisory agreements with one or more affiliated or unaffiliated investment advisers, each of which will serve as sub-adviser to a Fund (each, a ''Sub-Adviser''). Any Sub-Adviser will be registered under the Advisers Act or will not be subject to registration. The Distributor is a registered broker-dealer (''Broker'') under the Securities Exchange Act of 1934 (''Exchange Act'') and will act as the distributor and principal underwriter of the Funds.[1]

3. Applicants request that the order apply to the Initial Fund as well as to future series of the Trust and any future open-end management investment companies or series thereof that would operate as actively-managed exchange-traded funds (''Future Funds''). Any Future Fund will (a) be advised by the Initial Adviser or an entity controlling, controlled by, or under common control with the Initial Adviser (the Initial Adviser and each such other entity and any successor thereto included in the term ''Adviser'') and (b) comply with the terms and conditions of the application.[2] The Initial Fund and Future Funds together are the ''Funds.'' Each Fund will operate as an actively managed exchange-traded fund (''ETF''), and a Fund may operate as a feeder fund in a master-feeder structure (''Feeder Fund'').

4. Applicants state that the Funds, or their respective Master Funds (as defined below), may invest in equity securities or fixed income securities (''Fixed Income Funds'') traded in the U.S. or non-U.S. markets. Fixed Income Funds may also include Funds that invest in a combination of equity and fixed-income securities. Funds, or their respective Master Funds, that invest in foreign equity and/or fixed income securities, are ''Foreign Funds.'' Foreign Funds may also include Funds that invest in a combination of foreign and domestic equity and/or fixed income securities. Applicants state that the Funds may also invest in a broad variety of other instruments[3] and that a Foreign Fund, either directly or through a Master Fund, may invest a significant portion of its assets in depositary receipts representing foreign securities in which they seek to invest (''Depositary Receipts'').[4] Applicants further state that, in order to implement each Fund's investment strategy, the Adviser and/or Sub-Advisers of a Fund may review and change the securities, other assets and other positions held by the Fund or its respective Master Fund (''Portfolio Instruments'') daily.

5. With respect to section 12(d)(1), applicants are requesting relief (''Fund of Funds Relief'') to permit management investment companies and unit investment trusts (''UITs'') registered under the Act that are not part of the same ''group of investment companies,'' within the meaning of section 12(d)(1)(G)(ii) of the Act, as the Funds (such registered management investment companies are referred to as ''Investing Management Companies,'' such UITs are referred to as ''Investing Trusts,'' and Investing Management Companies and Investing Trusts are collectively referred to as ''Funds of Funds''), to acquire Shares beyond the limitations in section 12(d)(1)(A) and to permit the Funds, and any principal underwriter for the Funds, and any Broker, to sell Shares beyond the limitations in section 12(d)(l)(B) to Funds of Funds. Applicants request that any exemption under section 12(d)(1)(J) from sections 12(d)(1)(A) and (B) apply to: (1) Each Fund that is currently or subsequently part of the same ''group of investment companies'' as the Initial Fund within the meaning of section 12(d)(1)(G)(ii) of the Act, as well as any principal underwriter for the Funds and any Brokers selling Shares of a Fund to Funds of Funds; and (2) each Fund of Funds that enters into a participation agreement (''FOF Participation Agreement'') with a Fund. ''Funds of Funds'' do not include the Funds. Each Investing Management Company's investment adviser within the meaning of section 2(a)(20)(A) of the Act is the ''Fund of Funds Adviser.'' Similarly, each Investing Trust's sponsor is the ''Sponsor.'' Applicants represent that each Fund of Funds Adviser will be registered as an investment adviser under the Advisers Act and that no Fund of Funds Adviser or Sponsor will control, be controlled by, or be under common control with the Adviser.[5]

6. Applicants further request that the order permit a Fund to operate as a Feeder Fund (''Master-Feeder Relief''). Under the order, a Feeder Fund would be permitted to acquire shares of another registered investment company in the same group of investment companies having substantially the same investment objectives as the Feeder Fund (''Master Fund'') beyond the limitations in section 12(d)(1)(A) of the Act,[6] and the Master Fund, and any principal underwriter for the Master Fund, would be permitted to sell shares of the Master Fund to the Feeder Fund beyond the limitations in section 12(d)(1)(B) of the Act. Applicants request that the Master-Feeder Relief apply to any Feeder Fund, any Master Fund and any principal underwriter for the Master Funds selling shares of a Master Fund to a Feeder Fund. Applicants state that creating an exchange-traded feeder fund may be preferable to creating entirely new series for several reasons, including avoiding additional overhead costs and economies of scale for the Feeder Funds.[7] Applicants assert that, while certain costs may be higher in a master-feeder structure and there may possibly be lower tax efficiencies for the Feeder Funds, the Feeder Funds' Board will consider any such potential disadvantages against the benefits of economies of scale and other benefits of operating within a master-feeder structure.

7. With the exception of Shares issued in connection with a dividend

[1] Applicants request that the order apply to any future distributor of the Funds, which would be a registered broker-dealer under the Exchange Act and would comply with the terms and conditions of the application (''Future Distributor''). Applicants state that the Distributor or Future Distributor of any Fund may be an affiliated person or a second-tier affiliate of that Fund's Adviser and/or Sub-Advisers.

[2] All entities that currently intend to rely on the order are named as applicants. Any other entity that relies on the order in the future will comply with the terms and conditions of the application.

[3] If a Fund (or its respective Master Fund) invests in derivatives, then (a) the board of trustees (''Board'') of the Fund will periodically review and approve the Fund's (or, in the case of a Feeder Fund, its Master Fund's) use of derivatives and how the Adviser assesses and manages risk with respect to the Fund's (or, in the case of a Feeder Fund, its Master Fund's) use of derivatives and (b) the Fund's disclosure of its (or, in the case of a Feeder Fund, its Master Fund's) use of derivatives in its offering documents and periodic reports will be consistent with relevant Commission and staff guidance.

[4] Depositary Receipts are typically issued by a financial institution, a ''depositary,'' and evidence ownership in a security or pool of securities that have been deposited with the depositary. A Fund (or its respective Master Fund) will not invest in any Depositary Receipts that the Adviser or Sub-Adviser deems to be illiquid or for which pricing information is not readily available. No affiliated persons of applicants or any Sub-Adviser will serve as the depositary bank for any Depositary Receipts held by a Fund.

[5] A Fund of Funds may rely on the order only to invest in Funds and not in any other registered investment company.

[6] A Feeder Fund managed in a master-feeder structure will not make direct investments in any security or other instrument other than the securities issued by its respective Master Fund.

[7] In a master-feeder structure, the Master Fund, rather than the Feeder Fund, would invest its portfolio in compliance with the order. There would be no ability by Fund shareholders to exchange shares of Feeder Funds for shares of another feeder series of the Master Fund.

reinvestment plan,[8] each Fund will issue, on a continuous offering basis, its Shares in one or more groups of a fixed number of Shares (*e.g.,* at least 50,000 Shares). Applicants believe that a conventional trading range will be between $20–$50 per Share. All orders to purchase Creation Units must be placed with the Distributor by or through a party that has entered into a participant agreement with the Distributor of the Fund (''Authorized Participant'') with respect to the creation and redemption of Creation Units. An Authorized Participant is either: (a) A Broker or other participant in the Continuous Net Settlement System of the National Securities Clearing Corporation (''NSCC''), a clearing agency registered with the Commission, or (b) a participant in the DTC (such participant, ''DTC Participant'').

8. In order to keep costs low and permit each Fund to be as fully invested as possible, Shares (other than Shares issued in connection with a dividend reinvestment plan) will be purchased and redeemed in Creation Units and generally on an in-kind basis.[9] Except where the purchase or redemption will include cash under the limited circumstances specified below, purchasers will be required to purchase Creation Units by making an in-kind deposit of specified instruments (''Deposit Instruments''), and shareholders redeeming their Shares will receive an in-kind transfer of specified instruments (''Redemption Instruments'').[10] On any given Business Day [11] the names and quantities of the instruments that constitute the Deposit Instruments and the names and quantities of the instruments that constitute the Redemption Instruments will be identical, and these instruments may be referred to, in the case of either a purchase or redemption, as the ''Creation Basket.'' In addition, the Creation Basket will correspond pro rata to the positions in a Fund's portfolio (including cash positions),[12] except: (a) In the case of bonds, for minor differences when it is impossible to break up bonds beyond certain minimum sizes needed for transfer and settlement; (b) for minor differences when rounding is necessary to eliminate fractional shares or lots that are not tradeable round lots; [13] or (c) TBA Transactions,[14] short positions and other positions that cannot be transferred in kind [15] will be excluded from the Creation Basket.[16] If there is a difference between NAV attributable to a Creation Unit and the aggregate market value of the Creation Basket exchanged for the Creation Unit, the party conveying instruments with the lower value will also pay to the other an amount in cash equal to that difference (the ''Balancing Amount'').

9. Purchases and redemptions of Creation Units may be made in whole or in part on a cash basis, rather than in kind, solely under the following circumstances: (a) To the extent there is a Balancing Amount, as described above; (b) if, on a given Business Day, a Fund announces before the open of trading that all purchases, all redemptions or all purchases and redemptions on that day will be made entirely in cash; (c) if, upon receiving a purchase or redemption order from an Authorized Participant, a Fund determines to require the purchase or redemption, as applicable, to be made entirely in cash; (d) if, on a given Business Day, a Fund requires all Authorized Participants purchasing or redeeming Shares on that day to deposit or receive (as applicable) cash in lieu of some or all of the Deposit Instruments or Redemption Instruments, respectively, solely because: (i) Such instruments are not eligible for transfer through either the NSCC or DTC; or (ii) in the case of Foreign Funds, such instruments are not eligible for trading due to local trading restrictions, local restrictions on securities transfers or other similar circumstances; or (e) if a Fund permits an Authorized Participant to deposit or receive (as applicable) cash in lieu of some or all of the Deposit Instruments or Redemption Instruments, respectively, solely because: (i) Such instruments are, in the case of the purchase of a Creation Unit, not available in sufficient quantity; (ii) such instruments are not eligible for trading by an Authorized Participant or the investor on whose behalf the Authorized Participant is acting; or (iii) a holder of Shares of a Foreign Fund would be subject to unfavorable income tax treatment if the holder receives redemption proceeds in kind.[17]

10. Each Business Day, before the open of trading on a national securities exchange, as defined in section 2(a)(26) of the Act (''Exchange''), on which Shares are listed, each Fund will cause to be published through the NSCC the names and quantities of the instruments comprising the Creation Basket, as well as the estimated Balancing Amount (if any), for that day. The published Creation Basket will apply until a new Creation Basket is announced on the following Business Day, and there will be no intra-day changes to the Creation Basket except to correct errors in the published Creation Basket. The Exchange will disseminate every 15 seconds throughout the trading day an amount representing, on a per Share basis, the sum of the current value of the Portfolio Instruments that were publicly disclosed prior to the commencement of trading in Shares on the Exchange.

11. Transaction expenses, including operational processing and brokerage costs, may be incurred by a Fund when investors purchase or redeem Creation Units ''in-kind'' and such costs have the potential to dilute the interests of the Fund's existing beneficial owners. Accordingly, applicants state that each Fund may impose purchase or redemption transaction fees (''Transaction Fees'') in connection with effecting such purchases or redemptions.[18] Applicants further state

[8] The dividend reinvestment plan that a Fund may use is described in greater detail in the application.

[9] Feeder Funds will redeem shares from the appropriate Master Fund and then deliver to the redeeming shareholder the applicable redemption payment.

[10] The Funds must comply with the federal securities laws in accepting Deposit Instruments and satisfying redemptions with Redemption Instruments, including that the Deposit Instruments and Redemption Instruments are sold in transactions that would be exempt from registration under the Securities Act of 1933 (the ''Securities Act''). In accepting Deposit Instruments and satisfying redemptions with Redemption Instruments that are restricted securities eligible for resale pursuant to Rule 144A under the Securities Act, the Funds will comply with the conditions of Rule 144A.

[11] Each Fund will sell and redeem Creation Units on any day the Trust is open, including as required by section 22(e) of the Act (each, a ''Business Day'').

[12] The portfolio used for this purpose will be the same portfolio used to calculate the Fund's net asset value (''NAV'') for that Business Day.

[13] A tradeable round lot for a security will be the standard unit of trading in that particular type of security in its primary market.

[14] A TBA Transaction is a method of trading mortgage-backed securities. In a TBA Transaction, the buyer and seller agree on general trade parameters such as agency, settlement date, par amount and price.

[15] This includes instruments that can be transferred in kind only with the consent of the original counterparty to the extent the Fund does not intend to seek such consents.

[16] Because these instruments will be excluded from the Creation Basket, their value will be reflected in the determination of the Balancing Amount (defined below).

[17] A ''custom order'' is any purchase or redemption of Shares made in whole or in part on a cash basis in reliance on clause (e)(i) or (e)(ii).

[18] Applicants are not requesting relief from section 18 of the Act. Accordingly, a Master Fund may require a Transaction Fee payment to cover expenses related to purchases or redemptions of the Master Fund's shares by a Feeder Fund only if it requires the same payment for equivalent purchases or redemptions by any other feeder fund. Thus, for example, a Master Fund may require payment of a Transaction Fee by a Feeder Fund for transactions for 20,000 or more shares so long as it requires payment of the same Transaction Fee by all feeder funds for transactions involving 20,000 or more shares.

that, because the Transaction Fees are intended to defray the transaction expenses, as well as to prevent possible shareholder dilution resulting from the purchase or redemption of Creation Units, the Transaction Fees will be borne only by purchasers or redeemers of Creation Units and will be limited to amounts that have been determined appropriate by the Fund.[19] The Distributor will be responsible for delivering a Fund's current prospectus (''Prospectus'') or summary prospectus, if applicable, to purchasers of Shares in Creation Units and for maintaining records of both the orders placed with it and the confirmations of acceptance furnished by it.

12. Shares will be listed and traded at negotiated prices on an Exchange and traded in the secondary market. When NYSE Arca, Inc. is the principal secondary market on which the Shares are listed and traded (the ''Primary Listing Exchange''), it is expected that one or more Exchange member firms will be designated by the Exchange to act as a market maker (a ''Market Maker'').[20] The price of Shares trading on the Exchange will be based on a current bid/offer in the secondary market. Transactions involving the purchases and sales of Shares on the Exchange will be subject to customary brokerage commissions and charges.

13. Applicants expect that purchasers of Creation Units will include institutional investors and arbitrageurs. Market Makers, acting in their role to provide a fair and orderly secondary market for Shares, also may purchase Creation Units for use in their own market making activities. Applicants expect that secondary market purchasers of Shares will include both institutional and retail investors.[21] Applicants expect that arbitrage opportunities created by the ability to continually purchase or redeem Creation Units should ensure that the Shares will not trade at a material discount or premium in relation to their NAV.

14. Shares will not be individually redeemable, and only Shares combined into Creation Units of a specified size will be redeemable. Redemption requests must be placed by or through an Authorized Participant.

15. Neither the Trust nor any Fund will be marketed or otherwise held out as a ''mutual fund.'' Instead, each Fund will be marketed as an ''actively-managed exchange-traded fund.'' In any advertising material where features of obtaining, buying or selling Shares traded on the Exchange are described there will be an appropriate statement to the effect that Shares are not individually redeemable.

16. On each Business Day, before the commencement of trading in Shares on the Fund's Primary Listing Exchange, the Fund will disclose on the Trust's Web site (''Web site'') the identities and quantities of the Portfolio Instruments and other assets held by the Fund (or its respective Master Fund)[22] that will form the basis of the Fund's calculation of NAV at the end of the Business Day, the Fund's per Share NAV and the market closing price or the midpoint of the bid/ask spread at the time of the calculation of such NAV (''Bid/Ask Price''), and a calculation of the premium or discount of the market closing price or Bid/Ask Price against such NAV, all as of the prior Business Day.[23]

Applicants' Legal Analysis

1. Applicants request an order under section 6(c) of the Act for an exemption from sections 2(a)(32), 5(a)(1), 22(d) and 22(e) of the Act and rule 22c–1 under the Act, under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act, and under section 12(d)(1)(J) of the Act for an exemption from sections 12(d)(1)(A) and (B) of the Act.

2. Section 6(c) of the Act provides that the Commission may exempt any person, security or transaction, or any class of persons, securities or transactions, from any provisions of the Act, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Section 17(b) of the Act authorizes the Commission to exempt a proposed transaction from section 17(a) of the Act if evidence establishes that the terms of the transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned, and the proposed transaction is consistent with the policies of the registered investment company and the general provisions of the Act. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities or transactions, from any provision of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors.

Sections 5(a)(1) and 2(a)(32) of the Act

3. Section 5(a)(1) of the Act defines an ''open-end company'' as a management investment company that is offering for sale or has outstanding any redeemable security of which it is the issuer. Section 2(a)(32) of the Act defines a redeemable security as any security, other than short-term paper, under the terms of which the holder, upon its presentation to the issuer, is entitled to receive approximately a proportionate share of the issuer's current net assets, or the cash equivalent. Because Shares will not be individually redeemable, applicants request an order that would to permit the Trust to register as open-end management investment companies and issue Shares that are redeemable in Creation Units only.[24] Applicants state that investors may purchase Shares in Creation Units from each Fund and redeem Creation Units from each Fund. Applicants further state that, because of the arbitrage possibilities created by the redeemability of Creation Units, they

[19] In those instances in which a Fund permits an ''in-kind'' purchaser to substitute cash in lieu of depositing one or more of the requisite Deposit Instruments or Redemption Instruments, the purchaser or seller may be assessed a higher Transaction Fee on the ''cash in lieu'' portion of its investment to cover the cost of purchasing the necessary securities, including operational processing and brokerage costs, and part or all of the spread between the expected bid and offer side of the market relating to such Deposit Instruments or Redemption Instruments. In all cases, such Transaction Fees will be limited in accordance with requirements of the Commission applicable to management investment companies offering redeemable securities.

[20] If Shares are listed on The NASDAQ Stock Market LLC (''Nasdaq'') or a similar electronic Exchange (including NYSE Arca), one or more member firms of that Exchange will act as Market Maker and maintain a market for Shares trading on that Exchange. On Nasdaq, no particular Market Maker would be contractually obligated to make a market in Shares. However, the listing requirements on Nasdaq, for example, stipulate that at least two Market Makers must be registered in Shares to maintain a listing. In addition, on Nasdaq and NYSE Arca, registered Market Makers are required to make a continuous two-sided market or subject themselves to regulatory sanctions. No Market Maker will be an affiliated person, or a second-tier affiliate, of the Funds, except within section 2(a)(3)(A) or (C) of the Act due solely to ownership of Shares as discussed below.

[21] Shares will be registered in book-entry form only. DTC or its nominee will be the record or registered owner of all outstanding Shares. Beneficial ownership of Shares will be shown on the records of DTC or DTC Participants.

[22] Feeder Funds will disclose information about the securities and other assets held by the Master Fund.

[23] Under accounting procedures followed by the Funds, trades made on the prior Business Day (''T'') will be booked and reflected in NAV on the current Business Day (''T+1''). Accordingly, the Funds will be able to disclose at the beginning of the Business Day the portfolio that will form the basis for the NAV calculation at the end of the Business Day.

[24] The Master Funds will not require relief from sections 2(a)(32) and 5(a)(1) because the Master Funds will issue individually redeemable securities.

expect that the market price of individual Shares will not deviate materially from NAV.

Section 22(d) of the Act and Rule 22c–1 Under the Act

4. Section 22(d) of the Act, among other things, prohibits a dealer from selling a redeemable security that is currently being offered to the public by or through a principal underwriter, except at a current public offering price described in the prospectus. Rule 22c–1 under the Act generally requires that a dealer selling, redeeming, or repurchasing a redeemable security do so only at a price based on its NAV. Applicants state that secondary market trading in Shares will take place at negotiated prices, not at a current offering price described in the Prospectus, and not at a price based on NAV. Thus, purchases and sales of Shares in the secondary market will not comply with section 22(d) of the Act and rule 22c–1 under the Act. Applicants request an exemption under section 6(c) from these provisions.[25]

5. Applicants state that, while there is little legislative history regarding section 22(d), its provisions, as well as those of rule 22c–1, appear to have been designed to (a) to prevent dilution caused by certain riskless-trading schemes by principal underwriters and contract dealers, (b) to prevent unjust discrimination or preferential treatment among buyers and (c) to ensure an orderly distribution system of shares by contract dealers by eliminating price competition from non-contract dealers who could offer investors shares at less than the published sales price and who could pay investors a little more than the published redemption price.

6. Applicants assert that the protections intended to be afforded by section 22(d) and rule 22c–1 are adequately addressed by the proposed methods for creating, redeeming and pricing Creation Units and pricing and trading Shares. Applicants state that (a) secondary market trading in Shares does not involve the Funds as parties and cannot result in dilution of an investment in Shares and (b) to the extent different prices exist during a given trading day, or from day to day, such variances occur as a result of third-party market forces but do not occur as a result of unjust or discriminatory manipulation. Finally, applicants assert that competitive forces in the marketplace should ensure that the margin between NAV and the price for the Shares in the secondary market remains narrow.

Section 22(e) of the Act

7. Section 22(e) of the Act generally prohibits a registered investment company from suspending the right of redemption or postponing the date of payment of redemption proceeds for more than seven days after the tender of a security for redemption. Applicants observe that settlement of redemptions for Foreign Funds is contingent not only on the settlement cycle of the U.S. securities markets but also on the delivery cycles present in foreign markets in which those Funds invest. Applicants have been advised that the delivery cycles for transferring Redemption Instruments to redeeming investors, coupled with local market holiday schedules, will require a delivery process longer than seven calendar days. Applicants therefore request relief from the requirement imposed by section 22(e) to provide payment or satisfaction of redemptions within seven (7) calendar days following the tender of a Creation Unit of such Funds.[26]

8. Applicants state that section 22(e) was designed to prevent unreasonable, undisclosed and unforeseen delays in the actual payment of redemption proceeds. Applicants assert that the protections intended to be afforded by section 22(e) are adequately addressed by the proposed method and securities delivery cycles for redeeming Creation Units. Applicants state that allowing redemption payments for Creation Units of a Fund to be made within a maximum of fifteen (15) calendar days[27] would not be inconsistent with the spirit and intent of section 22(e).[28] Applicants represent that each Fund's statement of additional information will identify those instances in a given year where, due to local holidays, more than seven calendar days, up to a maximum of fifteen (15) calendar days, will be needed to deliver redemption proceeds and will list such holidays. Applicants are not seeking relief from section 22(e) with respect to Foreign Funds that do not effect redemptions in-kind.

Section 12(d)(1) of the Act

9. Section 12(d)(1)(A) of the Act prohibits a registered investment company from acquiring shares of an investment company if the securities represent more than 3% of the total outstanding voting stock of the acquired company, more than 5% of the total assets of the acquiring company, or, together with the securities of any other investment companies, more than 10% of the total assets of the acquiring company. Section 12(d)(1)(B) of the Act prohibits a registered open-end investment company, its principal underwriter, or any other broker or dealer from selling its shares to another investment company if the sale will cause the acquiring company to own more than 3% of the acquired company's voting stock, or if the sale will cause more than 10% of the acquired company's voting stock to be owned by investment companies generally.

10. Applicants request relief to permit Funds of Funds to acquire Shares in excess of the limits in section 12(d)(1)(A) of the Act and to permit the Funds, their principal underwriters and any Broker to sell Shares to Funds of Funds in excess of the limits in section 12(d)(l)(B) of the Act. Applicants submit that the proposed conditions to the requested relief address the concerns underlying the limits in section 12(d)(1), which include concerns about undue influence, excessive layering of fees and overly complex structures.

11. Applicants submit that certain of their proposed conditions address concerns about potential for undue influence. To limit the control that a Fund of Funds may have over a Fund, applicants propose a condition prohibiting the Fund of Funds Adviser, Sponsor, any person controlling, controlled by, or under common control with the Fund of Funds Adviser or Sponsor, and any investment company or issuer that would be an investment company but for sections 3(c)(1) or 3(c)(7) of the Act that is advised or sponsored by the Fund of Funds Adviser, the Sponsor, or any person controlling, controlled by, or under common control with the Fund of Funds Adviser or Sponsor (''Fund of Funds Advisory Group'') from controlling (individually or in the aggregate) a Fund within the meaning of section 2(a)(9) of the Act. The same prohibition would apply to any sub-adviser to an Investing Management Company (''Fund of Funds Sub-Adviser''), any person controlling, controlled by or under common control with the Fund of Funds Sub-Adviser,

[25] The Master Funds will not require relief from section 22(d) or rule 22c–1 because shares of the Master Funds will not trade at negotiated prices in the secondary market.

[26] Applicants acknowledge that no relief obtained from the requirements of section 22(e) will affect any obligations that it may otherwise have under rule 15c6–1 under the Exchange Act. Rule 15c6–1 requires that most securities transactions be settled within three business days of the trade date.

[27] Certain countries in which a Fund may invest have historically had settlement periods of up to 15 calendar days.

[28] Other feeder funds invested in any Master Fund are not seeking, and will not rely on, the section 22(e) relief requested herein.

and any investment company or issuer that would be an investment company but for sections 3(c)(1) or 3(c)(7) of the Act (or portion of such investment company or issuer) advised or sponsored by the Fund of Funds Sub-Adviser or any person controlling, controlled by or under common control with the Fund of Funds Sub-Adviser (''Fund of Funds Sub-Advisory Group'').

12. Applicants propose a condition to ensure that no Fund of Funds or Fund of Funds Affiliate [29] (except to the extent it is acting in its capacity as an investment adviser to a Fund) will cause a Fund to purchase a security in an offering of securities during the existence of an underwriting or selling syndicate of which a principal underwriter is an Underwriting Affiliate (''Affiliated Underwriting'').[30]

13. Applicants propose several conditions to address the potential for layering of fees. Applicants note that the board of directors or trustees of any Investing Management Company, including a majority of the directors or trustees who are not ''interested persons'' within the meaning of section 2(a)(19) of the Act (''independent Board members''), will be required to find that the advisory fees charged under the contract are based on services provided that will be in addition to, rather than duplicative of, services provided under the advisory contract of any Fund in which the Investing Management Company may invest. Applicants also state that any sales charges and/or service fees charged with respect to shares of a Fund of Funds will not exceed the limits applicable to a fund of funds as set forth in NASD Conduct Rule 2830.[31]

14. In order to address concerns about complexity, applicants propose condition B.12, which will prohibit Funds from acquiring securities of any investment company or company relying on section 3(c)(1) or 3(c)(7) of the Act in excess of the limits contained in section 12(d)(1)(A) of the Act, except to the extent permitted by exemptive relief from the Commission permitting a Fund to purchase shares of other investment companies for short-term cash management purposes.

15. Finally, each Fund of Funds must enter into an FOF Participation Agreement with the respective Funds, which will include an acknowledgement from the Fund of Funds that it may rely on the order only to invest in a Fund and not in any other investment company.

16. Applicants also are seeking relief from sections 12(d)(1)(A) and 12(d)(1)(B) to the extent necessary to permit the Feeder Funds to perform creations and redemptions of Shares in-kind in a master-feeder structure. Applicants assert that this structure is substantially identical to traditional master-feeder structures permitted pursuant to the exception provided in section 12(d)(1)(E) of the Act. Section 12(d)(1)(E) provides that the percentage limitations of sections 12(d)(1)(A) and (B) will not apply to a security issued by an investment company (in this case, the shares of the applicable Master Fund) if, among other things, that security is the only investment security held in the investing fund's portfolio (in this case, the Feeder Fund's portfolio). Applicants believe the proposed master-feeder structure complies with section 12(d)(1)(E) because each Feeder Fund will hold only investment securities issued by its corresponding Master Fund; however, the Feeder Funds may receive securities other than securities of its corresponding Master Fund if a Feeder Fund accepts an in-kind creation. To the extent that a Feeder Fund may be deemed to be holding both shares of the Master Fund and other securities, applicants request relief from sections 12(d)(1)(A) and (B). The Feeder Funds would operate in compliance with all other provisions of section 12(d)(1)(E).

Sections 17(a)(1) and (2) of the Act

17. Section 17(a) of the Act generally prohibits an affiliated person of a registered investment company, or an affiliated person of such a person (''second tier affiliate''), from selling any security to or purchasing any security from the company. Section 2(a)(3) of the Act defines ''affiliated person'' to include any person directly or indirectly owning, controlling, or holding with power to vote, 5% or more of the outstanding voting securities of the other person and any person directly or indirectly controlling, controlled by, or under common control with, the other person. Section 2(a)(9) of the Act defines ''control'' as the power to exercise a controlling influence over the management or policies of a company and provides that a control relationship will be presumed where one person owns more than 25% of another person's voting securities. Each Fund may be deemed to be controlled by the Adviser and hence affiliated persons of each other. In addition, the Funds may be deemed to be under common control with any other registered investment company (or series thereof) advised by the Adviser (an ''Affiliated Fund'').

18. Applicants request an exemption under sections 6(c) and 17(b) of the Act from sections 17(a)(1) and 17(a)(2) of the Act to permit in-kind purchases and redemptions of Creation Units by persons that are affiliated persons or second tier affiliates of the Funds solely by virtue of one or more of the following: (a) Holding 5% or more, or in excess of 25% of the outstanding Shares of one or more Funds; (b) having an affiliation with a person with an ownership interest described in (a); or (c) holding 5% or more, or more than 25% of the Shares of one or more Affiliated Funds.[32] Applicants also request an exemption in order to permit a Fund to sell its Shares to and redeem its Shares from, and engage in the in-kind transactions that would accompany such sales and redemptions with, certain Funds of Funds of which the Funds are affiliated persons or second-tier affiliates.[33]

19. Applicants assert that no useful purpose would be served by prohibiting such affiliated persons from making in-kind purchases or in-kind redemptions of Shares of a Fund in Creation Units. The deposit procedures for in-kind purchases of Creation Units and the redemption procedures for in-kind redemptions will be the same for all purchases and redemptions. Deposit Instruments and Redemption Instruments will be valued in the same manner as those Portfolio Instruments

[29] A ''Fund of Funds Affiliate'' is any Fund of Funds Adviser, Fund of Funds Sub-Adviser, Sponsor, promoter or principal underwriter of a Fund of Funds, and any person controlling, controlled by or under common control with any of these entities. A ''Fund Affiliate'' is the Adviser, Sub-Adviser, promoter, or principal underwriter of a Fund or any person controlling, controlled by or under common control with any of these entities.

[30] An ''Underwriting Affiliate'' is a principal underwriter in any underwriting or selling syndicate that is an officer, director, member of an advisory board, Fund of Funds Adviser, Fund of Funds Sub-Adviser, employee or Sponsor of the Fund of Funds, or a person of which any such officer, director, member of an advisory board, Fund of Funds Adviser, Fund of Funds Sub-Adviser, employee or Sponsor is an affiliated person (except any person whose relationship to the Fund is covered by section 10(f) of the Act is not an Underwriting Affiliate).

[31] Any reference to NASD Conduct Rule 2830 includes any successor or replacement rule that may be adopted by the Financial Industry Regulatory Authority.

[32] Applicants are not seeking relief from section 17(a) for, and the requested relief will not apply to, transactions where a Fund could be deemed an affiliated person, or an affiliated person of an affiliated person, of a Fund of Funds because the Adviser, or an entity controlling, controlled by or under common control with the Adviser is also an investment adviser to the Fund of Funds.

[33] To the extent that purchases and sales of Shares occur in the secondary market (and not through principal transactions directly between a Fund of Funds and a Fund), relief from section 17(a) would not be necessary. The requested relief is intended to cover, however, transactions directly between Funds and Funds of Funds.

currently held by the relevant Funds, and the valuation of the Deposit Instruments and Redemption Instruments will be made in the same manner and on the same terms for all, regardless of the identity of the purchaser or redeemer. Applicants do not believe that in-kind purchases and redemptions will result in abusive self-dealing or overreaching of the Fund.

20. Applicants also submit that the sale of Shares to and redemption of Shares from a Fund of Funds meets the standards for relief under sections 17(b) and 6(c) of the Act. Applicants note that any consideration paid for the purchase or redemption of Shares directly from a Fund will be based on the NAV of the Fund in accordance with policies and procedures set forth in the Fund's registration statement.[34] The FOF Participation Agreement will require any Fund of Funds that purchases Creation Units directly from a Fund to represent that the purchase of Creation Units from a Fund by a Fund of Funds will be accomplished in compliance with the investment restrictions of the Fund of Funds and will be consistent with the investment policies set forth in the Fund of Fund's registration statement.

21. In addition, to the extent that a Fund operates in a master-feeder structure, applicants also request relief permitting the Feeder Funds to engage in in-kind creations and redemptions with the applicable Master Fund. Applicants state that the request for relief described above would not be sufficient to permit such transactions because the Feeder Funds and the applicable Master Fund could also be affiliated by virtue of having the same investment adviser. However, applicants believe that in-kind creations and redemptions between a Feeder Fund and a Master Fund advised by the same investment adviser do not involve ''overreaching'' by an affiliated person. Applicants represent that such transactions will occur only at the Feeder Fund's proportionate share of the Master Fund's net assets, and the distributed securities will be valued in the same manner as they are valued for the purposes of calculating the applicable Master Fund's NAV. Further, all such transactions will be effected with respect to pre-determined securities and on the same terms with respect to all investors. Finally, such transaction would only occur as a result of, and to effectuate, a creation or redemption transaction between the Feeder Fund and a third-party investor. Applicants state that, in effect, the Feeder Fund will serve as a conduit through which creation and redemption orders by Authorized Participants will be effected.

22. Applicants believe that: (a) With respect to the relief requested pursuant to section 17(b), the proposed transactions are fair and reasonable, and do not involve overreaching on the part of any person concerned, the proposed transactions are consistent with the policy of each Fund, and the proposed transactions are consistent with the general purposes of the Act; and (b) with respect to the relief requested pursuant to section 6(c), the requested exemption for the proposed transactions is appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Applicants' Conditions

Applicants agree that any order of the Commission granting the requested relief will be subject to the following conditions:

A. ETF Relief

1. The requested relief to permit ETF operations will expire on the effective date of any Commission rule under the Act that provides relief permitting the operation of actively-managed ETFs, other than the Master-Feeder Relief.

2. As long as a Fund operates in reliance on the requested order, the Shares of the Fund will be listed on an Exchange.

3. Neither the Trust nor any Fund will be advertised or marketed as open-end investment companies or mutual funds. Any advertising material that describes the purchase or sale of Creation Units or refers to redeemability will prominently disclose that the Shares are not individually redeemable and that owners of the Shares may acquire Shares from the Fund (other than through a dividend reinvestment program) and tender Shares for redemption to the Fund in Creation Units only.

4. The Web site, which is and will be publicly accessible at no charge, will contain, on a per Share basis for the Fund, the prior Business Day's NAV and the market closing price or Bid/Ask Price of the Shares, and a calculation of the premium or discount of the market closing price or Bid/Ask Price against such NAV.

5. No Adviser or Sub-Adviser, directly or indirectly, will cause any Authorized Participant (or any investor on whose behalf an Authorized Participant may transact with the Fund) to acquire any Deposit Instrument for the Fund through a transaction in which the Fund could not engage directly.

6. On each Business Day, before the commencement of trading in Shares on the Fund's Primary Listing Exchange, the Fund will disclose on the Web site the identities and quantities of the Portfolio Instruments and other assets held by the Fund (or its respective Master Fund) that will form the basis of the Fund's calculation of NAV at the end of the Business Day.

B. Section 12(d)(1) Relief

1. The members of the Fund of Funds Advisory Group will not control (individually or in the aggregate) a Fund (or its respective Master Fund) within the meaning of section 2(a)(9) of the Act. The members of the Fund of Funds Sub-Advisory Group will not control (individually or in the aggregate) a Fund (or its respective Master Fund) within the meaning of section 2(a)(9) of the Act. If, as a result of a decrease in the outstanding voting securities of a Fund, the Fund of Funds Advisory Group or the Fund of Funds Sub-Advisory Group, each in the aggregate, becomes a holder of more than 25% of the outstanding voting securities of a Fund, it will vote its Shares of the Fund in the same proportion as the vote of all other holders of the Fund's Shares. This condition does not apply to the Fund of Funds Sub-Advisory Group with respect to a Fund (or its respective Master Fund) for which the Fund of Funds Sub-Adviser or a person controlling, controlled by or under common control with the Fund of Funds Sub-Adviser acts as the investment adviser within the meaning of section 2(a)(20)(A) of the Act.

2. No Fund of Funds or Fund of Funds Affiliate will cause any existing or potential investment by the Fund of Funds in a Fund to influence the terms of any services or transactions between the Fund of Funds or a Fund of Funds Affiliate and the Fund (or its respective Master Fund) or a Fund Affiliate.

3. The board of directors or trustees of an Investing Management Company, including a majority of the independent directors or trustees, will adopt procedures reasonably designed to ensure that the Fund of Funds Adviser and any Fund of Funds Sub-Adviser are conducting the investment program of the Investing Management Company

[34] Applicants acknowledge that the receipt of compensation by (a) an affiliated person of a Fund of Funds, or an affiliated person of such person, for the purchase by the Fund of Funds of Shares of the Fund or (b) an affiliated person of a Fund, or an affiliated person of such person, for the sale by the Fund of its Shares to a Fund of Funds, may be prohibited by section 17(e)(1) of the Act. The FOF Participation Agreement also will include this acknowledgment.

without taking into account any consideration received by the Investing Management Company or a Fund of Funds Affiliate from a Fund (or its respective Master Fund) or a Fund Affiliate in connection with any services or transactions.

4. Once an investment by a Fund of Funds in the Shares of a Fund exceeds the limit in section 12(d)(1)(A)(i) of the Act, the Board of the Fund (or its respective Master Fund), including a majority of the independent Board members, will determine that any consideration paid by the Fund (or its respective Master Fund) to the Fund of Funds or a Fund of Funds Affiliate in connection with any services or transactions: (i) Is fair and reasonable in relation to the nature and quality of the services and benefits received by the Fund (or its respective Master Fund); (ii) is within the range of consideration that the Fund (or its respective Master Fund) would be required to pay to another unaffiliated entity in connection with the same services or transactions; and (iii) does not involve overreaching on the part of any person concerned. This condition does not apply with respect to any services or transactions between a Fund (or its respective Master Fund) and its investment adviser(s), or any person controlling, controlled by or under common control with such investment adviser(s).

5. The Fund of Funds Adviser, or trustee or Sponsor of an Investing Trust, as applicable, will waive fees otherwise payable to it by the Fund of Funds in an amount at least equal to any compensation (including fees received pursuant to any plan adopted by a Fund (or its respective Master Fund) pursuant to rule 12b–1 under the Act) received from a Fund (or its respective Master Fund) by the Fund of Funds' Adviser, or trustee or Sponsor of the Investing Trust, or an affiliated person of the Fund of Funds' Adviser, or trustee or Sponsor of the Investing Trust, other than any advisory fees paid to the Fund of Funds' Adviser, or trustee, or Sponsor of an Investing Trust, or its affiliated person by the Fund (or its respective Master Fund), in connection with the investment by the Fund of Funds in the Fund. Any Fund of Funds Sub-Adviser will waive fees otherwise payable to the Fund of Funds Sub-Adviser, directly or indirectly, by the Investing Management Company in an amount at least equal to any compensation received from a Fund (or its respective Master Fund) by the Fund of Funds Sub-Adviser, or an affiliated person of the Fund of Funds Sub-Adviser, other than any advisory fees paid to the Fund of Funds Sub-Adviser or its affiliated person by the Fund (or its respective Master Fund), in connection with the investment by the Investing Management Company in the Fund made at the direction of the Fund of Funds Sub-Adviser. In the event that the Fund of Funds Sub-Adviser waives fees, the benefit of the waiver will be passed through to the Investing Management Company.

6. No Fund of Funds or Fund of Funds Affiliate (except to the extent it is acting in its capacity as an investment adviser to a Fund (or its respective Master Fund)) will cause a Fund (or its respective Master Fund) to purchase a security in an Affiliated Underwriting.

7. The Board of the Fund (or its respective Master Fund), including a majority of the independent Board members, will adopt procedures reasonably designed to monitor any purchases of securities by the Fund (or its respective Master Fund) in an Affiliated Underwriting, once an investment by a Fund of Funds in the securities of the Fund exceeds the limit of section 12(d)(1)(A)(i) of the Act, including any purchases made directly from an Underwriting Affiliate. The Board will review these purchases periodically, but no less frequently than annually, to determine whether the purchases were influenced by the investment by the Fund of Funds in the Fund. The Board will consider, among other things: (i) Whether the purchases were consistent with the investment objectives and policies of the Fund (or its respective Master Fund); (ii) how the performance of securities purchased in an Affiliated Underwriting compares to the performance of comparable securities purchased during a comparable period of time in underwritings other than Affiliated Underwritings or to a benchmark such as a comparable market index; and (iii) whether the amount of securities purchased by the Fund (or its respective Master Fund) in Affiliated Underwritings and the amount purchased directly from an Underwriting Affiliate have changed significantly from prior years. The Board will take any appropriate actions based on its review, including, if appropriate, the institution of procedures designed to ensure that purchases of securities in Affiliated Underwritings are in the best interest of beneficial owners of the Fund.

8. Each Fund (or its respective Master Fund) will maintain and preserve permanently in an easily accessible place a written copy of the procedures described in the preceding condition, and any modifications to such procedures, and will maintain and preserve for a period of not less than six years from the end of the fiscal year in which any purchase in an Affiliated Underwriting occurred, the first two years in an easily accessible place, a written record of each purchase of securities in Affiliated Underwritings once an investment by a Fund of Funds in the securities of the Fund exceeds the limit of section 12(d)(1)(A)(i) of the Act, setting forth from whom the securities were acquired, the identity of the underwriting syndicate's members, the terms of the purchase, and the information or materials upon which the Board's determinations were made.

9. Before investing in a Fund in excess of the limits in section 12(d)(1)(A), a Fund of Funds will execute a FOF Participation Agreement with the Fund stating that their respective boards of directors or trustees and their investment advisers, or trustee and Sponsor, as applicable, understand the terms and conditions of the order, and agree to fulfill their responsibilities under the order. At the time of its investment in Shares of a Fund in excess of the limit in section 12(d)(1)(A)(i), a Fund of Funds will notify the Fund of the investment. At such time, the Fund of Funds will also transmit to the Fund a list of the names of each Fund of Funds Affiliate and Underwriting Affiliate. The Fund of Funds will notify the Fund of any changes to the list as soon as reasonably practicable after a change occurs. The Fund and the Fund of Funds will maintain and preserve a copy of the order, the FOF Participation Agreement, and the list with any updated information for the duration of the investment and for a period of not less than six years thereafter, the first two years in an easily accessible place.

10. Before approving any advisory contract under section 15 of the Act, the board of directors or trustees of each Investing Management Company, including a majority of the independent directors or trustees, will find that the advisory fees charged under such contract are based on services provided that will be in addition to, rather than duplicative of, the services provided under the advisory contract(s) of any Fund (or its respective Master Fund) in which the Investing Management Company may invest. These findings and their basis will be recorded fully in the minute books of the appropriate Investing Management Company.

11. Any sales charges and/or service fees charged with respect to shares of a Fund of Funds will not exceed the limits applicable to a fund of funds as set forth in NASD Conduct Rule 2830.

12. No Fund (or its respective Master Fund) will acquire securities of an

investment company or company relying on section 3(c)(1) or section 3(c)(7) of the Act in excess of the limits contained in section 12(d)(1)(A) of the Act, except to the extent that (i) the Fund (or its respective Master Fund) acquires securities of another investment company pursuant to exemptive relief from the Commission permitting the Fund (or its respective Master Fund) to acquire securities of one or more investment companies for short-term cash management purposes, or (ii) the Fund acquires securities of the Master Fund pursuant to the Master-Feeder Relief.

For the Commission, by the Division of Investment Management, under delegated authority.

Jill M. Peterson,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–74186; File No. SR–NYSEArca-2014–139]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on Proposed Rule Change Relating to Shares of the iShares California AMT-Free Muni Bond ETF and iShares New York AMT-Free Muni Bond ETF

February 2, 2015.

On December 3, 2014, NYSE Arca, Inc. (''NYSE Arca'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change relating to shares of the iShares California AMT-Free Muni Bond ETF and iShares New York AMT-Free Muni Bond ETF. The proposed rule change was published for comment in the **Federal Register** on December 23, 2014.[3] The Commission received no comments on the proposal.

Section 19(b)(2) of the Act [4] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is February 6, 2015. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider this proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates March 23, 2015, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NYSEArca–2014–139).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2015–02342 Filed 2–5–15; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 73857 (Dec. 17, 2014), 79 FR 77069.

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #14215 and #14216]

Washington Disaster #WA–00052

AGENCY: Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of WASHINGTON dated 01/29/2015.

Incident: Severe Storms, Flooding and Mudslides.

Incident Period: 01/03/2015 through 01/06/2015.

DATES: *Effective Date:* 01/29/2015.

Physical Loan Application Deadline Date: 03/30/2015.

Economic Injury (EIDL) Loan Application Deadline Date: 10/29/2015.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Grays Harbor

Contiguous Counties:

Washington: Jefferson; Lewis; Mason; Pacific; Thurston

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	3.875
Homeowners Without Credit Available Elsewhere	1.938
Businesses With Credit Available Elsewhere	6.000
Businesses Without Credit Available Elsewhere	4.000
Non-Profit Organizations With Credit Available Elsewhere	2.625
Non-Profit Organizations Without Credit Available Elsewhere	2.625
For Economic Injury:	
Businesses & Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000
Non-Profit Organizations Without Credit Available Elsewhere	2.625

The number assigned to this disaster for physical damage is 14215 B and for economic injury is 14216 0.

The State which received an EIDL Declaration # is Washington.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Dated: January 29, 2015.

Maria Contreras-Sweet,

Administrator.

[FR Doc. 2015–02361 Filed 2–5–15; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #14217 and #14218]

Disaster #CA–00229

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the Soboba Band of Luiseno Indians (FEMA–4206–DR), dated 01/27/2015.

Incident: Severe Storms, Flooding, and Mudslides.

Incident Period: 12/04/2014 through 12/06/2014.

Effective Date: 01/27/2015.

Physical Loan Application Deadline Date: 03/30/2015.

Economic Injury (EIDL) Loan Application Deadline Date: 10/27/2015.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 01/27/2015, Private Non-Profit organizations that provide essential services of governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Area: Soboba Band of Luiseno Indians and Associated Lands

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations With Credit Available Elsewhere ...	2.625
Non-Profit Organizations Without Credit Available Elsewhere	2.625
For Economic Injury:	
Non-Profit Organizations Without Credit Available Elsewhere	2.625

The number assigned to this disaster for physical damage is 14217B and for economic injury is 14218B.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2015–02362 Filed 2–5–15; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice 9027]

Notice of Receipt From Pembina Prairie Pipeline (U.S.A.) Ltd., of a Notification Concerning Its Acquisition of Vantage Pipeline US LP, Which Holds a Presidential Permit To Operate and Maintain Pipeline Facilities on the Border of the United States and Canada

AGENCY: Department of State.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Department of State (''Department'') has received from Pembina Prairie Pipeline (U.S.A.) Ltd. (''Pembina'') notice that Pembina has acquired Vantage Pipeline US LP (''Vantage''), which owns, operates, and maintains pipeline facilities (''Vantage Pipeline'') that are permitted under a 2013 Presidential Permit issued to Vantage. Vantage will continue to own and operate the Vantage Pipeline.

Pembina's notification is available at *http://www.state.gov/e/enr/applicant/applicants/index.htm.* Pembina U.S.A. is a corporation duly organized under the laws of Delaware with its headquarters at Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801. Pembina U.S.A. is owned by Pembina Prairie Pipeline Holdco Ltd., which is an Alberta corporation that is owned by Pembina Pipeline Corporation (''PPC''). PPC is the ultimate parent of Pembina U.S.A.

Under E.O. 13337 the Secretary of State is designated and empowered to receive all applications for Presidential Permits for the construction, connection, operation, or maintenance at the borders of the United States, of facilities for the exportation or importation of liquid petroleum, petroleum products, or other non-gaseous fuels to or from a foreign country. The Department of State is circulating this notification to concerned federal agencies for comment. The Department of State will assess the U.S. national interest with regard to permitting for the Vantage pipeline border facilities in light of the change in upstream ownership of the Vantage Pipeline.

Consistent with Public Notice 5092, (*Procedures for Issuance of a Presidential Permit Where There Has Been a Transfer of the Underlying Facility, Bridge or Border Crossing for Land Transportation,* 70 FR30990, issued on May 31, 2005), the Department typically does not conduct environmental analysis when deciding whether to issue a permit that reflects a change in ownership or control of an existing border facility, where that change in ownership or control is not accompanied by changes to the facilities or their use as authorized by the existing permit unless information is brought to the Department's attention in connection with the application process that the transfer potentially would have a significant impact on the quality of the human environment.

DATES: Interested parties are invited to submit comments within 30 days of the publication date of this notice on *http://www.regulations.gov* with regard to the Department of State's consideration of Pembina's notification. To submit a comment, go to *http://www.regulations.gov,* enter the title of this Notice into the search field and follow the prompts. *Or:* To submit a comment, go to *http://www.regulations.gov, enter Docket no.* DOS–2015–0006*, and follow the prompts.* Written comments should be addressed to: Mr. Chris Davy, U.S. Department of State, 2201 C Street NW., Suite 4843, Washington, DC 20520.

Comments are not private. They will be posted on the site. The comments will not be edited to remove identifying or contact information, and the State Department cautions against including any information that one does not want publicly disclosed. The State Department requests that any party soliciting or aggregating comments received from other persons for submission to the State Department inform those persons that the State Department will not edit their comments to remove identifying or contact information, and that they should not include any information in their comments that they do not want publicly disclosed.

FOR FURTHER INFORMATION CONTACT: Office of Energy Diplomacy, Energy Resources Bureau (ENR/EDP/EWA) Department of State, 2201 C St. NW., Ste 4843, Washington, DC 20520, Attn: Chris Davy, Tel: 202–647–7553.

Dated: January 27, 2015.

Chris Davy,

Office Director, Office of Europe, Western Hemisphere and Africa, Bureau of Energy Resources, U.S. Department of State.

[FR Doc. 2015–02468 Filed 2–5–15; 8:45 am]

BILLING CODE 4710–AE–P

DEPARTMENT OF STATE

[Public Notice 9028]

Notice of Issuance of a Presidential Permit To Operate and Maintain Pipeline Facilities on the Border of the United States and Canada for NOVA Chemicals Inc. (Line 39)

AGENCY: Department of State.

ACTION: Notice.

SUMMARY: The Department of State issued a Presidential Permit to NOVA Chemicals, Inc. (''NOVA'') on November 19, 2014, authorizing NOVA to connect, operate, and maintain existing pipeline facilities (Line 39) it acquired at the border of the United States and Canada near Marysville, Michigan for the

transport of brine between the United States and Canada. The Department of State determined that issuance of this Permit would serve the national interest. In making this determination and issuing the Presidential Permit, the Department of State followed the procedures established under Executive Order 13337, and provided public notice and opportunity for comment.

FOR FURTHER INFORMATION CONTACT: Office of Europe, Western Hemisphere and Africa, Bureau of Energy Resources, U.S. Department of State (ENR/EDP/EWA) 2201 C St. NW., Ste. 4843, Washington, DC 20520 Attn: Chris Davy Deputy Director. Tel: 202–647–7553.

SUPPLEMENTARY INFORMATION: Additional information concerning NOVA Line 39 can be found at *http://www.state.gov/e/enr/applicant.* Following is the text of the issued permit:

PRESIDENTIAL PERMIT

AUTHORIZING NOVA CHEMICALS INC. TO CONSTRUCT, OPERATE, AND MAINTAIN EXISTING PIPELINE FACILITIES AT THE INTERNATIONAL BOUNDARY BETWEEN THE UNITED STATES AND CANADA

By virtue of the authority vested in me as Under Secretary of State for Economic Growth, Energy, and the Environment, including those authorities under Executive Order 11426, 33 FR 11741, as amended by Executive Order 12847 of May 17, 1993, 58 FR 29511, Executive Order 13284 of January 23, 2003, 68 FR 4075, and Executive Order 13337 of April 30, 2004, 69 FR 25299, and Department of State Delegation of Authority 118–2 of January 26, 2006; having requested and received the views of members of the public and various federal agencies; I hereby grant permission, subject to the conditions herein set forth, to NOVA Chemicals Inc. (hereinafter referred to as the ''permittee''), incorporated in the State of Delaware, to connect, operate, and maintain existing pipeline facilities at the border of the United States and Canada near Marysville, Michigan, for the transport of brine between the United States and Canada.

The term ''facilities'' as used in this permit means the relevant portion of the pipeline and any land, structures, installations or equipment appurtenant thereto.

The term ''United States facilities'' as used in this permit means those parts of the facilities located in the United States. The United States facilities consist of approximately 1,315 feet of 6-inch pipeline in existence at the time of this permit's issuance and known as Line 39 used to transport brine extending from St. Clair County, Michigan near the City of Marysville to the international border between the United States and Canada. The United States facilities also include certain appurtenant facilities.

This permit is subject to the following conditions:

Article 1. (1) The United States facilities herein described, and all aspects of their operation, shall be subject to all the conditions, provisions, and requirements of this permit and any amendment thereof. This permit may be terminated or amended at any time at the discretion of the Secretary of State or the Secretary's delegate or upon proper application therefor. The permittee shall make no substantial change in the United States facilities, the location of the United States facilities, or in the operation authorized by this permit until such changes have been approved by the Secretary of State or the Secretary's delegate.

(2) The connection, operation and maintenance of the United States facilities shall be in all material respects as described in the permittee's August 7, 2012 application for a Presidential Permit (the ''Application'').

Article 2. The standards for, and the manner of, the operation and maintenance of the United States facilities shall be subject to inspection and approval by the representatives of appropriate federal, state and local agencies. The permittee shall allow duly authorized officers and employees of such agencies free and unrestricted access to said facilities in the performance of their official duties.

Article 3. The permittee shall comply with all applicable federal, state, and local laws and regulations regarding the connection, operation, and maintenance of the United States facilities and with all applicable industrial codes. The permittee shall obtain all requisite permits from state and local government entities and relevant federal agencies.

Article 4. Connection, operation, and maintenance of the United States facilities hereunder shall be subject to the limitations, terms, and conditions issued by any competent agency of the United States Government. The permittee shall continue the operations hereby authorized and conduct maintenance in accordance with such limitations, terms, and conditions. Such limitations, terms, and conditions could address, for example, environmental protection and mitigation measures, safety requirements, export or import and customs regulations, measurement capabilities and procedures, requirements pertaining to the pipeline's capacity, and other pipeline regulations.

Article 5. Upon the termination, revocation, or surrender of this permit, and unless otherwise agreed by the Secretary of State or the Secretary's delegate, the United States facilities in the immediate vicinity of the international boundary shall be removed by and at the expense of the permittee within such time as the Secretary of State or the Secretary's delegate may specify, and upon failure of the permittee to remove, or to take such other action with respect to, this portion of the United States facilities as ordered, the Secretary of State or the Secretary's delegate may direct that possession of such facilities be taken and that they be removed or other action taken, at the expense of the permittee; and the permittee shall have no claim for damages by reason of such possession, removal, or other action.

Article 6. When, in the opinion of the President of the United States, the national security of the United States demands it, due notice being given by the Secretary of State or the Secretary's delegate, the United States shall have the right to enter upon and take possession of any of the United States facilities or parts thereof; to retain possession, management, or control thereof for such length of time as may appear to the President to be necessary; and thereafter to restore possession and control to the permittee. In the event that the United States shall exercise such right, it shall pay to the permittee just and fair compensation for the use of such United States facilities upon the basis of a reasonable profit in normal conditions, and the cost of restoring said facilities to as good condition as existed at the time of entering and taking over the same, less the reasonable value of any improvements that may have been made by the United States.

Article 7. Any change of ownership or control of the United States facilities or any part thereof shall be immediately notified in writing to the United States Department of State, including the submission of information identifying the new owner or controlling entity. This permit shall remain in force subject to all the conditions, permissions and requirements of this permit and any amendments thereto unless subsequently terminated or amended by the Secretary of State or the Secretary's delegate.

Article 8. (1) The permittee is responsible for acquiring any right-of-way grants or easements, permits, and other authorizations as may become necessary and appropriate.

(2) The permittee shall save harmless and indemnify the United States from any claimed or adjudged liability arising out of construction, connection, operation, or maintenance of the facilities, including but not limited to environmental contamination from the release or threatened release or discharge of hazardous substances and hazardous waste.

(3) The permittee shall maintain the United States facilities and every part thereof in a condition of good repair for their safe operation, and in compliance with prevailing environmental standards and regulations.

Article 9. The permittee shall take all necessary measures to prevent or mitigate adverse impacts on, or disruption of, the human environment in connection with connection, operation and maintenance of the United States facilities. Such measures will include any mitigation and control plans that are already approved or that are approved in the future by the Department of State or other relevant federal or state agencies, and any other measures deemed prudent by the permittee.

Article 10. The permittee shall file with the appropriate agencies of the United States Government such statements or reports under oath with respect to the United States facilities, and/or permittee's activities and operations in connection therewith, as are now or may hereafter be required under any laws or regulations of the United States Government or its agencies. The permittee shall file electronic Export Information where required.

Article 11. The permittee shall provide information upon request to the Department of State with regard to the United States facilities. Such requests could include, for example, information concerning current conditions or anticipated changes in ownership or control, construction, connection, operation, or maintenance of the U.S. facilities.

IN WITNESS WHEREOF, I, the Under Secretary of State for Economic Growth, Energy, and the Environment, have hereunto set my hand this 19th day of November, 2014 in the City of Washington, District of Columbia.

Catherine A. Novelli

Under Secretary of State for Economic Growth, Energy, and the Environment

Date: January 27, 2015.

Chris Davy,

Office Director, Office of Europe, Western Hemisphere and Africa, Bureau of Energy Resources, U.S. Department of State.

[FR Doc. 2015–02477 Filed 2–5–15; 8:45 am]

BILLING CODE 4710–AE–P

DEPARTMENT OF STATE

[Public Notice 9026]

Notice of Issuance of a Presidential Permit To Operate and Maintain Pipeline Facilities on the Border of the United States and Canada for NOVA Chemicals Inc. (Lines 16, 18, and 19)

AGENCY: Department of State.

ACTION: Notice.

SUMMARY: The Department of State issued a Presidential Permit to NOVA Chemicals Inc. (''NOVA Inc.'') on November 19, 2014, to connect, operate, and maintain three existing pipeline facilities (Lines 16, 18, and 19) it acquired at the border of the United States and Canada that transport proplylene, ethylene, and other natural gas liquids between the United States and Canada near Marysville, Michigan. The Department of State determined that issuance of this permit would serve the national interest. In making this determination and issuing the permit, the Department of State followed the procedures established under Executive Order 13337, and provided public notice and opportunity for comment.

FOR FURTHER INFORMATION CONTACT: Office of Europe, Western Hemisphere and Africa, Bureau of Energy Resources, U.S. Department of State (ENR/EDP/EWA), 2201 C St. NW., Ste. 4843, Washington, DC 20520. Attn: Chris Davy, Deputy Director. Tel: 202–736–7149.

SUPPLEMENTARY INFORMATION: Additional information concerning NOVA Lines 16, 18, and 19 can be found at *http://www.state.gov/e/enr/applicant.* Following is the text of the issued permit:

PRESIDENTIAL PERMIT

AUTHORIZING NOVA CHEMICALS, INC. TO CONSTRUCT, OPERATE, AND MAINTAIN THREE EXISTING PIPELINE FACILITIES AT THE INTERNATIONAL BOUNDARY BETWEEN THE UNITED STATES AND CANADA

By virtue of the authority vested in me as Under Secretary of State for Economic Growth, Energy, and the Environment, including those authorities under Executive Order 13337, 69 FR 25299 (2004), and Department of State Delegation of Authority 118–2 of January 26, 2006; having requested and received the views of members of the public and various federal agencies; I hereby grant permission, subject to the conditions herein set forth, to NOVA Chemicals Inc. (hereinafter referred to as the ''permittee''), incorporated in the State of Delaware, to connect, operate, and maintain existing pipeline facilities at the border of the United States and Canada near Marysville, Michigan, for the transport of propylene, ethylene, and other natural gas liquids between the United States and Canada.

The term ''facilities'' as used in this permit means the relevant portion of the pipelines and any land, structures, installations or equipment appurtenant thereto.

The term ''United States facilities'' as used in this permit means those parts of the facilities located in the United States. The United States facilities consist of three pipelines—Lines 16, 18, and 19—in existence at the time of this permit's issuance extending from the international border between the United States and Canada underneath the St. Clair River to the first block valve for each pipeline in the United States, located at points onshore near Marysville, Michigan, in existence at the time of this permit's issuance. Line 16 is an 8-inch pipeline. Line 18 and Line 19 are 6-inch pipelines. The United States facilities also include certain appurtenant facilities.

This permit is subject to the following conditions:

Article 1. (1) The United States facilities herein described, and all aspects of their operation, shall be subject to all the conditions, provisions, and requirements of this permit and any amendment thereof. This permit may be terminated or amended at any time at the discretion of the Secretary of State or the Secretary's delegate or upon proper application therefor. The permittee shall make no substantial change in the United States facilities, the location of the United States facilities, or in the operation authorized by this permit until such changes have been approved by the Secretary of State or the Secretary's delegate.

(2) The connection, operation and maintenance of the United States facilities shall be in all material respects as described in the permittee's August 7, 2012 application for a Presidential Permit (the ''Application'').

Article 2. The standards for, and the manner of, the operation and maintenance of the United States facilities shall be subject to inspection

and approval by the representatives of appropriate federal, state and local agencies. The permittee shall allow duly authorized officers and employees of such agencies free and unrestricted access to said facilities in the performance of their official duties.

Article 3. The permittee shall comply with all applicable federal, state, and local laws and regulations regarding the connection, operation, and maintenance of the United States facilities and with all applicable industrial codes. The permittee shall obtain all requisite permits from state and local government entities and relevant federal agencies.

Article 4. Connection, operation, and maintenance of the United States facilities hereunder shall be subject to the limitations, terms, and conditions issued by any competent agency of the United States Government. The permittee shall continue the operations hereby authorized and conduct maintenance in accordance with such limitations, terms, and conditions. Such limitations, terms, and conditions could address, for example, environmental protection and mitigation measures, safety requirements, export or import and customs regulations, measurement capabilities and procedures, requirements pertaining to the pipeline's capacity, and other pipeline regulations.

Article 5. Upon the termination, revocation, or surrender of this permit, and unless otherwise agreed by the Secretary of State or the Secretary's delegate, the United States facilities in the immediate vicinity of the international boundary shall be removed by and at the expense of the permittee within such time as the Secretary of State or the Secretary's delegate may specify, and upon failure of the permittee to remove, or to take such other action with respect to, this portion of the United States facilities as ordered, the Secretary of State or the Secretary's delegate may direct that possession of such facilities be taken and that they be removed or other action taken, at the expense of the permittee; and the permittee shall have no claim for damages by reason of such possession, removal, or other action.

Article 6. When, in the opinion of the President of the United States, the national security of the United States demands it, due notice being given by the Secretary of State or the Secretary's delegate, the United States shall have the right to enter upon and take possession of any of the United States facilities or parts thereof; to retain possession, management, or control thereof for such length of time as may appear to the President to be necessary; and thereafter to restore possession and control to the permittee. In the event that the United States shall exercise such right, it shall pay to the permittee just and fair compensation for the use of such United States facilities upon the basis of a reasonable profit in normal conditions, and the cost of restoring said facilities to as good condition as existed at the time of entering and taking over the same, less the reasonable value of any improvements that may have been made by the United States.

Article 7. Any change of ownership or control of the United States facilities or any part thereof shall be immediately notified in writing to the United States Department of State, including the submission of information identifying the new owner or controlling entity. This permit shall remain in force subject to all the conditions, permissions and requirements of this permit and any amendments thereto unless subsequently terminated or amended by the Secretary of State or the Secretary's delegate.

Article 8. (1) The permittee is responsible for acquiring any right-of-way grants or easements, permits, and other authorizations as may become necessary and appropriate.

(2) The permittee shall save harmless and indemnify the United States from any claimed or adjudged liability arising out of construction, connection, operation, or maintenance of the facilities, including but not limited to environmental contamination from the release or threatened release or discharge of hazardous substances and hazardous waste.

(3) The permittee shall maintain the United States facilities and every part thereof in a condition of good repair for their safe operation, and in compliance with prevailing environmental standards and regulations.

Article 9. The permittee shall take all necessary measures to prevent or mitigate adverse impacts on, or disruption of, the human environment in connection with connection, operation and maintenance of the United States facilities. Such measures will include any mitigation and control plans that are already approved or that are approved in the future by the Department of State or other relevant federal or state agencies, and any other measures deemed prudent by the permittee.

Article 10. The permittee shall file with the appropriate agencies of the United States Government such statements or reports under oath with respect to the United States facilities, and/or permittee's activities and operations in connection therewith as are now, or may hereafter, be required under any laws or regulations of the United States Government or its agencies. The permittee shall file electronic Export Information where required.

Article 11. The permittee shall provide information upon request to the Department of State with regard to the United States facilities. Such requests could include, for example, information concerning current conditions or anticipated changes in ownership or control, construction, connection, operation, or maintenance of the U.S. facilities.

IN WITNESS WHEREOF, I, the Under Secretary of State for Economic Growth, Energy, and the Environment, have hereunto set my hand this 19th day of November, 2014 in the City of Washington, District of Columbia.

Catherine A. Novelli

Under Secretary of State for Economic Growth, Energy, and the Environment

Dated: January 27, 2015.

Chris Davy,

Office Director, Office of Europe, Western Hemisphere and Africa, Bureau of Energy Resources, U.S. Department of State.

[FR Doc. 2015–02479 Filed 2–5–15; 8:45 am]

BILLING CODE 4710–AE–P

SUSQUEHANNA RIVER BASIN COMMISSION

Commission Meeting

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: The Susquehanna River Basin Commission will hold its regular business meeting on March 5, 2015, in Hershey, Pennsylvania. Details concerning the matters to be addressed at the business meeting are contained in the Supplementary Information section of this notice.

DATES: March 5, 2015, at 9:00 a.m.

ADDRESSES: Hershey Lodge, 325 University Drive, Hershey, PA 17033.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, Regulatory Counsel, telephone: (717) 238–0423, ext. 1312; fax: (717) 238–2436.

SUPPLEMENTARY INFORMATION: The business meeting will include actions or presentations on the following items: (1) Informational presentation of interest to the Lower Susquehanna Subbasin area; (2) revision of FY–2016 budget; (3) ratification/approval of contracts/grants; (4) resolution to encourage the use of dry cooling technology for power generation and other facilities for the

conservation of the waters of the Susquehanna River Basin; (5) notice for Four Seasons Golf Course project sponsor to appear and show cause before the Commission; (6) regulatory compliance matter for Cabot Oil & Gas Corporation; and (7) Regulatory Program projects. Projects listed for Commission action are those that were the subject of a public hearing conducted by the Commission on January 29, 2015, and identified in the notice for such hearing, which was published in 80 FR 98, January 2, 2015.

Opportunity To Appear and Comment:

Interested parties are invited to attend the business meeting and encouraged to review the Commission's Public Meeting Rules of Conduct, which are posted on the Commission's Web site, *www.srbc.net.* As identified in the public hearing notices referenced above, written comments on the Regulatory Program projects that were the subject of a public hearing, and are listed for action at the business meeting, are subject to a comment deadline of February 9, 2015. Written comments pertaining to any other matters listed for action at the business meeting may be mailed to the Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, Pennsylvania 17110–1788, or submitted electronically through *http://www.srbc.net/pubinfo/publicparticipation.htm.* Any such comments mailed or electronically submitted must be received by the Commission on or before February 27, 2015, to be considered.

Authority: Pub. L. 91–575, 84 Stat. 1509 *et seq.,* 18 CFR parts 806, 807, and 808.

Dated: January 30, 2015.

Stephanie L. Richardson,

Secretary to the Commission.

[FR Doc. 2015–02409 Filed 2–5–15; 8:45 am]

BILLING CODE 7040–01–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket OST–2011–0022]

On-Line Complaint Form for Service-Related Issues in Air Transportation

AGENCY: Office of the Secretary, Department of Transportation.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended) this notice announces the Department of Transportation's intention to renew an OMB control number for an on-line complaint form by which a consumer can electronically submit a service-related complaint against an air carrier.

DATES: Comments on this notice must be received by April 7, 2015.

ADDRESSES: To ensure that you do not duplicate your docket submissions, please submit them by only one of the following means:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for submitting comments;
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave. SE., West Building Ground Floor Room W–12/140, Washington, DC 20590–0001; or
- *Hand delivery:* West Building Ground Floor, Room W–12/140, 1200 New Jersey Ave. SE., between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

FOR FURTHER INFORMATION CONTACT: Blane Workie or Daeleen Chesley, Office of the Secretary, Office of the Assistant General Counsel for Aviation Enforcement and Proceedings (C–70), Department of Transportation, 1200 New Jersey Ave. SE., Washington, DC 20590, 202 366–9342 (voice) or at *Blane.Workie@dot.gov* or *Daeleen.Chesley@dot.gov.*

SUPPLEMENTARY INFORMATION:

Title: Renewal of Aviation Consumer Protection Division Webpage On-Line Complaint Form.

OMB Control Number: 2105–0568.

Type of Request: Request to renew an OMB control number for a current information collection form.

Abstract: The Department of Transportation's (Department) Office of the Assistant General Counsel for Aviation Enforcement and Proceedings (Enforcement Office) has broad authority under 49 U.S.C., Subtitle VII, to investigate and enforce consumer protection and civil rights laws and regulations related to air transportation. The Enforcement Office, including its Aviation Consumer Protection Division (ACPD), monitors compliance with and investigates violations of the Department of Transportation's aviation economic, consumer protection, and civil rights requirements.

Among other things, the office is responsible for receiving and investigating service-related consumer complaints filed against airlines and other travel-related companies. Once received, the complaints are reviewed by the office to determine the extent to which these entities are in compliance with federal aviation consumer protection and civil rights laws and what, if any, action should be taken.

The key reason for this request is to enable consumers to continue to file their complaints (or comments) to the Department using an on-line form, whether via their personal computer or on their mobile device. If the information collection form is not available, the Department may receive fewer complaints from consumers. The lack of consumer-driven information could inhibit the office's ability to effectively investigate both individual complaints against airlines and other air travel-related companies. It would also impact the Department's Enforcement Office's ability to become aware of patterns and practices that may develop in violation of our rules. The information collection continues to further the objectives of 49 U.S.C. 41712, 40101, 40127, 41702, and 41705 to protect consumers from unfair or deceptive practices, to protect the civil rights of air travelers, and to ensure safe and adequate service in air transportation.

Filing a complaint using a web-based form is voluntary and minimizes the burden on respondents. Based on CY14 information, 14,479 of the 17,308 cases filed with the ACPD were filed electronically (83.7%). Consumers can also choose to file a complaint with the Department using regular mail or by phone message. The type of information requested on the form includes complainant's name, address, phone number (including area code), email address, and name of the airline or company about which she/he is complaining, as well as the flight date and flight itinerary (where applicable) of complainant's trip. A consumer may also use the form to give a description of a specific air-travel related problem or to ask for air-travel related information from the ACPD. The Department has limited its informational request to that necessary to meet its program and administrative monitoring and enforcement activities.

Respondents: Consumers that Choose to File an On-Line Complaint with the Aviation Consumer Protection Division.

Estimated Number of Respondents: 14,479 (based on CY 2014 data).

Estimated Total Burden on Respondents: 3,619.75 hours, 217,185 minutes (based on 15 minutes per respondent to fill out the on-line form).

The information collection is available for inspection in regulations.gov, as noted in the **ADDRESSES** section of his document.

Comments are Invited on: (a) Whether the collection of information is necessary for the proper performance of

the functions of the Department, including whether the information will have practical utility; (b) the accuracy of the Department'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.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record on the docket.

Issued in Washington, DC, on January 30, 2015.

Blane Workie,

Assistant General Counsel for Aviation Enforcement and Proceedings.

[FR Doc. 2015–02405 Filed 2–5–15; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Aviation Rulemaking Advisory Committee Meeting on Transport Airplane and Engine Issues

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of public meeting.

SUMMARY: This notice announces a public meeting via teleconference of the FAA's Aviation Rulemaking Advisory Committee (ARAC) Transport Airplane and Engine (TAE) Subcommittee to discuss TAE issues.

DATES: The teleconference is scheduled for Tuesday, February 24, 2015, starting at 7:30 a.m. PST/10:30 a.m. EST. The public must make arrangements by February 20, 2015, to present oral statements at the meeting.

ADDRESSES: N/A.

FOR FURTHER INFORMATION CONTACT: Ralen Gao, Office of Rulemaking, ARM–209, FAA, 800 Independence Avenue SW., Washington, DC 20591, Telephone (202) 267–3168, FAX (202) 267–5075, or email at *ralen.gao@faa.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. app. 2), notice is given of an ARAC Subcommittee meeting via teleconference to be held February 24, 2015.

The agenda for the meeting is as follows:

- Engine Harmonization Working Group—Vote on Bird Ingestion Tasking Report
- Avionics System Harmonization Working Group—Phase 2 Low Speed Alerting Response to FAA request for clarification
- Proposed tasking on Transport Airplane Crashworthiness and Ditching Evaluation
- Materials Flammability Working Group—new tasking
- Transport Airplane Metallic and Composite Structures Working Group—new tasking
- Any other business

Participation is open to the public, but will be limited to the availability of teleconference lines.

To participate, please contact the person listed in **FOR FURTHER INFORMATION CONTACT** by email or phone for the teleconference call-in number and passcode. Please provide the following information: Full legal name, country of citizenship, and name of your industry association, or applicable affiliation. If you are participating as a public citizen, please indicate so. Anyone calling from outside the Arlington, VA, metropolitan area will be responsible for paying long-distance charges.

The public must make arrangements by February 20, 2015, to present oral or written statements at the meeting. Written statements may be presented to the Subcommittee by providing a copy to the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Copies of the documents to be presented to the Subcommittee may be made available by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

If you need assistance or require a reasonable accommodation for the meeting or meeting documents, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Issued in Washington, DC on February 3, 2015.

Lirio Liu,

Designated Federal Officer, Aviation Rulemaking Advisory Committee.

[FR Doc. 2015–02416 Filed 2–5–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

National Aging and Disability Transportation Center (NADTC) Under FTA's Technical Assistance Program

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice; Request for Proposals (RFP).

SUMMARY: The Federal Transit Administration (FTA) is soliciting proposals under the Moving Ahead for Progress in the 21st Century Act's Section 5314 Technical Assistance and Standards Development Program from national non-profit organizations for a cooperative agreement to fund a National Aging and Disability Transportation Center (NADTC). FTA is releasing this notice of funding availability to promote the availability and accessibility of transportation options that serve the needs of people with disabilities, seniors and caregivers with a focus on effectively leveraging MAP–21 Section 5310 (5310) Enhanced Mobility of Seniors and Individuals with Disabilities Formula Grants and other transit investments. The NADTC builds upon twenty-five years of investment in accessible transportation training and technical assistance that improves mobility for seniors and individuals with disabilities throughout the country by removing barriers to transportation services and expanding community transportation mobility options.

DATES: Complete proposals must be submitted electronically by 11:59 p.m., Eastern Time on March 31, 2015. All proposals must be submitted electronically through the ''GRANTS.GOV'' APPLY function. Interested organizations that have not already done so should initiate the process of registering on the GRANTS.GOV site immediately to ensure completion of registration before the deadline for submission.

ADDRESSES: Proposals must be submitted electronically to *http://www.Grants.Gov.*

FOR FURTHER INFORMATION CONTACT: For general program information, as well as proposal-specific questions, please send an email to *Hendrik.opstelten@dot.gov* or call Rik Opstelten at (202)–366–8094. A TDD is available at 1–800–877–8339 (TDD/FIRS).

SUPPLEMENTARY INFORMATION:

I. Overview

The Federal Transit Administration (FTA) is soliciting proposals to create a technical assistance center called the National Aging and Disability Transportation Center (NADTC). The need for accessible transportation that supports independent community living is growing in the United States. The U.S. Census Bureau American Community Survey in 2012 estimates that over 12 percent of the U.S. population (38 million) living in the community has a disability—up 2 percent from 2009. As people age, some will acquire a disability. For the fastest growing population in the U.S., older

adults over 65 (over 42 million people), the disability rate for those seniors living in the community was 36 percent in 2012. By 2030, people over 65 are expected to comprise 20 percent of the US population—72.1 million people. Employment and poverty rates also disproportionately negatively affect people with disabilities. More resources are needed to help communities build ladders of opportunity so everyone can have access to a job, healthcare, a home in the community of their choice, recreation/leisure opportunities and education. Our communities greatly benefit by ensuring full inclusion for everyone regardless of their age, disability, income, and education level. Accessible public transportation, including the over $280 million spent in 5310 projects is an important enabler of the American Dream for many people. This center will make a significant difference in helping communities ensure the contributions of public transportation, including high impact 5310 projects that improve mobility for people with disabilities and seniors.

Ladders of opportunity build upon the legacy of United We Ride extending coordination to ensure persons of low income, disadvantaged communities and all groups benefit from coordinated planning activities and the resulting projects. So, targeting activities to address low income seniors, caregivers, and people with disabilities or those living in communities with limited resources, is an important component of this center's efforts. The NADTC will carry-out activities that demonstrate impact and achieve the below goals:

- Promoting the essential role of accessible public transportation in furthering the economic inclusion, access to healthcare, links to education, connections to recreation/leisure activities, and independent living of people with disabilities and seniors;
- Increasing the effectiveness, efficiency and quality of coordinated human service transportation activities;
- Ensuring that the planning of transportation services for people with disabilities, seniors and caregivers is done in conjunction with broader planning activities at all levels;
- Highlighting and assisting in the development of promising practices, including the use of technology, to solve transportation challenges, maximizing the effectiveness of federal investments in specialized transportation services.

The NADTC will achieve their goals through the following functions:

- Training: Developing training materials in accessible transportation for people with disabilities and seniors that is online and available 24/7;
- Peer Networks: Encouraging peer exchanges through webinars and online forums;
- Product Development: Creating high quality useful products on topics associated with the above goals;
- Targeted Technical Assistance: Providing targeted technical assistance at the state and local level;
- 800# Information and Referral: Supporting an 800# for ad hoc information referral and technical assistance that tracks trends, connects with other I&R resources, helps seniors and people with disabilities find a ride, and catalogs customer data;
- Online Tools: Maintaining a compelling Web site and online presence including a monthly newsletter and use of social media to promote promising practices;
- Community Grants: As FTA deems feasible and necessary, take some portion of overall funding per year to provide community grants that enhance accessibility and encourage innovation;
- Outreach: Implementing a yearly outreach project to publicize the resources, activities and findings of the center;
- Technology: monitor and promote emerging technologies that facilitate accessibility, wayfinding, scheduling/dispatching, one call and evolving public/private sector partnerships that can improve access to transportation options and improve mobility;
- Information Clearinghouse: Acting as a clearinghouse for useful and promising practices in human services transportation and provide online access to success stories;
- Community Accessibility Scorecard: Developing and maintaining a community accessibility scorecard and index to help communities easily assess where they are, what needs exist in their community and where gaps may exist—targeted technical assistance would then be available to address these gaps and help the community develop a roadmap to expanding accessible transportation;
- Broad Stakeholder Review Committees: Ensuring that people with disabilities and seniors themselves as well as the human services organizations that provide services for these individuals collaborate along with FTA in the work of the center and help to oversee and review materials, training courses and other activities;
- Bridging Research to Practice: Connecting research to practice by bridging the research efforts of university transit centers, gerontology university programs, university disability centers, evolving technology initiatives and TRB project findings with the training and technical assistance activities of the center;
- Yearly Trends Report: Writing a yearly state of accessible transportation report that identifies key trends, key issues, sustainable solutions and recommends areas of focus in accessible transportation to support the development of the following year's statement of work;
- Program Evaluation: Supporting a robust program evaluation component by an outside source that does a yearly assessment of the center including surveying key stakeholders on the utility they derived in working with the center;

FTA intends to fund the NADTC at up to $ 2,500,000 for the first year with the option to extend for up to four additional years. FTA's decision to exercise these options will depend upon: 1) Decisions and program priorities established by the Secretary of Transportation related to the implementation of provisions set forth in Section 5314, Technical Assistance and Standards, of the Moving Ahead for Progress in the 21st Century Act (MAP–21); 2) future appropriations; and, 3) annual reviews of the NADTC's performance. The announcement below connects to the solicitation and describes the goals, functional activities, and evaluation measures established for the NADTC; the proposal submission process; and criteria upon which proposals will be reviewed.

This announcement is available on the FTA's Web site at: *http://WWW.FTA.DOT.GOV/GRANTS/13077.HTML.* The funding opportunity RFP is posted in the FIND module of the government-wide electronic grants Web site at *http://www.grants.gov.*

Therese McMillan,

Acting Administrator.

[FR Doc. 2015–02378 Filed 2–5–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35901]

Paul Didelius—Continuance in Control—CCET, LLC

Paul Didelius (Didelius), an individual and noncarrier, has filed a verified notice of exemption pursuant to 49 CFR 1180.2(d)(2) to continue in control of CCET, LLC (CCET), a Class III rail carrier.[1] Didelius owns 100% of

[1] Didelius currently owns 100% of LRY, LLC d/b/a Lake Railway (LRY), a Class III carrier that

Continued

CCET, a short line rail carrier organized for the purpose of leasing and operating a line of railroad owned by the Norfolk Southern Railway Company (NSR).

This transaction is related to a concurrently filed verified notice of exemption in *CCET, LLC—Lease & Operation Exemption—Rail Line of Norfolk Southern Railway in Clermont, Brown, & Adams Counties, Ohio,* Docket No. FD 35900, in which CCET seeks Board approval to amend an agreement to allow CCET to lease additional NSR CT Line trackage, from milepost CT 32.83 to milepost CT 62.20, east of Seaman, Ohio.[2]

The transaction may be consummated on or after February 21, 2015, the effective date of the exemption (30 days after the verified notice of exemption was filed).

Didelius represents that: (1) CCET does not connect with any of the other rail lines operated and controlled by Didelius; (2) there are no plans to acquire additional rail lines for the purpose of making a connection; and (3) each of the carriers involved the continuance in control transaction is a Class III carrier. Therefore, the transaction is exempt from the prior approval requirements of 49 U.S.C. 11323. *See* 49 CFR 1180.2(d)(2).

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. Section 11326(c), however, does not provide for labor protection for transactions under §§ 11324 and 11325 that involve only Class III rail carriers. Accordingly, the Board may not impose labor protective conditions here, because all of the carriers involved are Class III carriers.

If the verified notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than February 13, 2015 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35901, must be filed with Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, one copy of each pleading must be served on James H. M. Savage, 22 Rockingham Court, Germantown, MD 20874.

Board decisions and notices are available on our Web site at ''*WWW.STB.DOT.GOV.''*

Decided: February 3, 2015.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Brendetta S. Jones,

Clearance Clerk.

[FR Doc. 2015–02411 Filed 2–5–15; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35900]

CCET, LLC—Lease and Operation Exemption—Rail Line of Norfolk Southern Railway Company in Clermont, Brown, and Adams Counties, Ohio

CCET, LLC (CCET), a Class III carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to lease from Norfolk Southern Railway (NSR) and operate a portion of NSR's CT Line, between milepost CT 32.83 and milepost CT 62.20, east of Seaman, Ohio (Line Extension).

CCET and NSR entered into a lease agreement on March 14, 2014, under which CCET currently leases a 24-mile portion of the CT Line between milepost CT 9.0 at Clare, Ohio, and milepost CT 32.83, west of Williamsburg, Ohio.[1] The parties now desire to amend the lease to include the Line Extension to the east, which would allow CCET to pursue additional commercial opportunities.[2] NSR will retain limited overhead trackage rights over the Line Extension.

This transaction is related to a concurrently filed verified notice of exemption in *Paul Didelius—Continuance in Control—CCET, LLC,* Docket No. FD 35901, in which Paul Didelius seeks Board approval to continue in control of CCET under 49 CFR 1180.2(d)(2).

CCET states that the lease between CCET and NSR does not contain any provision that prohibits, restricts, or would otherwise limit future interchange of traffic with any third-party carrier.

CCET has certified that its projected annual revenues as a result of this transaction will not result in CCET's becoming a Class II or Class I rail carrier and will not exceed $5 million.

CCET states that the lease and operation of the Line Extension will commence on or after February 21, 2015, the effective date of the exemption (30 days after the verified notice of exemption was filed).

If the verified notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than February 13, 2015 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35900, must be filed with Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, one copy of each pleading must be served on James H.M. Savage, 22 Rockingham Court, Germantown, MD 20874.

Board decisions and notices are available on our Web site at ''*www.stb.dot.gov.''*

Decided: February 3, 2015.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Brendetta S. Jones,

Clearance Clerk.

[FR Doc. 2015–02410 Filed 2–5–15; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE TREASURY

Open Meeting of the President's Advisory Council on Financial Capability for Young Americans

AGENCY: Department of the Treasury.

ACTION: Notice of meeting.

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leases and operates rail lines owned by Union Pacific Railroad Company in California and Oregon; he also owns 49% of YCR Corporation (YRC), a Class III rail carrier established for the purpose of leasing and operating a line of railroad owned by Yakima County, Washington.

[2] It appears that Didelius controlled LRY and YCR when CCET first became a carrier through its lease of another portion of the CT Line in 2014, but he failed to seek authority for continuance in control at that time. *See CCET, LLC—Lease & Operation Exemption—Rail Line of Norfolk S. Ry.,* FD 35810 (STB served Apr. 4, 2014). Therefore, Didelius should have sought continuance in control authority at that time. We will treat the current verified notice of exemption as a belated request for continuance in control authority.

[1] *See CCET, LLC—Lease & Operation Exemption—Rail Line of Norfolk S. Ry.,* FD 35810 (STB served Apr. 4, 2014).

[2] On January 15, 2015, the Board allowed NSR to discontinue its freight rail service over approximately 40.7 miles of rail line, including the Line Extension, in Clermont, Brown, and Adams Counties, Ohio; the exemption should become effective on February 14, 2015. *See Norfolk S. Ry.—Discontinuance of Serv. Exemption—in Clermont, Brown, & Adams Cntys., Ohio,* AB 290 (Sub-No. 370X) (STB served Jan. 15, 2015). Upon reaching an agreement with CCET to lease and operate the Line Extension, however, NSR informed the Board by letter dated January 20, 2015, that it will not effectuate discontinuance over the Line Extension. *See* CCET Petition, Ex. D.

SUMMARY: The President's Advisory Council on Financial Capability for Young Americans (Council) will convene for an open meeting on March 3, 2015, at the Eisenhower Executive Office Building, 1650 Pennsylvania Avenue NW., Washington, DC 20502, beginning at 10:30 a.m. Eastern Time. The meeting will be open to the public via live webcast at *http://www.whitehouse.gov/live.*

DATES: The meeting will be held on March 3, 2015 at 10:30 a.m. Eastern Time.

Submission of Written Statements: The public is invited to submit written statements to the Council. Written statements should be sent by any one of the following methods:

Electronic Statements

Email: *pacfcya@treasury.gov;* or

Paper Statements

Send paper statements to the Department of the Treasury, Office of Consumer Policy, 1500 Pennsylvania Avenue NW., Washington, DC 20220.

In general, the Department will make all statements available in their original format, including any business or personal information provided such as names, addresses, email addresses, or telephone numbers, for public inspection and photocopying in the Department's library located at Treasury Department Annex, 1500 Pennsylvania Avenue NW., Washington, DC 20220. The library is open on business days between the hours of 10:00 a.m. and 5:00 p.m. You can make an appointment to inspect statements by calling (202) 622–0990. All statements received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. You should only submit information that you wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: Louisa Quittman, Director, Financial Education, Office of Consumer Policy, Department of the Treasury, 1500 Pennsylvania Avenue NW., Washington, DC 20220, at (202) 622–5770 or *pacfcya@treasury.gov.*

SUPPLEMENTARY INFORMATION: On June 25, 2013, the President signed Executive Order 13646, creating the Council to help build the financial capability of young people at an early age, in schools, communities and the workplace. Having a basic understanding of money management at an early age will make our young people better equipped to tackle more complex financial decisions in their transition to adulthood, when critical decisions about financing higher education and saving for retirement can have lasting consequences for financial security. Strengthening the financial capability of our young people is an investment in our nation's economic prosperity. The Council is composed of three federal officials as well as 22 non-governmental members appointed by the President with relevant backgrounds, such as financial services, consumer protection, financial access, and education. The role of the Council is to advise the President and the Secretary of the Treasury on means to promote and enhance the financial capability of young Americans. In accordance with section 10(a) of the Federal Advisory Committee Act, 5 U.S.C. App. 2 and the regulations thereunder, Louisa Quittman, Designated Federal Officer of the Council, has ordered publication of this notice that the Council will convene its third meeting on March 3, 2015, at the Eisenhower Executive Office Building, 1650 Pennsylvania Avenue NW., Washington, DC 20502, beginning at 10:30 a.m. Eastern Time. Members of the public can access the meeting via live webcast at *http://www.whitehouse.gov/live.* During this meeting, the Council will: (i) Discuss the role of cities and communities in promoting financial empowerment and (ii) hear reports from each of the Council's subcommittees.

David G. Clunie,

Executive Secretary, U.S. Department of the Treasury.

[FR Doc. 2015–02470 Filed 2–5–15; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Designation of Individuals and Entities Pursuant to Executive Order 13660

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (''OFAC'') is publishing the names of seventeen individuals and seven entities whose property and interests in property have been blocked pursuant to Executive Order 13660 of March 6, 2014, ''Blocking Property of Certain Persons Contributing to the Situation in Ukraine.''

DATES: The designation by the Director of OFAC of the seventeen individuals and seven entities identified in this notice, pursuant to Executive Order 13660 of March 6, 2014, is effective on December 19, 2014.

FOR FURTHER INFORMATION CONTACT: Assistant Director, Sanctions, Compliance & Evaluations, Office of Foreign Assets Control, Department of the Treasury, 1500 Pennsylvania Avenue NW., (Treasury Annex), Washington, DC 20220, Tel.: 202/622–2490.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available from OFAC's Web site (*www.treas.gov/ofac*). Certain general information pertaining to OFAC's sanctions programs is available via facsimile through a 24-hour fax-on-demand service, tel.: 202/622–0077.

Background

On March 6, 2014, President Barack Obama issued Executive Order ''Blocking Property of Certain Persons Contributing to the Situation in Ukraine'' (the ''Order''), pursuant to, *inter alia,* the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (IEEPA), declaring a national emergency to deal with the usual and extraordinary threat to the national security and foreign policy of the United States posed by the actions and policies of persons including persons who have asserted governmental authority in the Crimean region without the authorization of the Government of Ukraine—that undermine democratic processes and institutions in Ukraine; threaten its peace, security, stability, sovereignty, and territorial integrity; and contribute to the misappropriation of its assets.

Section 1 of the Order blocks, with certain exceptions, all property and interests in property that are in, or thereafter come within, the United States, or within the possession or control of United States persons, as well as those persons determined by the Secretary of the Treasury, after consultation with the Secretary of State, to meet any of the criteria set forth in subparagraphs (a)(i)–(v) of Section 1 of the Order.

On December 19, 2014, the Director of OFAC exercised the Secretary of the Treasury's authority to designate, pursuant to one or more of the criteria set forth in Section 1 of the Order, the seventeen individuals and seven entities listed below, whose property and interests in property therefore are blocked pursuant to the Order.

The listings of the blocked individuals and entities appear as follows:

Individuals

1. ANTYUFEYEV, Vladimir (a.k.a. ALEXANDROV, Vladimir Gheorghievici; a.k.a. ANTIUFEEV, Vladimir Iurievici; a.k.a. ANTIUFEYEV, Vladimir; a.k.a. ANTYUFEYEV, Vladimir Yuryevich; a.k.a. SHEVTSOV, Vadim; a.k.a. SHEVTSOV, Vadim Gheorghievici; a.k.a. SHEVTSOV, Vladimir); DOB 19 Feb 1951; POB Novosibirsk, Russia (individual) [UKRAINE–EO13660].
2. BEREZIN, Fedor (a.k.a. BEREZIN, Fyodor; a.k.a. BEREZIN, Fyodor Dmitrievich); DOB 07 Feb 1960; POB Donetsk, Ukraine (individual) [UKRAINE–EO13660].
3. BEZLER, Igor Nikolayevich (a.k.a. BEZLER, Igor; a.k.a. BEZLER, Igor Mykolaiovych; a.k.a. BEZLER, Ihor); DOB 1965 (individual) [UKRAINE–EO13660].
4. GUBAREV, Pavel (a.k.a. HUBARYEV, Pavlo); DOB 10 Feb 1983; POB Sievierodonetsk, Ukraine (individual) [UKRAINE–EO13660].
5. KARYAKIN, Alexei Vyacheslavovich (a.k.a. KARIAKIN, Aleksey; a.k.a. KARYAKIN, Aleksey; a.k.a. KARYAKIN, Alexei); DOB 07 Apr 1980; POB Stahanov, Luhansk Oblast, Ukraine (individual) [UKRAINE–EO13660].
6. KHRYAKOV, Alexander (a.k.a. KHRYAKOV, Aleksandr Vitaliyovych; a.k.a. KHRYAKOV, Alexander Vitaliyovych; a.k.a. KHRYAKOV, Alexandr; a.k.a. KHRYAKOV, Oleksandr; a.k.a. KHRYAKOV, Oleksandr Vitaliyovych), Donetsk, Ukraine; DOB 06 Nov 1958; POB Donetsk, Ukraine (individual) [UKRAINE–EO13660].
7. KOZITSYN, Nikolai (a.k.a. KOZITSYN, Mykola; a.k.a. KOZITSYN, Mykola Ivanovych; a.k.a. KOZITSYN, Nikolay); DOB 20 Jun 1956; POB Donetsk Region; citizen Russia (individual) [UKRAINE–EO13660].
8. MALOFEYEV, Konstantin (a.k.a. MALOFEEV, Konstantin Valerevich; a.k.a. MALOFEEV, Konstantin Valerievich); DOB 03 Jul 1974; POB Pushchino, Moscow, Russia; Managing Partner of Marshall Capital Partners (individual) [UKRAINE–EO13660] (Linked To: MARSHALL CAPITAL PARTNERS).
9. MOZGOVOY, Aleksey (a.k.a. MOZGOVOI, Aleksei; a.k.a. MOZGOVOI, Alexei; a.k.a. MOZGOVOI, Oleksiy; a.k.a. MOZGOVOY, Aleksei; a.k.a. MOZGOVOY, Alexei; a.k.a. MOZGOVOY, Oleksiy; a.k.a. MOZGOVY, Aleksei; a.k.a. MOZGOVY, Oleksiy; a.k.a. MOZHOVVY, Oleksiy; a.k.a. MOZHOVY, Aleksei; a.k.a. MOZHOVY, Oleksiy; a.k.a. MOZHOVYY, Aleksei), Luhansk, Ukraine; DOB 03 Apr 1975; POB Nyzhnya Duvanka, Ukraine (individual) [UKRAINE–EO13660].
10. NEKLYUDOV, Dmitry Sergeyevich (a.k.a. NEKLYUDOV, Dmitriy Sergeyevich); DOB 17 Feb 1969; POB Simferopol, Ukraine (individual) [UKRAINE–EO13660].
11. PLOTNITSKY, Igor Venediktovich (a.k.a. PLOTNITSKY, Igor); DOB 24 Jun 1964; POB Kelmentsi, Ukraine (individual) [UKRAINE–EO13660].
12. POKLONSKAYA, Natalia Vladimirovna (a.k.a. POKLONSKA, Natalya; a.k.a. POKLONSKAYA, Natalia; a.k.a. POKLONSKAYA, Natalya); DOB 18 Mar 1980; POB Eupatoria, Ukraine; Prosecutor of Crimea (individual) [UKRAINE–EO13660].
13. RUDENKO, Miroslav Vladimirovich (a.k.a. RUDENKO, Miroslav; a.k.a. RUDENKO, Myroslav), Donetsk, Ukraine; DOB 21 Jan 1983; alt. DOB 1983; POB Debaltsevo, Donetsk Region, Ukraine (individual) [UKRAINE–EO13660].
14. SAVCHENKO, Petr (a.k.a. SAVCHENKO, Peter; a.k.a. SAVCHENKO, Peter A.; a.k.a. SAVCHENKO, Petro Oleksiiovych), Makeyevka, Ukraine; DOB 23 Feb 1968 (individual) [UKRAINE–EO13660] (Linked To: PROFAKTOR, TOV).
15. TSARYOV, Oleh Anatolievich (a.k.a. TSAREV, Oleg; a.k.a. TSARIOV, Oleh; a.k.a. TSAROV, Oleg; a.k.a. TSARYOV, Oleh), Stari Kodaky, Dnepropetrovsk Oblast, Ukraine; DOB 02 Jun 1970; POB Dnepropetrovsk, Ukraine (individual) [UKRAINE–EO13660].
16. ZAKHARCHENKO, Alexander; DOB 1976; POB Donetsk, Ukraine (individual) [UKRAINE–EO13660].
17. ZALDOSTANOV, Aleksandr (a.k.a. ZALDASTANOV, Aleksandr Sergeevich; a.k.a. ZALDOSTANOV, Alexander; a.k.a. ZALDOSTANOV, Alexander Sergeyevich; a.k.a. ''Khirurg''; a.k.a. ''The Surgeon''); DOB 19 Jan 1963; POB Kirovograd, Ukraine (individual) [UKRAINE–EO13660].

Entities

1. DONBASS PEOPLE'S MILITIA (a.k.a. PEOPLE'S MILITIA OF DONBASS), Prospect Zasyadko.13, Donetsk, Ukraine; Email Address *voenkom.dnr@mail.ru;* alt. Email Address *mobilisation@novorossia.co;* alt. Email Address *novoross24@mail.ru* [UKRAINE–EO13660].
2. MARSHALL CAPITAL PARTNERS (a.k.a. MARSHALL CAPITAL), 5th Floor, Novinsky Passage Business Center, 31 Novinsky Boulevard, Moscow 123242, Russia; Web site *www.marcap.ru;* Email Address *info@marcap.ru* [UKRAINE–EO13660].
3. NIGHT WOLVES (a.k.a. MOLODEZHNAYA AVTONOMNAYA NEKOMMERCHESKAYA ORGANIZATSIYA NOCHNYE VOLKI; a.k.a. NOCHNIYE VOLKI; a.k.a. NOCHNYE VOLKI), Nizhnije Mnevniki, 110 ''Bike Center'', Moscow, Russia; 110 Nizhniye Mnevniki, Moscow, Russia; 110 Nizhnie Mnevniki Ul., Moscow 123423, Russia; Registration ID 1037717009846; Government Gazette Number 14188237 [UKRAINE–EO13660].
4. NOVOROSSIYA PARTY (a.k.a. NEW RUSSIA PARTY), Ukraine [UKRAINE–EO13660].
5. OPLOT, Donetsk, Ukraine; Kharkiv, Ukraine [UKRAINE–EO13660].
6. PROFAKTOR, TOV (a.k.a. PROFAKTOR, LLC), Bud, 22/28, vul. Dzerzhynskogo, Makiivka 86100, Ukraine; Makeevka str., Donetsk Region 86157, Ukraine; Government Gazette Number 32084605 [UKRAINE–EO13660].
7. SOUTH–EAST MOVEMENT (a.k.a. SOUTHEAST MOVEMENT; a.k.a. YUGO–VOSTOK MOVEMENT), Ukraine [UKRAINE–EO13660].

Dated: December 19, 2014.

John E. Smith,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2015–02483 Filed 2–5–15; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0799]

Proposed Information Collection (Casket/Urn Reimbursement) Activity: Withdrawal

AGENCY: National Cemetery Administration, Department of Veterans Affairs.

ACTION: Notice; withdrawal.

SUMMARY: On Wednesday January 28, 2015, The National Cemetery

Administration (NCA), Department of Veterans Affairs (VA), published a notice in the **Federal Register** announcing an opportunity for public comment on the proposed collection Casket/Urn Reimbursement. This notice (FR Vol. 80, Number 18, January 28, 2015) was published in error; therefore this document corrects that error by withdrawing this FR notice, document number 2015–01581.

DATES: Withdraw FR notice published on Wednesday, January 28, 2015.

FOR FURTHER INFORMATION CONTACT: Crystal Rennie, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, at (202) 632–7492.

FR Doc. 2015, published on January 28, 2015 (FR Vol 80, Number 18), is withdrawn by this notice.

Dated: February 3, 2015.

Crystal Rennie,

Department Clearance Officer, Department of Veterans Affairs.

[FR Doc. 2015–02387 Filed 2–5–15; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Health Services Research and Development Service, Scientific Merit Review Board; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2, that the Health Services Research and Development Service Scientific Merit Review Board will conduct in-person and teleconference meetings of its seven Health Services Research (HSR) subcommittees on the dates from 8:00 a.m. to approximately 5:00 p.m. (unless otherwise listed) and at the Veterans Health Administration National Conference Center in Arlington, Virginia:

- HSR 1—Health Care and Clinical Management on March 3–4, 2015;
- HSR 2—Behavioral, Social, and Cultural Determinants of Health and Care on March 3–4, 2015;
- HSR 4—Mental and Behavioral Health on March 3–4, 2015;
- HSR 5—Health Care System Organization and Delivery on March 3–4, 2015;
- HSR 7—Aging and Diminished Capacity in the Context of Aging on Wednesday, March 4, 2015;
- Nursing Research Initiative (NRI) from 8:00 a.m. to 12:00 p.m. on Thursday, March 5, 2015;
- HSR 3—Healthcare Informatics on Thursday, March 5, 2015; and
- HSR 6—Post-acute and Long-term Care on Thursday, March 5, 2015.

The purpose of the Board is to review health services research and development applications involving the measurement and evaluation of health care services, the testing of new methods of health care delivery and management, and nursing research. Applications are reviewed for scientific and technical merit, mission relevance, and the protection of human and animal subjects. Recommendations regarding funding are submitted to the Chief Research and Development Officer.

Each subcommittee meeting of the Board will be open to the public the first day for approximately one half-hour at the start of the meeting on March 3–4 (HSR 1, 2, 4, 5, and 7) and on March 5 (NRI, HSR 3, and 6), to cover administrative matters and to discuss the general status of the program. Members of the public who wish to attend the open portion of the subcommittee meetings may dial (toll-free) (800) 767–1750, participant code 10443. Because the meeting will be in a Government building, anyone attending must be prepared to show a valid photo ID for checking in. Please allow 15 minutes before the meeting begins for this process.

The remaining portion of each subcommittee meeting will be closed for the discussion, examination, reference to, and oral review of the intramural research proposals and critiques. During the closed portion of each subcommittee meeting, discussion and recommendations will include qualifications of the personnel conducting the studies (the disclosure of which would constitute a clearly unwarranted invasion of personal privacy), as well as research information (the premature disclosure of which would likely compromise significantly the implementation of proposed agency action regarding such research projects). As provided by subsection 10(d) of Public Law 92–463, as amended by Public Law 94–409, closing the meeting is in accordance with 5 U.S.C. 552b(c)(6) and (9)(B). No oral or written comments will be accepted from the public for either portion of the meetings. Those who plan to participate during the open portion of a subcommittee meeting should contact Mr. John Midolo, Designated Federal Officer, Scientific Merit Review Board, Department of Veterans Affairs, Health Services Research and Development Service (10P9H), 810 Vermont Avenue NW., Washington, DC 20420, or email at *John.Midolo@va.gov.* For further information, please call Mr. Midolo at (202) 443–5752.

Dated: February 2, 2015.

Rebecca Schiller,

Advisory Committee Management Officer.

[FR Doc. 2015–02317 Filed 2–5–15; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 314 and 320

Abbreviated New Drug Applications and 505(b)(2) Applications; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314 and 320

[Docket No. FDA–2011–N–0830]

RIN 0910–AF97

Abbreviated New Drug Applications and 505(b)(2) Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing regulations to implement Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which amended provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) that govern the approval of 505(b)(2) applications and abbreviated new drug applications (ANDAs). This proposed rule would implement portions of Title XI of the MMA that pertain to provision of notice to each patent owner and the new drug application (NDA) holder of certain patent certifications made by applicants submitting 505(b)(2) applications or ANDAs; the availability of 30-month stays of approval on 505(b)(2) applications and ANDAs that are otherwise ready to be approved; submission of amendments and supplements to 505(b)(2) applications and ANDAs; and the types of bioavailability and bioequivalence data that can be used to support these applications. This proposed rule also would amend certain regulations regarding 505(b)(2) applications and ANDAs to facilitate compliance with and efficient enforcement of the FD&C Act.

DATES: Submit either electronic or written comments on the proposed rule by May 7, 2015. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by March 9, 2015 (see the ''Paperwork Reduction Act of 1995'' section of this document). See section VII of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: You may submit comments by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document).

Electronic Submissions

Submit electronic comments in the following way:

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

Written Submissions

Submit written submissions in the following way:

• *Mail/Hand delivery/Courier (For paper, disk, or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include Docket No. FDA–2011–N–0830 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Janice L. Weiner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6268, Silver Spring, MD 20993–0002, 301–796–3601.

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Executive Summary

Purpose of the Regulatory Action

This proposed rule would implement portions of Title XI of the MMA and revise and clarify FDA regulations relating to 505(b)(2) applications and ANDAs in a manner intended to reduce unnecessary litigation, reduce delays in the approval of 505(b)(2) applications and ANDAs that are otherwise ready to be approved, and provide business certainty to both brand name and generic drug manufacturers. The MMA and sections 505, 505A, and 527 of the FD&C Act (21 U.S.C. 355, 355a, and 360cc), in conjunction with our general rulemaking authority in section 701(a) of the FD&C Act (21 U.S.C. 371(a)), serve as our principal legal authority for this proposal.

Title XI of the MMA addressed two key concerns identified in a Federal Trade Commission (FTC) report on anticompetitive strategies that may delay access to generic drugs by: (1) Limiting the availability of 30-month stays of approval on 505(b)(2) applications and ANDAs that are otherwise ready to be approved and (2) establishing conditions under which a first applicant would forfeit the 180-day exclusivity period such that approval of subsequent ANDAs would no longer be blocked. FDA has been implementing the MMA directly from the statute for several years. Based on this experience, FDA is proposing to amend its regulations to implement portions of the MMA that pertain to 30-month stays and other matters not related to 180-day exclusivity.

FDA is proposing to amend its regulations regarding 505(b)(2) applications and ANDAs to facilitate compliance with and efficient enforcement of the FD&C Act, and to clarify and update these regulations based on recent court decisions and our practical experience implementing provisions related to the approval of 505(b)(2) applications and ANDAs. For example, we are proposing to clarify requirements for the NDA holder's description of the patented method of use (the ''use code'') required for publication in FDA's ''Approved Drug Products With Therapeutic Equivalence Evaluations'' (commonly known as the Orange Book) to avoid overbroad use codes that may delay approval of generic drugs. This is intended to facilitate FDA's implementation of the statutory provisions that permit 505(b)(2) and ANDA applicants to omit (''carve out'') protected conditions of use from labeling and obtain approval for conditions of use that are not covered by unexpired patents or exclusivity. As the U.S. Supreme Court recently noted in *Caraco Pharm. Labs.* v. *Novo Nordisk A/S:* ''An overbroad use code . . . throws a wrench into the FDA's ability to approve generic drugs as the statute contemplates'' (132 S. Ct. 1670, at 1684 (2012)).

Finally, we are proposing to update the regulations to codify FDA's current practice and policy and thereby promote transparency.

Summary of the Major Provisions of the Regulatory Action

Submission of Patent Information. The proposed rule would revise and streamline requirements related to submission of patent information on: (1) Patents that claim the drug substance and/or drug product and meet the requirements for patent listing on that basis; (2) drug substance patents that claim only a polymorph of the active ingredient; and (3) certain NDA supplements. The proposed rule would clarify requirements for the submission of information related to patents that have been reissued by the Patent and Trademark Office (PTO). The proposed rule describes our approach to treating the original and reissued patents as a ''single bundle'' of patent rights, which first became relevant to approval of 505(b)(2) applications and ANDAs with the submission of the original patent information.

We are proposing to codify our long-standing requirement that the NDA holder's description of the patented method of use required for publication in the Orange Book must contain adequate information to assist FDA and 505(b)(2) and ANDA applicants in determining whether a listed method-of-use patent claims a use for which the 505(b)(2) or ANDA applicant is not seeking approval. To restrain overbroad use codes, the proposed rule would expressly require that if the scope of the method-of-use claim(s) of the patent does not cover every approved use of the drug, the NDA holder's use code must describe only the specific portion(s) of the indication or other method of use claimed by the patent.

Timing of Submission of Patent Information. We are proposing to expressly describe our current practice with respect to listing patent information that has not been submitted to FDA within 30 days after patent issuance. Although we list untimely filed patents pursuant to section 505(c)(2) of the FD&C Act, we generally do not require an applicant with a pending 505(b)(2) application or ANDA to provide a patent certification to the untimely filed patent. Thus, the untimely filed patent will neither delay approval of a pending 505(b)(2) application or ANDA until patent expiration nor necessitate a carve-out of information related to a patented method of use.

We are proposing to expand the category of untimely filed patent information to include certain amendments to the NDA holder's description of the approved method(s) of use claimed by the patent, if such changes do not relate to a corresponding change in approved labeling or are submitted more than 30 days after such labeling change. This proposed regulatory revision is intended to reduce delays in approval related to manipulation of patent use codes in a manner not contemplated by the FD&C Act.

In addition, we are proposing to establish that the submission date of patent information provided by an NDA holder after approval would be the earlier of the date on which Form FDA 3542 is date-stamped by the Office of Generic Drugs (OGD) Document Room or officially received electronically by FDA. These proposed revisions are intended to facilitate prompt listing in the Orange Book and to remove any

ambiguity about the date of submission in light of the implications for the patent certification obligations of 505(b)(2) and ANDA applicants that rely upon the listed drug.

Correction or Change of Patent Information. We are proposing to enhance FDA's response to challenges to the accuracy or relevance of submissions of patent use code information to the Agency, in certain circumstances. If, in response to such a challenge, the NDA holder confirms the accuracy of the information, fails to timely respond, or submits a revision to the use code that does not provide adequate clarity for FDA to determine whether the scope of a proposed labeling carve-out would be appropriate based on the NDA holder's use code and approved labeling, we are proposing to review proposed labeling carve-out(s) for the 505(b)(2) application or ANDA with deference to the 505(b)(2) or ANDA applicant's interpretation of the scope of the patent. In addition, we are proposing to expressly require the correction or change of patent information by the NDA holder if: (1) The patent or patent claim no longer meets the statutory requirements for listing; (2) the NDA holder is required by court order to amend patent information or withdraw a patent from the list; or (3) the term of a listed patent is extended under patent term restoration provisions. These proposed revisions would facilitate implementation of the MMA provision related to patent withdrawal and efficient enforcement of the FD&C Act.

Notice of Paragraph IV Certification—Timing. We are proposing to revise our regulations to clearly delineate the two limitations on the time frame within which notice of a paragraph IV certification can be provided to the NDA holder and each patent owner: (1) The date before which notice may not be given (reflecting FDA's long-standing practice) and (2) the date, established by MMA, by which notice must be given.

For an original application, a 505(b)(2) or ANDA applicant must send notice of a paragraph IV certification on or after the date on which it receives an ''acknowledgment letter'' or a ''paragraph IV acknowledgment letter'' from FDA stating that the application is sufficiently complete to permit a substantive review, but not later than 20 days after the date of the ''postmark'' (as defined in the proposed rule) on such letter.

For an amendment or supplement, a 505(b)(2) or ANDA applicant must send notice of a paragraph IV certification contained in an amendment to an application (that has been received for substantive review) or in a supplement to an approved application at the same time that the amendment or supplement is submitted to FDA. We are proposing to establish a date (the first working day after the day the patent is published in the Orange Book) before which an ANDA applicant cannot send valid notice of a paragraph IV certification to a newly listed patent. This approach is intended to promote equity among ANDA applicants seeking eligibility for 180-day exclusivity and to reduce the burden on industry and FDA associated with serial submissions and multiple notices of paragraph IV certifications related to a newly issued patent.

Notice of a paragraph IV certification that has been sent prematurely is invalid, and will not be considered to comply with the FD&C Act's notice requirement. We are proposing administrative consequences for ANDA applicants who fail to send notice of paragraph IV certification within the statutory time frame established by the MMA. The date the ANDA was submitted would be deemed to be delayed by the number of days by which the time frame was exceeded, which may result in the applicant losing eligibility for 180-day exclusivity.

Notice of Paragraph IV Certification—Content and Methods. We are proposing revisions to the content of notice of a paragraph IV certification to incorporate requirements added by the MMA and to support the efficient enforcement of our regulations. We also are proposing to expand the acceptable methods of sending notice of a paragraph IV certification beyond registered or certified mail to include ''designated delivery services.'' This would reduce the burden on 505(b)(2) and ANDA applicants who currently must submit requests to send notice by common alternate delivery methods.

Amended Patent Certifications. We are proposing to clarify the requirements for a 505(b)(2) or ANDA applicant to amend a paragraph IV certification after a judicial finding of patent infringement to reflect statutory changes made by the MMA. We also are proposing to clarify the circumstances and time frame in which a 505(b)(2) or ANDA applicant must submit an amended patent certification after an NDA holder has withdrawn a patent and requested removal of the patent from the Orange Book. The proposed rule would codify our current practice of not removing a withdrawn patent from the list until FDA has determined that no first applicant is eligible for 180-day exclusivity or such exclusivity is extinguished, and exempting 505(b)(2) applicants from providing or maintaining a certification to withdrawn patents. The proposed rule also clarifies an applicant's current patent certification obligations with respect to a reissued patent, and proposes implications for 180-day exclusivity and a 30-month stay. In addition, the proposed rule would expressly codify the current requirement for a 505(b)(2) or ANDA applicant to submit a patent certification to a newly issued patent that claims the listed drug or an approved method of use.

Amendments or Supplements: Patent Certification Requirements. We are proposing to clarify and augment the patent certification requirements for amendments and supplements to 505(b)(2) applications and ANDAs to ensure that changes to the drug product that could be protected by patent are accompanied by a new patent certification. A new patent certification currently is required to accompany an amendment or supplement to add a new indication or other condition of use, or to add a new strength or change an existing strength. The regulations also currently require a patent certification to be amended if, at any time before approval, the applicant learns that the previously submitted patent certification is no longer accurate. We are proposing to augment this regulation by requiring a new patent certification with an amendment to make other-than-minor changes in product formulation or to change the physical form or crystalline structure of the active ingredient.

Limitation on Submission of Certain Amendments and Supplements to a 505(b)(2) Application or ANDA. We are proposing to codify our current interpretation of the MMA's prohibition on submitting an amendment or a supplement to seek approval of: (1) ''[A] drug that is a different drug'' than the drug identified in the original 505(b)(2) application; or (2) ''a drug referring to a different listed drug'' than the drug cited as the basis for ANDA submission. We are implementing these parallel restrictions on submission of certain types of changes in an amendment or a supplement to a 505(b)(2) application or ANDA in a manner that is consistent with the statutory text and preserves a meaningful opportunity for a single 30-month stay.

505(b)(2) Applications. We are proposing to require a 505(b)(2) applicant to identify a pharmaceutically equivalent product, if already approved, as a listed drug relied upon, and comply with applicable regulatory requirements. This is intended to help ensure that the 505(b)(2) pathway is not used to circumvent the statutory patent

certification obligations that would have applied if the proposed product was not ineligible for approval in an ANDA.

Date of Approval of a 505(b)(2) Application or ANDA. The proposed rule would describe, in a more comprehensive manner, the timing of approval of a 505(b)(2) application or ANDA based on the patent certification(s) or statement(s) submitted by the 505(b)(2) or ANDA applicant. We are proposing to revise the regulations to reflect the MMA's limitation on multiple 30-month stays of approval of a 505(b)(2) application or an ANDA containing a paragraph IV certification to certain patents submitted to FDA on or after August 18, 2003.

We are proposing to clarify that the statutory 30-month stay begins on the later of the date of receipt of notice of paragraph IV certification by any owner of the listed patent or by the NDA holder who is an exclusive licensee (or their representatives). This proposed revision codifies our current practice and provides an efficient means of ensuring that each patent owner or NDA holder receives the full statutory 30-month stay.

We are proposing to codify the MMA's amendments that clarify the type of Federal district and appellate court decisions in patent litigation that will terminate a 30-month stay and lead to approval of a 505(b)(2) application or ANDA that is otherwise eligible for approval. We also are proposing to address other scenarios in which a stay may be terminated, including written consent to approval by the patent owner or exclusive patent licensee, a court order terminating the stay, or a court order of dismissal without a finding of infringement. This is intended to avoid unnecessary delays in approval of generic drugs while upholding the statutory purpose of the stay (*i.e.,* to allow time for patent infringement claims to be litigated prior to approval of the potentially infringing product).

Notification of Commercial Marketing. We are proposing to update the regulations to reflect the MMA provisions that modify the types of events that can trigger the start of the 180-day exclusivity period. A first applicant would be required to submit correspondence to its ANDA notifying FDA within 30 days of the date of first commercial marketing of the drug product. If the first applicant does not notify FDA within this time frame, we are proposing to deem the date of first commercial marketing to be the date of the drug product's approval. This may have the effect of shortening the 180-day exclusivity period in a similar manner to the current regulatory consequence for failure to provide ''prompt'' notice of first commercial marketing.

Notification of Court Actions or Documented Agreements. We are proposing to expand the scope of documentation that an applicant must submit to FDA regarding patent-related court actions and documented agreements to ensure that FDA is promptly advised of information that may affect the timing of approval of a 505(b)(2) application or ANDA.

Costs and Benefits

FDA is proposing to amend the regulations for further implementation of and consistency with the MMA and to make other changes related to 505(b)(2) applications and ANDAs. These changes would improve transparency, facilitate compliance and enforcement, and preserve the balance struck in the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417).

Although many provisions of this proposed rule would codify current practice, elements of this proposal would lead to changes that generate additional benefits and costs. The estimated annual monetized benefits of this proposed rule are $194,314, and estimated annual monetized costs are $91,371. We have identified, but are unable to quantify, impacts from proposed changes to submitted patent information and the implementation of an administrative consequence for ANDA applicants who fail to provide notice of a paragraph IV certification within the time frame required by the MMA.

I. Background

On December 8, 2003, the MMA (Pub. L. 108–173) was signed into law. Title XI of the MMA significantly amended provisions of the FD&C Act that govern the approval of NDAs described by section 505(b)(2) of the FD&C Act (21 U.S.C. 355(b)(2)) (505(b)(2) applications) and ANDAs described by section 505(j) of the FD&C Act.

I.A. Hatch-Waxman Amendments

The 505(b)(2) application and ANDA approval pathways were enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (Hatch-Waxman Amendments). The Hatch-Waxman Amendments reflect Congress's efforts to balance the need to ''make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962'' with new incentives for drug development in the form of marketing exclusivity and patent term extensions (see H. Rept. 98–857, part 1, at 14–15 (1984), reprinted in 1984 U.S. Code Congressional and Administrative News 2647 at 2647–2648). With passage of the Hatch-Waxman Amendments, the FD&C Act describes different routes for obtaining approval of two broad categories of drug applications: An NDA, for which the requirements are set out in section 505(b) and (c) of the FD&C Act, and an ANDA, for which the requirements are set out in section 505(j). These categories can be further subdivided into a ''stand-alone'' NDA, a 505(b)(2) application, an ANDA, and a petitioned ANDA.

A ''stand-alone NDA'' is an application submitted under section 505(b)(1) of the FD&C Act that contains full reports of investigations of safety and effectiveness that were conducted by or for the applicant or for which the applicant has a right of reference or use.

A 505(b)(2) application is an NDA that contains full reports of investigations of safety and effectiveness, where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use (*e.g.,* published literature or the Agency's finding of safety and/or effectiveness for one or more listed drugs).

An ANDA is an application for a duplicate of a previously approved drug that is submitted under the abbreviated approval pathway described in section 505(j) of the FD&C Act. An ANDA must contain information to show that the proposed product is the same as a previously approved drug (the reference listed drug or RLD) with respect to active ingredient, dosage form, route of administration, strength, labeling, and conditions of use, among other characteristics. An ANDA applicant also must demonstrate that its proposed product is bioequivalent to the drug product selected by the Agency as the reference standard for assessing bioequivalence with the RLD (see section II.A.2.z). (We note that the drug product designated as the RLD may not necessarily be the drug product identified in the Orange Book as the reference standard for bioequivalence studies, for example, for drug product lines with multiple strengths.) An applicant that can meet the requirements for approval under section 505(j) of the FD&C Act may rely upon the Agency's finding of safety and effectiveness for the RLD and need not repeat the extensive nonclinical and clinical investigations required for approval of a ''stand-alone'' NDA

submitted under section 505(b)(1) of the FD&C Act.

A ''petitioned ANDA'' is a type of ANDA for a drug that differs from a previously approved drug product in dosage form, route of administration, strength, or active ingredient (in a product with more than one active ingredient), for which FDA has determined, in response to a suitability petition submitted under section 505(j)(2)(C) of the FD&C Act, that clinical studies are not necessary to demonstrate safety and effectiveness.

The timing of approval for a 505(b)(2) application and an ANDA (including a petitioned ANDA) is subject to the patent and marketing exclusivity protections accorded the listed drug(s) relied upon and the RLD, respectively. An NDA applicant (including a 505(b)(2) applicant) is required to ''file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture[,] use, or sale of the drug'' (section 505(b)(1) of the FD&C Act). Upon approval of an application under section 505(c) of the FD&C Act, we publish the patent information provided by the applicant in the Orange Book, available electronically on FDA's Web site at *http://www.fda.gov/cder.*

I.B. Requirements for Patent Certification or Statement

A 505(b)(2) application and ANDA must include a patent certification described in section 505(b)(2) or 505(j)(2)(A)(vii) of the FD&C Act, respectively, for each timely filed patent that claims the listed drug(s) relied upon or RLD, respectively, or a method of using the drug for which the applicant is seeking approval and for which information is required to be filed under section 505(b) or 505(c) of the FD&C Act. For each unexpired patent listed in the Orange Book, the 505(b)(2) or ANDA applicant must submit either a paragraph III certification (section 505(b)(2)(A)(iii) or 505(j)(2)(A)(vii)(III) of the FD&C Act) (delaying approval until the date on which such patent will expire), a paragraph IV certification (section 505(b)(2)(A)(iv) or 505(j)(2)(A)(vii)(IV) of the FD&C Act) (certifying that such patent is invalid or will not be infringed by the manufacture, use, or sale of the drug product for which the 505(b)(2) application or ANDA is submitted), or, with respect to a method-of-use patent, a statement that the patent does not claim a use for which the applicant is seeking approval (section 505(b)(2)(B) or 505(j)(2)(A)(viii) of the FD&C Act). If the patent information has not been filed with FDA (*i.e.,* is not listed in the Orange Book because the patent information has not been submitted or is not eligible for listing) or the patent has expired, a 505(b)(2) or ANDA applicant may submit a paragraph I certification or paragraph II certification, respectively (see section 505(b)(2)(A)(i) and (ii) and 505(j)(2)(A)(vii)(I) and (II) of the FD&C Act). If, in the opinion of the 505(b)(2) or ANDA applicant and to the best of their knowledge, there are no patents that claim the listed drug(s) relied upon or the RLD, respectively, or that claim a use of such drug, the 505(b)(2) or ANDA applicant may submit a ''no relevant patents'' certification (see § 314.50(i)(1)(ii) or § 314.94(a)(12)(ii) (21 CFR 314.50(i)(1)(ii) or 314.94(a)(12)(ii)).

An applicant submitting a paragraph IV certification is required to give notice of its paragraph IV certification to the holder of the NDA for the listed drug(s) relied upon or RLD and each owner of the patent that is the subject of the certification. Notice of a paragraph IV certification subjects the 505(b)(2) or ANDA applicant to the risk that it will be sued for patent infringement. If the NDA holder or patent owner initiates a patent infringement action within 45 days after receiving notice of the paragraph IV certification, there generally will be a statutory 30-month stay of approval of the 505(b)(2) application or ANDA while the patent infringement litigation is pending (see section 505(c)(3)(C) and (j)(5)(B)(ii) of the FD&C Act). ANDA applicants have a statutory incentive to challenge listed patents that may be invalid, unenforceable, or not infringed by the drug product described in the ANDA. The first applicant to submit a substantially complete ANDA that contains, and for which the applicant lawfully maintains, a paragraph IV certification may be eligible for a 180-day period of marketing exclusivity (180-day exclusivity) during which approval of subsequent ANDAs containing a paragraph IV certification to a listed patent for the same drug product will not be granted (see section 505(j)(5)(B)(iv) of the FD&C Act).

I.C. Patent Listing Requirements

In July 2002, the FTC published a report on ''Generic Drug Entry Prior to Patent Expiration: An FTC Study'' (FTC Report) that, among other things, identified circumstances in which ANDA applicants were delayed in entering the market (see *http://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf*). These circumstances included multiple 30-month stays of approval (related to paragraph IV certifications for additional patents listed after ANDA submission) and a delay in ''triggering'' the start of a first applicant's 180-day period of marketing exclusivity thereby blocking subsequent ANDA applicants. In response to the FTC Report, FDA published a proposed rule in October 2002 to amend its patent listing requirements and to permit only a single 30-month stay of approval for a 505(b)(2) application or ANDA (see 67 FR 65448, October 24, 2002) (October 2002 proposed rule). The final rule on ''Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of [ANDAs] Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed'' was published in June 2003 (68 FR 36676, June 18, 2003) (June 2003 final rule).

I.D. MMA

The MMA was enacted on December 8, 2003, and superseded certain sections of the June 2003 final rule regarding the application of 30-month stays of approval of certain 505(b)(2) applications and ANDAs; the superseded regulations were subsequently revoked by technical amendment (see ''Application of 30-Month Stays on Approval of [ANDAs] and Certain [NDAs] Containing a Certification That a Patent Claiming the Drug Is Invalid or Will Not Be Infringed; Technical Amendment'' (69 FR 11309, March 10, 2004).

Title XI of the MMA addressed two key concerns identified in the FTC Report by limiting the availability of 30-month stays of approval on 505(b)(2) applications and ANDAs that are otherwise ready to be approved (30-month stays) and by establishing conditions under which a first applicant would forfeit the 180-day exclusivity period such that approval of subsequent ANDAs would no longer be blocked. Section 1101 of the MMA provides that a 30-month stay of approval of a 505(b)(2) application or ANDA is available only if patent infringement litigation was initiated within the 45-day period after receipt of notice of a paragraph IV certification for a patent that had been submitted to FDA *before* the date of submission of the 505(b)(2) application or ANDA (excluding an amendment or supplement to the

application). The resulting incentive for an applicant to change the listed drug relied upon through an amendment of or a supplement to a 505(b)(2) application or ANDA is addressed by the MMA's prohibition of the submission of certain types of changes (including those requiring reference to a different listed drug) in an amendment of or supplement to a 505(b)(2) application or ANDA. In addition, section 1101 of the MMA amended the FD&C Act to specify the types of court actions that will terminate a 30-month stay of approval.

Section 1101 of the MMA also created new requirements for 505(b)(2) and ANDA applicants sending notice of a paragraph IV certification, including changes to the timing and contents of such notice. In addition, the MMA established conditions under which a 505(b)(2) or ANDA applicant may bring a declaratory judgment action to obtain ''patent certainty'' (*i.e.,* obtain a judicial determination of non-infringement, invalidity, or unenforceability) with respect to a listed patent for which it has given notice of a paragraph IV certification but has not been sued by the NDA holder or patent owner(s) within the statutory timeframe. If a patent infringement action is initiated against the 505(b)(2) or ANDA applicant, the MMA provides that the applicant may assert a counterclaim seeking an order requiring a correction or deletion of the patent information submitted to FDA for listing by the NDA holder or patent owner.

Section 1102 of the MMA altered the conditions under which a 180-day period of marketing exclusivity is granted by requiring, among other things, that a first applicant lawfully maintain the paragraph IV certification contained in its submission of a substantially complete ANDA. In addition, section 1102 of the MMA established conditions under which a first applicant would forfeit the 180-day exclusivity period.

Section 1103 of the MMA clarified the types of bioavailability and bioequivalence data that can be used to support a 505(b)(2) application or ANDA for a drug that is not intended to be absorbed into the bloodstream.

On March 3, 2004, we published a notice in the **Federal Register** entitled ''Generic Drug Issues; Request for Comments'' (69 FR 9982) (Request for MMA Comments) which invited public comment to further identify issues related to the MMA provisions regarding 30-month stays, 180-day exclusivity, and bioavailability and bioequivalence, along with any suggestions for how to resolve those issues. Comments received in response to the Agency's Request for MMA Comments are addressed in this document, as appropriate.

We are currently implementing the 180-day exclusivity provisions of the MMA directly from the statute and will determine if additional rulemaking is necessary in the future. Where a novel issue of interpretation is raised by a particular factual scenario regarding forfeiture of 180-day exclusivity, we may open a public docket or otherwise seek comment from affected parties in advance of taking action (see, *e.g.,* Docket Nos. FDA–2007–N–0445 (acarbose tablets), FDA–2007–N–0269 (granisetron hydrochloride injection), FDA–2007–N–0035 (ramipril capsules), and FDA–2008–N–0483 (dorzolamide hydrochloride—timolol maleate ophthalmic solution), available at *http://www.regulations.gov*).

We invite interested parties to comment on any aspect of this proposed rule. In addition to requesting general comments on this proposal, we have identified issues throughout this document on which we are specifically seeking comments.

II. Description of the Proposed Rule

This proposed rule implements portions of the MMA that pertain to 30-month stays and other matters not related to 180-day exclusivity, and makes our regulations governing 505(b)(2) applications and ANDAs consistent with amendments made to the FD&C Act by the MMA. In addition, FDA is proposing to amend its regulations regarding 505(b)(2) applications and ANDAs to facilitate compliance with and efficient enforcement of the FD&C Act, and to clarify and update these regulations based on our practical experience implementing the provisions related to approval of 505(b)(2) applications and ANDAs.

Table 1 summarizes the proposed changes related to FDA's patent listing, patent certification, and 30-month stay regulations in part 314 (21 CFR part 314) and bioavailability and bioequivalence regulations in part 320 (21 CFR part 320):

TABLE 1—HIGHLIGHTS OF PROPOSED CHANGES TO FDA'S PATENT LISTING, PATENT CERTIFICATION, AND 30-MONTH STAY REGULATIONS [1]

21 CFR Section to which changes apply	Proposed Changes See section of this document (identified in parentheses) for more detailed information regarding the proposed change
314.3	Overview of New, Revised, and Relocated Definitions (II.A.1). Proposed Amendments to Definitions in § 314.3 (II.A.2). Definitions in Current § 314.108 (II.A.3). Definitions in Current § 320.1 (II.A.4).
314.50(i)(1)	Patent Certification Requirements for Method-of-Use Patents (II.C.1). Procedure for Submission of an Application Requiring Investigations for Approval of a New Indication for, or Other Change From, a Listed Drug (II.H).
314.50(i)(2)	Patent Certification Requirements for Method-of-Manufacturing Patents. (II.C.2).
314.50(i)(3)	Licensing Agreements (II.C.3).
314.50(i)(4)	Untimely Filing of Patent Information (II.B.2).
314.50(i)(6)	Amended Patent Certifications, including: a. Amended patent certifications after a finding of infringement; b. Amended certifications after a request by the NDA holder to remove a patent from the list; c. Amended certifications upon patent reissuance; and d. Other amended certifications. (II.E.1 through II.E.4).
314.52(b) and (d)	Timing of Notice of Paragraph IV Certification, including: a. Date before which notice may not be given; b. Date by which notice must be given; and c. Certification of provision of notice. (II.D.1).

TABLE 1—HIGHLIGHTS OF PROPOSED CHANGES TO FDA'S PATENT LISTING, PATENT CERTIFICATION, AND 30-MONTH STAY REGULATIONS [1]—Continued

21 CFR Section to which changes apply	Proposed Changes See section of this document (identified in parentheses) for more detailed information regarding the proposed change
314.52(c)	Contents of Notice of Paragraph IV Certification, including: a. Statement that any required bioavailability or bioequivalence studies for a 505(b)(2) application have been submitted; b. Statement confirming receipt of an acknowledgment letter or a paragraph IV acknowledgment letter; c. Documentation that paragraph IV certification was submitted and notice was sent only for patents listed in the Orange Book; and d. Offer of confidential access accompanying notice. (II.D.3).
314.52(d)	Notice Required for All Paragraph IV Certifications. (II.D.2).
314.52(e)	Documentation of Timely Sending and Receipt of Notice of Paragraph IV Certification, including: a. Acceptable methods of sending notice of paragraph IV certification; and b. Amendment documenting timely sending and confirmation of receipt of notice of paragraph IV certification. (II.D.4).
314.53(b) and (c)	General Requirements for Submission of Patent Information, including: Revisions to scope of required submission of patent information. (II.B.1).
314.53(d)	When and Where To Submit Patent Information, including: a. Submission of patent information for NDA supplements; b. Untimely filing of patent information; c. Where to send submissions of Form FDA 3542a and 3542; and d. Submission date of patent information. (II.B.2).
314.53(e)	Public Disclosure of Patent Information (II.B.3).
314.53(f)	Correction or Change of Patent Information, including: a. Patents that claim an approved method of using the drug product (method-of-use patents); and b. Requests by NDA holder to remove patent information from the list. (II.B.4).
314.54	Procedure for Submission of an Application Requiring Investigations for Approval of a New Indication for, or Other Change From, a Listed Drug. (II.H).
314.60(e)	Amendments to an Unapproved 505(b)(2) Application for A Different Drug, including: a. Applications within the scope of section 505(b)(4)(A) of the FD&C Act; b. Proposed amendments subject to section 505(b)(4)(A) of the FD&C Act; c. Exception for amendments to seek approval of a different strength; and (II.G.3).
314.60(f)	Patent Certification Requirements for Amendments to 505(b)(2) Applications (II.F).
314.70(h)	Supplements to a 505(b)(2) Application for A Different Drug (II.G.4).
314.70(i)	Patent Certification Requirements for Supplements to 505(b)(2) Applications (II.F).
314.90	Refusal to Approve an NDA (II.L).
314.93	Petition to Request a Change From a Listed Drug (II.I).
314.94(a)(12)(iii)	Patent Certification Requirements for Method-of-Use Patents (II.C.2).
314.94(a)(12)(iv)	Patent Certification Requirements for Method-of-Manufacturing Patents (II.C.3).
314.94(a)(12)(viii)	Amended Patent Certifications, including: a. Amended patent certifications after a finding of infringement; b. Amended certifications after a request by the NDA holder to remove a patent from the list; c. Amended certifications upon patent reissuance; and d. Other amended certifications. (II.E.1 through II.E.4).
314.95(b) and (d)	Timing of Notice of Paragraph IV Certification, including: a. Date before which notice may not be given; b. Date by which notice must be given; and c. Certification of provision of notice. (II.D.1).
314.95(c)	Contents of Notice of Paragraph IV Certification, including: a. Statement confirming receipt of an acknowledgment letter or a paragraph IV acknowledgment letter; b. Clarification that paragraph IV certifications may be submitted only for patents listed in the Orange Book; and c. Offer of confidential access accompanying notice. (II.D.3).
314.95(d)	Notice Required for All Paragraph IV Certifications (II.D.2).
314.95(e)	Documentation of Timely Sending and Receipt of Notice of Paragraph IV. Certification, including: a. Acceptable methods of sending notice of paragraph IV certification; and b. Amendment documenting timely sending and confirmation of receipt of notice of paragraph IV certification. (II.D.4).

TABLE 1—HIGHLIGHTS OF PROPOSED CHANGES TO FDA'S PATENT LISTING, PATENT CERTIFICATION, AND 30-MONTH STAY REGULATIONS [1]—Continued

21 CFR Section to which changes apply	Proposed Changes See section of this document (identified in parentheses) for more detailed information regarding the proposed change
314.96(c)	Amendments to an Unapproved ANDA That Reference a Different Listed Drug, including: a. Approval of a pharmaceutically equivalent RLD in an NDA; b. Changes to the proposed drug product would result in pharmaceutical equivalence to a different RLD; c. Exception for amendments to seek approval of a different strength; and d. Procedure for submission of a new ANDA that identifies a different RLD. (II.G.1).
314.96(d)	Patent Certification Requirements for Amendments to ANDAs (II.F).
314.97(b)	Supplements to an ANDA That Reference a Different Listed Drug. a. Changes to the proposed drug product would result in pharmaceutical equivalence to a different RLD; b. Exception for supplements to seek approval of a different strength; and c. Procedure for submission of a new ANDA that identifies a different RLD. (II.G.2).
314.97(c)	Patent Certification Requirements for Supplements to ANDAs (II.F).
314.99	Refusal to Approve an ANDA (II.L).
314.101	Notification of Filing of a 505(b)(2) Application or Receipt of an ANDA and Other Proposed Revisions (II.J.1 through II.J.2). Administrative Consequence for Late Notice of Paragraph IV Certification (II.D.5).
314.105	Approval of an NDA and ANDA (II.K).
314.107(a)	Date of Approval of a 505(b)(2) Application or ANDA (II.M.1).
314.107(b)	Effect of Patent(s) on the Listed Drug, including: a. Timing of approval based on patent certification or statement; b. Patent information filed after submission of 505(b)(2) application or ANDA; c. Disposition of patent litigation; and d. Tentative approval. (II.M.2).
314.107(c)	Subsequent ANDA Submission (II.M.3).
314.107(d)	Delay of Approval Due to Exclusivity (II.M.4).
314.107(e)	Notification of Court Actions or Documented Agreement (II.M.5).
314.107(f)	Computation of the 45-day time clock (II.M.6).
314.107(g)	Conversion of Approval to Tentative Approval (II.M.7).
314.108	Definitions in Current § 314.108 (II.A.3).
314.125	Refusal to Approve an NDA (II.L).
314.127	Refusal to Approve an ANDA (II.L).
320.1	Definitions in Current § 320.1 (II.A.4).
320.23	Assessing Bioavailability and Bioequivalence for Drugs Not Intended To Be Absorbed Into the Bloodstream (II.N).

[1] These highlights reference important proposed revisions to our regulations, but should not be relied upon in place of the proposed regulation.

II.A. Definitions

II.A.1. Overview of New, Revised, and Relocated Definitions

We are proposing to amend § 314.3(b) to define terms relevant to amendments to the FD&C Act made by the MMA and to add definitions of terms that have been used by the Agency for several years in the context of implementing section 505(b) and (j) of the FD&C Act. We also are proposing amendments to § 314.3(b) and elsewhere to conform with other changes that we are proposing in this regulation and to incorporate new definitions. Although some of these revisions are not required for implementation of the MMA, these proposed changes are intended to enhance the clarity of our regulations in part 314 and promote consistency throughout our regulations.

Several definitions that we are proposing to add to § 314.3(b) involve terms that are defined specifically by the MMA (see definitions of ''180-day exclusivity,'' ''first applicant,'' ''substantially complete application,'' and ''tentative approval'' in section II.A.2. Our proposed definitions of these terms closely track the statutory language with only minor editorial changes (see section 505(j)(5)(B)(iv)(I) and (j)(5)(B)(iv)(II) of the FD&C Act). We also are proposing to add definitions of a ''paragraph IV acknowledgment letter'' and an ''acknowledgment letter'' to § 314.3(b), as the term ''paragraph IV acknowledgment letter'' is relevant to amendments made to section 505(b)(3)(B)(i) and (j)(2)(B)(ii)(I) of the FD&C Act regarding timing requirements for notices of paragraph IV certifications (see section II.A.2).

We are proposing to add definitions of terms that have been commonly used by the Agency over the years in the context of implementing section 505(b) and (j) of the FD&C Act and part 314, but that have not been expressly defined in § 314.3(b) (see definitions of ''abbreviated new drug application,'' ''ANDA,'' ''dosage form,'' ''new drug application,'' ''NDA,'' ''ANDA holder,'' ''NDA holder,'' ''patent owner,'' ''reference standard,'' ''strength,'' and ''therapeutic equivalents'' in section II.A.2). These proposed definitions are intended to codify our longstanding use of these terms, rather than substantively change the meaning.

We are proposing to revise the definitions of certain existing terms in § 314.3(b) (see definitions of ''listed drug'' and ''the list'' in section II.A.2) to conform with other changes we are proposing in this regulation and to clarify the distinction between approvals and tentative approvals (see section II.K). We also are proposing to revise the definitions of ''abbreviated application'' and ''applicant'' in § 314.3(b) to reflect statutory changes made by the Food and Drug Administration Modernization Act of

1997 (Public Law 105–115) (FDAMA) that eliminated the previous need to distinguish between ANDAs and abbreviated antibiotic applications. We are proposing amendments to § 314.3(b) and elsewhere to incorporate terms used by the Agency into existing definitions (see proposed amendments to definition of ''applicant'' to use terms ''NDA'' and ''ANDA'' in lieu of ''application'' and ''abbreviated application,'' respectively, in section II.A.2).

For clarity and ease of reference, we are proposing to add definitions of ''paragraph IV certification'' and ''commercial marketing'' to § 314.3(b) based on the current use of these terms in other sections of part 314. As discussed in section II.A.2.v, a paragraph IV certification is defined by section 505(b)(2)(A)(iv) and (j)(2)(A)(vii)(IV) of the FD&C Act and currently described in implementing regulations in part 314. Commercial marketing of certain drug products is a statutory trigger for beginning the period of 180-day exclusivity and is described in current and proposed regulations (see sections II.A.2.*l* and II.M.3). We also are proposing to move the definitions of the terms ''active moiety'' and ''date of approval'' in current § 314.108(a) to § 314.3(b). These definitions are relevant to matters covered in other sections of part 314 and thus appropriate for inclusion in the general definition section for this part.

We also are proposing to add definitions of ''active ingredient,'' ''inactive ingredient,'' and the related term ''component'' to § 314.3(b) based on the current definitions in § 210.3(b) (21 CFR 210.3(b)). These definitions reflect the current use of these terms in other sections of part 314.

Finally, we are proposing to move the definitions that currently are in § 320.1(a) through (g) to § 314.3(b) for ease of reference and organizational convenience. The terms currently defined in § 320.1 (''bioavailability,'' ''drug product,'' ''pharmaceutical equivalents,'' ''pharmaceutical alternatives,'' ''bioequivalence,'' ''bioequivalence requirement,'' and ''same drug product formulation'') are relevant to matters covered in part 314 in addition to matters in part 320, and certain of these terms are already used in part 314. (As noted elsewhere in this document, our proposed amendments to part 320 (discussed in section II.N) would make clear that proposed terms defined in § 314.3 will be applicable to part 320 when those terms are used in part 320.) With three exceptions (the definitions of ''bioavailability,'' ''bioequivalence,'' and ''drug product,'' discussed in section II.A.2), we are proposing to move the definitions in existing § 320.1(a) through (g) to § 314.3(b) without changes. We are proposing to modify the definition of bioavailability in current § 320.1(a) to reflect a statutory change made by the MMA. We are proposing conforming revisions to the definition of bioequivalence. It is not necessary to move the definition of drug product in § 320.1(b) to § 314.3 because this section already includes a definition of drug product that we believe is functionally identical.

II.A.2. Proposed Amendments to Definitions in § 314.3

II.A.2.a. *180-day exclusivity period.* The MMA defines the term ''180-day exclusivity period'' for purposes of section 505(j)(5) of the FD&C Act to mean ''the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause'' (see section 505(j)(5)(B)(iv)(II)(aa) of the FD&C Act). We are proposing to supplement this definition for ANDAs subject to the MMA to incorporate the statutory trigger for 180-day exclusivity, as described in section 505(j)(5)(B)(iv)(I) of the FD&C Act, and make minor editorial changes. In proposed § 314.3(b), the term ''180-day exclusivity period'' is defined as the 180-day period beginning on the date of the first commercial marketing of the drug (including the commercial marketing of the RLD) by any first applicant of an ANDA (see discussion of ''commercial marketing'' and ''first applicant'' in sections II.A.2.*l* and II.A.2.q). The 180-day period ends on the day before the date on which an ANDA submitted by an applicant other than a first applicant could be approved (see section 505(j)(5)(B)(iv)(I) through (j)(5)(B)(iv)(II)(aa) of the FD&C Act). As reflected in the parenthetical reference to commercial marketing of the RLD, the 180-day exclusivity period may be triggered by the commercial marketing of an ''authorized generic drug,'' as that term is currently defined in § 314.3(b).

FDA interprets the 180-day exclusivity provisions added by the MMA to apply only to ANDAs referring to an RLD for which the first ANDA was submitted after December 8, 2003, whether or not that ANDA contained a paragraph IV certification at the time of submission (see section 1102(b)(1) of the MMA (Effective Date provision)). If one or more ANDAs were submitted before December 8, 2003, but the first paragraph IV certification was submitted in an ANDA after that date, all ANDAs would be governed by the pre-MMA 180-day exclusivity provisions in order to impose the same statutory exclusivity scheme on all ANDAs referencing a specific RLD and avoid a possible disparate effect on ANDA applicants simultaneously undertaking the same patent challenge (see FDA's letter to ANDA applicants for topiramate sprinkle capsules dated April 15, 2009, available on FDA's Web site at *http://www.fda.gov*).

II.A.2.b. *Abbreviated application, abbreviated new drug application, or ANDA.* We are proposing to revise the definition of ''abbreviated application'' to include the alternate terms ''abbreviated new drug application'' and ''ANDA'' for clarity and administrative efficiency. Conforming revisions have been proposed throughout the sections of parts 314 and 320 in this rulemaking to incorporate the commonly used acronym ''ANDA'' in place of references to ''abbreviated application'' and ''abbreviated new drug application.''

In addition, we are proposing to delete the text in § 314.3(b) that explains that the term '' '[a]bbreviated application' applies to both an abbreviated new drug application and an abbreviated antibiotic application'' to reflect statutory changes made by FDAMA. Section 125 of FDAMA repealed section 507 of the FD&C Act under which marketing applications, including ANDAs, for antibiotics had been approved. FDAMA provided that ANDAs for antibiotics previously approved under section 507 of the FD&C Act would be deemed approved under section 505(j) of the FD&C Act. We note that there have been subsequent amendments to the FD&C Act involving applications for antibiotic drugs (see QI Program Supplemental Funding Act of 2008, Public Law 110–379 (2008)); however, these amendments are not specifically addressed in this proposed rulemaking.

II.A.2.c. *Acknowledgment letter.* We are proposing to define the term ''acknowledgment letter'' as a counterpart to the term ''paragraph IV acknowledgment letter,'' which is proposed for inclusion in § 314.3(b) to facilitate implementation of the MMA's requirements for the timing of notice of a paragraph IV certification (see sections II.A.2.u and II.D.1). We propose to define ''acknowledgment letter'' as a written, postmarked communication from FDA to an applicant stating that the Agency has determined that a 505(b)(2) application or ANDA is sufficiently complete to permit a substantive review. The proposed definition states that an acknowledgment letter indicates that the 505(b)(2) application is regarded as

filed or the ANDA is regarded as received. An acknowledgment letter is used for 505(b)(2) applications and ANDAs that contain a patent certification or statement other than a paragraph IV certification for the listed drug(s) relied upon or RLD, respectively (compare definition of ''paragraph IV acknowledgment letter'' discussed in section II.A.2.u).

Although the term ''acknowledgment letter'' applies to both 505(b)(2) applications and ANDAs that contain a patent certification or statement other than a paragraph IV certification, there are important practical differences between the letters for each type of application. In FDA's Center for Drug Evaluation and Research (CDER), the Office of Generic Drugs (OGD) reviews ANDAs after submission to determine whether the ANDA may be received for substantive review under § 314.101(b)(1). OGD will send an acknowledgment letter (or a paragraph IV acknowledgment letter, if appropriate) to the applicant after a determination has been made that the ANDA is sufficiently complete to permit a substantive review.

For NDAs, including 505(b)(2) applications, a determination regarding whether the application may be filed is made within 60 days after FDA is in receipt of the application as provided in § 314.101(a)(1). In the absence of a refusal to file letter sent to the NDA applicant on or before day 60, the NDA is deemed filed. In the context of a 505(b)(2) application, our proposed definition of ''acknowledgment letter'' reflects the current practice by CDER's Office of New Drugs (OND) with respect to its notification of issues identified during the filing review (filing communication) to the applicant generally not later than 14 calendar days after the 60-day filing date. This filing communication is informally known as a ''74-day letter'' (see Manual of Policies and Procedures (MAPP) 6010.5, ''NDAs: Filing Review Issues'' (effective May 8, 2003) (available on FDA's Web site at *http://www.fda.gov*). Under our proposed definition, the filing communication sent by the OND review division to the 505(b)(2) applicant is the ''acknowledgment letter'' from FDA stating that the 505(b)(2) application is sufficiently complete to permit a substantive review.

It should be noted that if an original ANDA contains a patent certification or statement other than a paragraph IV certification, and the applicant submits an amendment containing a paragraph IV certification before the ANDA has been received for substantive review, the applicant may receive, for administrative reasons, an acknowledgment letter, rather than a paragraph IV acknowledgment letter. This contingency is addressed in proposed § 314.95 by the use of both terms.

II.A.2.d. *Act.* We are proposing to modify the definition of ''act'' in § 314.3(b) so that the citation to the U.S. Code reflects sections added to the FD&C Act by FDAMA, the Food and Drug Administration Amendments Act of 2007 (FDAAA), the Food and Drug Administration Safety and Innovation Act (FDASIA), and other legislation.

II.A.2.e. *Active ingredient.* We are proposing to add the definition of ''active ingredient'' currently in § 210.3(b)(7) to § 314.3(b) without changes. The term ''active ingredient'' is relevant to matters covered in part 314 in addition to matters in part 210 and thus appropriate for inclusion in the general definition section for this part.

II.A.2.f. *Active moiety.* We are proposing to move the definition of the term ''active moiety'' in current § 314.108(a) to § 314.3(b) without changes. This definition is relevant to matters covered in other sections of part 314 and thus appropriate for inclusion in the general definition section for this part.

II.A.2.g. *ANDA holder and NDA holder.* We are proposing to define the terms ''ANDA holder'' and ''NDA holder'' to mean the applicant that owns an approved ANDA or NDA, respectively. These terms have been commonly used by the Agency over the years in the context of implementing section 505(b) and (j) of the FD&C Act and part 314, but have not been expressly defined in § 314.3(b).

II.A.2.h. *Applicant.* We are proposing to revise the definition of ''applicant'' to conform with other changes that we are proposing in this regulation and incorporate the commonly used acronyms ''NDA'' and ''ANDA.'' In addition, we are proposing to delete the reference to ''an antibiotic drug'' in the current definition of ''applicant'' to reflect statutory changes made by FDAMA that eliminated the previous need to distinguish between a new drug and an antibiotic drug.

II.A.2.i. *Application, new drug application, or NDA.* We are proposing to revise the definition of ''application'' to include the alternate terms ''new drug application'' and ''NDA'' for clarity and administrative efficiency. Conforming revisions have been proposed throughout the sections of parts 314 and 320 in this rulemaking to incorporate the commonly used acronym ''NDA'' in place of references to ''application'' and ''new drug application.'' In addition, we are proposing to expressly state that the terms ''application, new drug application, or NDA'' refer to ''stand-alone'' applications submitted under section 505(b)(1) of the FD&C Act and to 505(b)(2) applications. Although certain regulations in part 314 refer specifically to 505(b)(2) applications, 505(b)(2) applications also are subject to any applicable regulations governing new drug applications.

We considered replacing the term ''application'' with ''new drug application or NDA,'' rather than including ''new drug application'' or ''NDA'' as alternate terms, because the term ''application'' is sometimes used to generally refer to any application (*e.g.,* a ''stand-alone'' NDA, 505(b)(2) application, or ANDA) in a concise manner. However, such a proposal would have necessitated additional conforming revisions throughout part 314 that are beyond the scope of this rulemaking. We are proposing to replace the term ''application'' with ''NDA or ANDA'' in certain sections of part 314 to clarify the text and reflect FDA's longstanding interpretation of the provision (see, *e.g.,* the definition of ''specification'' in proposed § 314.3(b)).

II.A.2.j. *Bioavailability, bioequivalence.* The MMA amended the definitions of ''bioavailability'' and ''bioequivalence'' in section 505(j)(8)(A) and (j)(8)(C) of the FD&C Act to confirm that, for drugs not intended to be absorbed into the bloodstream, FDA may ''assess bioavailability by *scientifically valid* measurements intended to reflect the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of drug action'' (emphasis added). For such drugs, the MMA provides that FDA may establish ''alternative *scientifically valid* methods to show bioequivalence . . .'' (see section 505(j)(8)(C) of the FD&C Act (emphasis added)). Section 1103(b) of the MMA expressly states that the amendments to section 505(j)(8)(A) and (j)(8)(C) of the FD&C Act ''do[] not alter the standards for approval of drugs under section 505(j)'' of the FD&C Act.

The amendments to section 505(j)(8)(A) and (C) of the FD&C Act codify FDA's current practice, based on its existing regulations in §§ 320.1(a) and (e), 320.23(a)(1), and 320.24 and implementation of those regulations, regarding assessment of bioavailability and demonstration of bioequivalence for drugs not intended to be absorbed into the bloodstream (see *Schering Corp.* v. *FDA,* 51 F.3d 390 (3d Cir. 1995), *cert. denied,* 516 U.S. 907 (1995) (holding that FDA's regulatory standard in § 320.1(e) for bioequivalence of non-

systemically effective drugs is a permissible construction of the statute); see also section II.N).

We are proposing to revise the definitions of bioavailability and bioequivalence in § 320.1(a) and (e) to incorporate the textual revisions made in section 505(j)(8)(A) of the FD&C Act and move the revised definitions to § 314.3(b) in light of their relevance to matters covered in part 314 in addition to matters in part 320. The proposed definitions include a statement that for drug products that are not intended to be absorbed into the bloodstream, bioavailability and bioequivalence may be assessed by *scientifically valid* measurements intended to reflect the rate and extent to which the active ingredient or active moiety becomes available at the site of action (emphasis added). FDA will evaluate the scientific appropriateness of methodologies to assess the bioavailability or demonstrate the bioequivalence of non-systemically absorbed drugs based on the best available scientific evidence. We do not interpret section 505(j)(8)(A) and (j)(8)(C) of the FD&C Act to require full analytical method validation (which may have the effect of altering the standards for approval of ANDAs, contrary to section 1103(b) of the MMA), but rather methods that FDA considers to be scientifically valid or appropriate (see Docket No. FDA–2004–N–0062–0013 (comment submitted by the Biotechnology Industry Organization (BIO)) at 2 to 3, available at *http://www.regulations.gov* (BIO MMA Comment).

To clarify our interpretation of ''bioavailability'' and conform the definition with terminology used to define bioequivalence, we are proposing to revise the reference to ''site of action'' in current § 320.1(a) to ''site of drug action'' (see § 320.1(e)). For locally-acting drug products that are not systemically absorbed or have low systemic bioavailability, a pharmacokinetic comparison of drug and/or metabolite concentrations in plasma would not always reflect the rate and extent to which the active ingredient or active moiety becomes available at the site of drug action (*e.g.,* gastrointestinal tract or lungs). This is consistent with our historical interpretation and application of this term and the express language of section 505(j)(8)(A) of the FD&C Act.

In addition, we are proposing to substitute the term ''active moiety'' for the statutory term ''therapeutic ingredient'' in the definitions of ''bioavailability'' and ''bioequivalence.'' This approach reflects our longstanding judgment that the term ''active moiety'' is more appropriate than the term ''therapeutic ingredient'' in the context of section 505(j)(8)(A) of the FD&C Act (see, *e.g.,* ''Abbreviated New Drug Application Regulations''; final rule, 57 FR 17950 at 17972, April 28, 1992) (1992 final rule) (''Congress clearly intended a meaning different from 'active ingredient' by the term 'therapeutic ingredient' or it would not have used both terms [in what is now section 505(j)(8) of the FD&C Act]. The term 'active moiety' refers to the molecule or ion in an active ingredient, excluding those appended portions of the molecule that cause the ingredient to be an ester, or a salt or other noncovalent derivative that is responsible for the physiological or pharmacological action of the ingredient.'')

We also are proposing clarifying revisions in § 314.94(a)(7)(iii) relevant to bioequivalence studies. Proposed § 314.94(a)(7)(iii) would state that the requirements for submission of a description of the analytical and statistical methods used in each bioequivalence study applies to in vitro bioequivalence studies as well as in vivo bioequivalence studies. An in vitro study used to establish or support bioequivalence may include, for example, an in vitro kinetic binding study, an in vitro equilibrium binding study, a permeability study, and a study of plume geometry, spray pattern, or droplet or particle size distribution for nasal spray products.

II.A.2.k. *Bioequivalence requirement.* We are proposing to move the definition of ''bioequivalence requirement'' currently in § 320.1(f) to § 314.3(b), with a minor grammatical correction, for ease of reference and organizational convenience. The term ''bioequivalence requirement'' is relevant to matters covered in part 314 in addition to matters in part 320 and thus appropriate for inclusion in the general definition section for this part.

II.A.2.*l. Commercial marketing.* We are proposing to define ''commercial marketing'' to mean the introduction or delivery for introduction into interstate commerce of a drug product described in an approved ANDA, outside the control of the ANDA holder, except for investigational use under part 312 of this chapter, but does not include transfer of the drug product for reasons other than sale *to parties identified in the approved ANDA.*

This proposed definition is based on the use of this term in current § 314.107(c)(4); however, we are proposing to alter the scope of the exclusion for transfer of the drug product for reasons other than sale. Section 314.107(c)(4) currently provides that commercial marketing ''does not include transfer of the drug product for reasons other than sale *within the control of the manufacturer or application holder''* (emphasis added). Our proposed definition is intended to clarify that the ANDA holder's shipment of a drug product described in an approved ANDA to any party named in the ANDA for purposes described in the ANDA (*e.g.,* contract packaging) is not ''commercial marketing'' of the drug product even though such transfer arguably places the drug products outside of the control of the manufacturer for some period of time. However, shipment of the drug product to any other party or for any other purpose would not fall within this exception and would be considered ''commercial marketing'' (*i.e.,* an introduction or delivery for introduction into interstate commerce of a drug product described in an approved ANDA outside the ANDA holder's control). For example, if the ANDA holder ships the drug product to a wholesaler, a repackager not identified in the ANDA, or directly to a pharmacy, hospital, health maintenance organization, or other like entity, the ANDA holder will have commercially marketed the product as of the date of its shipment (if the ANDA holder complies with the notification requirement described in proposed § 314.107(c)(2)).

The first commercial marketing of a drug is discussed in section II.A.2.a (definition of the 180-day exclusivity period).

II.A.2.m. *Component.* We are proposing to add the definition of ''component'' currently in § 210.3(b)(3) to § 314.3(b) without changes. The term ''component'' is used within the defined term ''active ingredient'' and thus is appropriate for inclusion in the general definition section for this part (see section II.A.2.e).

II.A.2.n. *Date of approval.* We are proposing to move the definition of ''date of approval'' currently in § 314.108(a) to § 314.3(b) with several revisions. These proposed revisions to the definition of ''date of approval'' are not intended to alter our interpretation of § 314.108.

Our proposed revisions to the definition of ''date of approval'' incorporate use of the term ''approval letter,'' which also is defined in § 314.3(b), and broaden the definition to include the date of approval for an ANDA. In addition, we are proposing to remove from the definition of ''date of approval'' the caveat that the date of approval is the date on the approval

letter ''whether or not final printed labeling or other materials must still be submitted as long as approval of such labeling or materials is not expressly required'' (§ 314.108(a)). This qualification is inapplicable to the date of approval of an ANDA because final printed labeling is required as a condition of approval (see §§ 314.94(a)(8) and 314.127(a)(7)). With respect to NDAs (including 505(b)(2) applications), § 314.105(b) specifically addresses the circumstances under which FDA will approve an NDA and issue the applicant an approval letter on the basis of draft labeling, and it is unnecessary to summarize this approach in the definition of ''date of approval.''

As proposed for revision, the ''date of approval'' is the date on the approval letter from FDA stating that the NDA or ANDA is approved. The date of approval refers only to a final approval and not to a tentative approval. We note that the date on the approval letter generally appears on the last page containing the electronic signature (endorsement).

II.A.2.o. *Dosage form.* We are proposing to define ''dosage form'' to mean the physical manifestation containing the active and inactive ingredients that delivers a dose of the drug product. This includes such factors as (i) the physical appearance of the drug product, (ii) the physical form of the drug product prior to dispensing to the patient, (iii) the way the product is administered, and (iv) design features that affect frequency of dosing. This term has been commonly used by the Agency over the years in the context of implementing section 505(j) of the FD&C Act and part 314. However, except for the examples of dosage forms used in the definition of ''drug product,'' the term ''dosage form'' not been expressly defined in § 314.3(b).

The dosage form is generally determined based on the form of the product before dispensing to the patient (see *Abbott Laboratories* v. *Young,* 691 F. Supp. 462, 464 n. 1 (D.D.C. 1988) (''The final dosage form of a drug is the form in which it appears prior to administration to the patient''), *remanded on other grounds,* 920 F.2d 984 (D.C. Cir. 1990), *cert. denied,* 502 U.S. 819 (1991)). This is consistent with other factors such as physical recognition, dosing, and manner of administration that contribute to the determination of dosage form. Appendix C to the Orange Book lists the dosage form categories for currently marketed products.

II.A.2.p. *Drug product.* A ''drug product'' is a finished dosage form (for example, a tablet, capsule, or solution) that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients. We are proposing to delete a similar definition of ''drug product'' in current § 320.1(b) when we move the definitions in § 320.1 to § 314.3(b), to reflect the fact that § 314.3(b) already includes a definition of drug product. Although the two definitions of ''drug product'' differ slightly in wording, we believe that they are functionally identical, so that this proposed revision is intended to eliminate redundancy but not result in any substantive change in our interpretation of part 320.

II.A.2.q. *First applicant.* The MMA defines the term ''first applicant'' for purposes of section 505(j)(5) of the FD&C Act (see section 505(j)(5)(B)(iv)(II)(bb) of the FD&C Act). We are proposing to add the statutory definition, with minor editorial changes and additional clarifying text, to § 314.3(b) to facilitate our continuing implementation of the 180-day exclusivity provisions of the FD&C Act. We are proposing to define ''first applicant'' in § 314.3(b) to mean an applicant that, on the first day on which a substantially complete ANDA containing a paragraph IV certification is submitted for approval of a drug, submits a substantially complete ANDA that contains, and for which the applicant lawfully maintains, a paragraph IV certification for the drug. We are proposing to delete the definition of ''applicant submitting the first application'' in current § 314.107(c)(2) because it is superseded by the statutory definition (see section II.M.3). We note that an applicant may be a ''first applicant'' based on the submission of a paragraph IV certification in an amendment to an ANDA if other criteria are met.

We interpret the term ''drug'' in the statutory definition of ''first applicant'' to mean ''drug product'' as currently defined in § 314.3(b) (see section 505(j)(5)(B)(iv)(II)(bb) of the FD&C Act). Consistent with our longstanding practice, we note that different strengths of a drug product constitute different drug products. For example, different ANDA applicants seeking approval for different strengths of a drug product approved in a single NDA may each be first applicants with respect to a different strength of the drug product, if other applicable statutory and regulatory requirements are met (see *Apotex, Inc.* v. *Shalala,* 53 F. Supp. 2d 454 (D.D.C.), *aff'd,* 1999 U.S. App. LEXIS 29571 (D.C. Cir. 1999)). In addition, there may be multiple first applicants for a single drug product if more than one ANDA applicant first submitted a substantially complete ANDA that contains, and for which the applicant lawfully maintains, a paragraph IV certification on the same day.

We have interpreted the statutory requirement for a first applicant to ''lawfully maintain'' a paragraph IV certification to mean that the ANDA applicant must, as a condition of retaining first applicant status, continue to lawfully assert that a relevant listed patent (*i.e.,* at least one of the patents for which a paragraph IV certification qualified the ANDA applicant for first applicant status) is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the drug for which the ANDA is submitted (see Letter from G. Buehler, Director, Office of Generic Drugs, to ANDA Applicant regarding 180-day exclusivity for dorzolamide/timolol ophthalmic solution, Docket No. FDA–2008–N–0483–0017 at 5–6, available at *http://www.regulations.gov*) (Dorzolamide/Timolol Letter). This approach comports with comments that we received on the interpretation of the phrase ''lawfully maintained'' in response to the Request for MMA Comments (see Docket No. FDA–2004–N–0062–0006 (comment submitted by the Pharmaceutical Research and Manufacturers of America (PhRMA)) at 3–5, available at *http://www.regulations.gov* (PhRMA MMA Comment); see also Docket No. FDA–2004–N–0062–0009 (comment submitted by Eli Lilly and Company) at 1–2, available at *http://www.regulations.gov* (Lilly MMA Comment)).

For example, if an ANDA applicant is sued for infringement of a patent that qualified the applicant for first applicant status and a court enters a final decision from which no appeal has been or can be taken that the patent is infringed (or signs a settlement order or consent decree in the action that includes a finding of infringement and does not permit market entry before patent expiration), the ANDA applicant can no longer lawfully maintain a paragraph IV certification with respect to the infringed patent (see Dorzolamide/Timolol Letter at 6). As discussed in section II.E.1, the ANDA applicant is required to submit an amended patent certification under § 314.94(a)(12)(i)(A)(*3*) (paragraph III certification) in these circumstances. In addition, an ANDA applicant can no longer lawfully maintain a paragraph IV certification when the patent expires or if an ANDA applicant changes its certification from a paragraph IV certification to a 505(j)(2)(A)(viii)

statement (see proposed § 314.94(a)(12)(viii)(C) and (D); see also Dorzolamide/Timolol Letter at 6, note 5).

It should be noted that an amendment to a substantially complete ANDA does not mean that the ANDA is no longer substantially complete or that a first applicant has not lawfully maintained its paragraph IV certification (unless the amendment requires a new patent certification and the amended patent certification is not a paragraph IV certification). However, if a first applicant submits several major amendments to its ANDA, there is a risk that the applicant may not be able to obtain tentative approval within 30 months after the date on which the ANDA is filed, thereby forfeiting its eligibility for any 180-day exclusivity period (see section 505(j)(5)(D)(i)(IV) of the FD&C Act).

We note that certain definitions, such as the definition of ''first applicant,'' may be revised or supplemented in the future as we continue to implement the 180-day exclusivity provisions of the MMA.

II.A.2.r. *Inactive ingredient.* We are proposing to add the definition of ''inactive ingredient'' currently in § 210.3(b)(8) to § 314.3(b) without changes. The term ''inactive ingredient'' is relevant to matters covered in part 314 in addition to matters in part 210 and thus appropriate for inclusion in the general definition section for this part.

II.A.2.s. *Listed drug.* We are proposing to revise the definition of ''listed drug'' to clarify that a listed drug includes a drug product that is listed in the discontinued section of the Orange Book and that has not been withdrawn or suspended under section 505(e)(1) through (e)(5) or 505(j)(6) of the FD&C Act or withdrawn from sale (irrespective of whether the NDA has been withdrawn) for what FDA has determined are reasons of safety or effectiveness. Accordingly, the proposed definition in § 314.3(b) would state that a listed drug is a new drug product that ''has been approved'' instead of one that ''has an effective approval.'' With respect to the exceptions to listed drug status, we are correcting the paragraph number in the reference to the statutory provision under which an ANDA may be withdrawn or suspended for reasons of safety or effectiveness (see section 505(j)(6) of the FD&C Act).

In addition, we are proposing conforming revisions to incorporate other changes we are proposing in this rulemaking regarding the distinction between approvals and tentative approvals (see section II.K) and reliance upon the electronic version of the Orange Book (see section II.A.2.ee).

Listed drug status is evidenced by the drug product's identification in the current FDA's ''Approved Drug Products With Therapeutic Equivalence Evaluations'' (the list) as an approved drug. However, we note that a drug product is deemed to be a listed drug on the date of the approval letter for the NDA or ANDA for that drug product, rather than the date on which the product is listed in the Orange Book.

II.A.2.t. *Original application, original NDA.* We are proposing to revise the definition of ''original application'' to include the alternate term ''original NDA'' for clarity and administrative efficiency. In addition, we are proposing to replace references to ''application'' with ''NDA'' for consistency with other changes in this proposed rulemaking. These minor revisions are not intended to substantively change the meaning of the term ''original application.''

II.A.2.u. *Paragraph IV acknowledgment letter.* We are proposing to define ''paragraph IV acknowledgment letter'' to mean a written, postmarked communication from the FDA to an applicant stating that the Agency has determined that a 505(b)(2) application or ANDA containing a paragraph IV certification is sufficiently complete to permit a substantive review (compare definition of ''acknowledgment letter'' discussed in section II.A.2.c). An acknowledgment letter or paragraph IV acknowledgment letter indicates that the 505(b)(2) application is regarded as filed or the ANDA is regarded as received.

The proposed definition of ''paragraph IV acknowledgment letter'' is intended to facilitate implementation of the MMA's timing requirements for notice to the NDA holder and each patent owner of a paragraph IV certification. A 505(b)(2) or ANDA applicant is required to send notice of its paragraph IV certification within 20 days after the date of the postmark on the paragraph IV acknowledgment letter (see section 505(b)(3)(B)(i) and (j)(2)(B)(ii)(I) of the FD&C Act and section II.D.1).

In response to the Request for MMA Comments, the Generic Pharmaceutical Association (GPhA) requested that FDA amend § 314.101(b)(2) to state that FDA will notify the applicant ''in writing via a postmarked notice'' that the ANDA has been received in light of the MMA's timing requirements for notice of paragraph IV certification (see Docket No. FDA–2004–N–0062–0012 (comment submitted by GPhA) at 4–5, available at *http://www.regulations.gov*) (GPhA MMA Comment). Incorporation of the term ''paragraph IV acknowledgment letter'' in proposed § 314.101(b)(2) would address this concern with respect to ANDAs (see section II.J). In addition, although OGD currently sends a paragraph IV acknowledgment letter in an envelope bearing a postmark made by the U.S. Postal Service, we are proposing to broaden the definition the ''postmark'' to accommodate electronic transmissions in the future (see section II.A.2.y).

For ANDAs, OGD currently sends a ''paragraph IV acknowledgment letter'' to confirm the date on which the ANDA was received and to establish the timeframe within which an ANDA applicant must send notice of a paragraph IV certification contained in the original ANDA (see section II.D.1). The letter also provides ANDA applicants with an overview of the notice requirements associated with submission of a paragraph IV certification to a listed patent for the RLD.

For 505(b)(2) applications that rely on the Agency's finding of safety and/or effectiveness for a listed drug and include a paragraph IV certification for a listed patent, the Notification of Issues Identified during the Filing Review (filing communication), sometimes referred to as the ''74-day letter,'' would constitute the ''paragraph IV acknowledgment letter'' defined in § 314.3. Unlike the paragraph IV acknowledgment letter for ANDAs, the OND filing communication is typically sent in a franked envelope that may not bear a postmark made by the U.S. Postal Service. For purposes of § 314.52(b) and (c) (21 CFR 314.52(b) and (c)) only, the ''date of the postmark'' on the ''paragraph IV acknowledgment letter'' will be considered to be 4 calendar days after the date on which the filing communication is signed by the signatory authority (generally the Division Director or designee in the OND review division), which generally reflects the date on which the document is received by the U.S. Postal Service (see definition of ''postmark'' in proposed § 314.3). For example, if the filing communication is electronically signed by the Division Director or designee on Thursday, April 7th, the date of the postmark on the paragraph IV acknowledgment letter for the 505(b)(2) application, for purposes of § 314.52(b), would be Monday, April 11th. If OND sends the filing communication via electronic transmission in the future, then our proposed definition of ''postmark'' in § 314.3(b) would apply.

As noted previously, the paragraph IV acknowledgment letter triggers the

requirements in proposed §§ 314.52(b) and 314.95(b) for sending notice of the paragraph IV certification. The proposed difference in interpreting the term ''postmark'' as applied to paragraph IV acknowledgment letters for 505(b)(2) applications reflects current OND practice regarding the mailing of filing communications, which should occur no later than 74 days after the date of submission of the 505(b)(2) application. In addition, although an indisputable date of mailing is needed for competing ANDAs that may be eligible for a period of 180-day exclusivity, a 505(b)(2) application does not raise these concerns. We invite comment on this proposed approach or whether an alternative approach should be considered.

II.A.2.v. *Paragraph IV certification.* We are proposing to define ''paragraph IV certification'' in § 314.3(b) to mean a patent certification of invalidity, unenforceability, or noninfringement described in § 314.50(i)(1)(i)(A)(*4*) or § 314.94(a)(12)(i)(A)(*4*) for 505(b)(2) applications and ANDAs, respectively. This term is routinely used by the Agency and applicants to refer to this type of patent certification. The addition of the term ''paragraph IV certification'' to § 314.3(b) would provide a convenient means of clearly referencing the patent certification described in the section 505(b)(2)(A)(iv) and (j)(2)(A)(vii)(IV) of the FD&C Act and implementing regulations.

II.A.2.w. *Patent owner.* We are proposing to define ''patent owner'' as the owner of the patent for which information is submitted for an NDA. A patent may be owned by more than one person. If a patent owner seeks to have its designated representative receive notice of a paragraph IV certification by a 505(b)(2) or ANDA applicant that relies upon a listed drug claimed by the patent, the patent owner should ensure that current information regarding the correspondence address, in accordance with 37 CFR 1.33(d), is submitted to the PTO.

II.A.2.x. *Pharmaceutical alternatives and pharmaceutical equivalents.* We are proposing to revise the definition of ''pharmaceutical equivalents'' to clarify that this term is intended to refer to drug products in identical dosage forms *and route(s) of administration* that contain identical amounts of the identical active ingredient. The requirement for pharmaceutically equivalent products to have the same route(s) of administration is consistent with FDA's current practice, as described in section 1.2 of the preface to the Orange Book (33rd Edition, 2013, at vii). We are not proposing any changes to the definition of ''pharmaceutical alternatives.''

We are proposing to move the definitions of ''pharmaceutical alternatives'' and ''pharmaceutical equivalents'' currently in § 320.1(c) and (d) to § 314.3(b), for ease of reference and organizational convenience. The concepts of ''pharmaceutical alternatives'' and ''pharmaceutical equivalents'' are relevant to matters covered in part 314 (including but not limited to § 314.94 and proposed §§ 314.50(i)(1)(i)(C), 314.93(f), 314.96(c), and 314.97(b), discussed in section II.G.1–2, II.H, and II.I) in addition to matters in part 320 (21 CFR part 320).

II.A.2.y. *Postmark.* We are proposing to define the term ''postmark'' in § 314.3(b) to address the MMA's requirement that a 505(b)(2) or ANDA applicant send notice of its paragraph IV certification within ''20 days after the date of the postmark on the notice [*i.e.,* the paragraph IV acknowledgment letter] with which [FDA] informs the applicant that the application has been filed'' (see section 505(b)(3)(B)(i) and 505(j)(2)(B)(ii)(I) of the FD&C Act). The term ''postmark'' is not used elsewhere in section 505 of the FD&C Act or in our current regulations in part 314. In light of the transition by FDA and regulated industry to electronic communications, an interpretation of the term ''postmark'' to mean a postmark made by the U.S. Postal Service (''U.S. postmark'') could quickly become outdated. The purpose of the postmark in section 505(b)(3)(B)(i) and (j)(2)(B)(ii)(I) of the FD&C Act is to establish a verifiable date from which the 20-day notice period runs. Accordingly, we are proposing a broader definition of a ''postmark'' to mean ''an independently verifiable evidentiary record of the date on which a document is transmitted, in an unmodifiable format, to another party. For postmarks made by the U.S. Postal Service or a designated delivery service, the date of transmission is the date on which the document is received by the domestic mail service of the U.S. Postal Service or by a designated delivery service. For postmarks documenting an electronic event, the date of transmission is the date (in a particular time zone) that FDA sends the electronic transmission on its host system as evidenced by a verifiable record. If the sender and the intended recipient are located in different time zones, it is the sender's time zone that provides the controlling date of electronic transmission.'' This proposed definition of ''postmark'' is adapted from the definition of ''electronic postmark'' in regulations issued by the Internal Revenue Service (IRS) with respect to electronic filing of documents required under 26 U.S. C. 7502 (see 26 CFR 301.7502–1(d)(3)(ii)).

We invite comment on our proposed interpretation of the term ''postmark'' in the context of a paragraph IV acknowledgment letter from FDA to an applicant for a 505(b)(2) application or ANDA, and whether our regulations should be amended to define differently the specific date from which the 20-day notice period runs.

II.A.2.z. *Reference standard.* We are proposing to define ''reference standard'' as the drug product selected by FDA that an applicant seeking approval of an ANDA must use in conducting an in vivo bioequivalence study required for approval. This proposed definition reflects the Agency's longstanding use of this term, as described in the preamble to our 1992 final rule implementing the Hatch-Waxman Amendments (''FDA intends the reference listed drug to be the same drug product selected by the agency as the reference standard for bioequivalence determinations'' (57 FR 17950 at 17954). By generally designating a single drug product as the standard to which generic versions must be shown to be bioequivalent, FDA seeks to avoid possible significant variations among generic drugs, which could result if such drugs were compared to different drug products.

The reference standard is identified in the Orange Book by the word ''yes'' in the ''RLD'' column. In certain circumstances, a drug product approved in an ANDA (including a petitioned ANDA) may be designated as the reference standard for bioequivalence studies intended to support approval of an ANDA. For example, if the RLD is a drug product approved in an NDA that has been withdrawn from marketing (for reasons other than safety or effectiveness), a therapeutically equivalent drug product approved in an ANDA may be designated as the reference standard.

We recognize that the term ''reference standard'' has other meanings, including in the context of part 314 (see § 314.50(e)(1)(C)) regarding submission of representative samples of reference standards used in analytical studies, excluding pharmacopoeial reference standards). The proposed definition of ''reference standard'' applies solely to the product used in conducting an in vivo bioequivalence study required for approval.

II.A.2.aa. *Same drug product formulation.* We are proposing to move the definition of ''same drug product formulation'' currently in § 320.1(g) to § 314.3(b), without changes, for ease of reference and organizational

convenience. The term ''same drug product formulation'' is relevant to matters covered in part 314 (including but not limited to §§ 314.94 and 314.96) in addition to matters in part 320.

II.A.2.bb. *Strength.* We are proposing to define the term ''strength'' in § 314.3(b) to mean the amount of drug substance contained in, delivered, or deliverable from a drug product. The amount of drug substance contained in, delivered, or deliverable from a drug product includes: (i)(A) The total quantity of drug substance in mass or units of activity in a dosage unit or container closure (*e.g.,* weight/unit dose, weight/volume or weight/weight in a container closure, or units/volume or units/weight in a container closure) and/or, as applicable (i)(B) the concentration of the drug substance in mass or units of activity per unit volume or mass (*e.g.,* weight/weight, weight/volume, or units/volume). If these weights and measures are not applicable to a type of drug product or dosage form, then the strength of the drug product may be described by such other criteria the Agency establishes for determining the amount of drug substance contained in, delivered, or deliverable from the drug product. For example, the strength of certain drug-device combination products (such as a transdermal delivery system) may be expressed as the amount of drug substance delivered per unit time.

This proposed definition is intended to codify FDA's interpretation of the term ''strength'' in the context of section 505(j)(2)(A)(iii) of the FD&C Act. This proposed definition also will facilitate implementation of certain statutory provisions added by the MMA regarding amendments and supplements that seek approval of a ''different strength'' (see section 505(b)(4)(B) and (j)(2)(D)(ii) of the FD&C Act). Different strengths of a drug product constitute different drug products.

The amount of the drug substance ''delivered'' from a drug product is intended to describe the mass of drug substance delivered to the patient either per unit time (*e.g.,* as in transdermal delivery system) or per actuation (*e.g.,* as in metered dose inhalers) and excludes excess drug substance that although not available for labeled use, is necessary to allow for the specified total delivery (*e.g.,* a specified number of hours for a transdermal delivery system or a specified number of actuations for a metered dose inhaler).

The amount of drug substance ''deliverable from'' a drug product is intended to exclude the excess volume allowed by the U.S. Pharmacopeia (USP) (to permit withdrawal and administration of the labeled volume of an injectable product) from the description of the ''strength'' of the drug product (see 21 CFR 201.51(g)).

FDA has a longstanding history of considering a difference in the total quantity of drug substance of a parenteral product (*e.g.,* a single or multiple dose vial) or a difference in the concentration of a parenteral product to be a difference in the ''strength'' of the product for purposes of section 505(j)(2)(A)(iii) of the FD&C Act. FDA considers it important to review proposed differences in the total drug content or the concentration of a parenteral product because such changes can result in medication errors and incorrect dosing of patients. Accordingly, the strength of a parenteral drug product is determined by both criteria in paragraph (i) of the proposed definition—*i.e.,* the total quantity of drug substance in a container closure and the concentration of the drug substance.

For other dosage forms, the strength of the drug product is determined based only on the criteria in paragraph (i)(A) or (i)(B) of the proposed definition. For example, the strength of a solid oral dosage form is determined only by the total quantity of drug substance in a dosage unit (*e.g.,* a 25-milligram (mg) tablet). In contrast, the strength of a semisolid dosage form is typically determined by the concentration of the drug substance. For example, the strength of a cream is generally expressed by the concentration as a weight/weight percentage reflecting the mass of the drug substance per unit mass of the drug product.

We recognize that the weights and measures described in paragraph (i) of the proposed definition may not be applicable to all types of drug product or dosage forms. Accordingly, paragraph (ii) of the proposed definition provides that the strength of the drug product may be described by such other criteria as the Agency establishes for determining the amount of drug substance contained in, delivered, or deliverable from the drug product.

It should be emphasized that the proposed definition of strength refers to the amount of the drug substance (active ingredient), and not the amount of the active moiety, in the drug product. However, we recognize that approved drug products formulated with a salt of an acid or a base (commonly referred to as ''salt drug products'') may use the active moiety in the name rather than the drug substance to conform with a drug product naming policy established by the USP. Although the USP naming policy describes the ''strength'' of a drug product as the amount of active moiety present in the product, the strength of the drug product for purposes of section 505(j)(2)(A)(iii) of the FD&C Act is the amount of the drug substance. These approaches to describing the strength of the drug product do not conflict because if two drug products containing the same drug substance are demonstrated to have the same ''strength'' in terms of active moiety, they will always have the same strength in terms of drug substance. For example, a tablet drug product that contains 125 mg of the drug substance ''novelpril maleate'' equivalent to 100 mg of the active moiety ''novelpril'' would be expressed as ''novelpril tablet 100 mg.'' Based on the proposed definition in § 314.3(b), the strength of the drug product is 125 mg of the drug substance ''novelpril maleate.'' The label for this product would describe both the ''strength'' expressed in terms of active moiety and the strength expressed in terms of drug substance. The Agency recognizes that this naming policy will result in situations in which the ''strength'' that directly follows the drug product name for such products will be expressed in terms of active moiety and not in terms of drug substance, and that this might be confusing. FDA seeks comment on this approach to the proposed definition of strength in light of these considerations.

We also generally invite comment on whether this proposed definition adequately encompasses the broad range of dosage forms and drug products to which a proposed definition of ''strength'' in § 314.3(b) would apply.

II.A.2.cc. *Substantially complete application.* The MMA defines the term ''substantially complete application'' for purposes of section 505(j)(5) of the FD&C Act (see section 505(j)(5)(B)(iv)(II)(cc) of the FD&C Act). We are proposing to define ''substantially complete application'' in § 314.3(b) to incorporate this statutory definition with minor editorial revisions. As proposed, a ''substantially complete application'' would mean an ANDA that on its face is sufficiently complete to permit a substantive review and contains all the information required under section 505(j)(2)(A) of the FD&C Act and § 314.94. For an application to be substantially complete, any information referenced in the application must have been provided to the Agency. For example, FDA will refuse to receive an ANDA for which a referenced Drug Master File has not been submitted or that omitted relevant stability or bioequivalence data as of the date of submission of the ANDA. There may be other bases for finding that an application is not substantially

complete—for example, electronic submissions that are not readable or do not follow FDA's recommendations for electronic application format may be determined to be not substantially complete and refused for receipt.

In addition, we are proposing conforming revisions to § 314.101(b) to clarify that receipt of an ANDA means that FDA has made a threshold determination that the ANDA is substantially complete (see section II.J). Our proposed replacement of the current criterion ''sufficiently complete to permit a substantive review'' with the synonymous term ''substantially complete application'' is not intended to alter the meaning. Rather, we are seeking to use defined terms consistently throughout our regulations.

II.A.2.dd. *Tentative approval.* The MMA defines the term ''tentative approval'' for purposes of section 505(j)(5) of the FD&C Act to mean ''notification to an applicant by the Secretary that an [ANDA] meets the requirements of [section 505(j)(2)(A)], but cannot receive effective approval because the application does not meet the requirements of [section 505(j)(5)(B)], there is a period of exclusivity for the listed drug under [section 505(j)(5)(F)] or section 505A, or there is a 7-year period of exclusivity for the listed drug under section 527'' (section 505(j)(5)(B)(iv)(II)(dd)(AA) of the FD&C Act). We are proposing to define ''tentative approval'' in § 314.3(b) to incorporate the statutory text and extend this general definition, with appropriate conforming revisions, to include tentative approval of an NDA (including a 505(b)(2) application).

Proposed § 314.3(b) defines ''tentative approval'' to mean the notification that an NDA (including a 505(b)(2) application) or ANDA otherwise meets the requirements for approval under the FD&C Act, but cannot be approved because there is unexpired orphan drug exclusivity for a listed drug, or that a 505(b)(2) application or ANDA otherwise meets the requirements for approval under the FD&C Act, but cannot be approved until the conditions in § 314.107(b)(1)(iii), (b)(3), or (c) are met, because there is a period of exclusivity for the listed drug under § 314.108 or section 505A of the FD&C Act (21 U.S. C. 355a), or because a court order pursuant to 35 U.S. C. 271(e)(4)(A) orders that the application may be approved no earlier than the date specified. Proposed § 314.107(b)(4) describes the circumstances in which FDA will issue a tentative approval letter (see section II.M.2.d).

The proposed definition of ''tentative approval'' clarifies that a drug product that is granted tentative approval is not an approved drug and will not be approved until FDA issues an approval letter after any necessary additional review of the NDA or ANDA (compare section 505(j)(5)(B)(iv)(II)(dd)(BB) of the FD&C Act). We have proposed minor editorial revisions to the limitation described in the statute to replace references to ''effective approval'' of an NDA or ANDA with language reflecting our current practice. As discussed in section II.K, the Agency does not issue approval letters with delayed effective dates.

II.A.2.ee. *The list.* We are proposing to revise the definition of ''the list'' to mean the list of approved drug products published in FDA's current ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' available electronically on FDA's Web site (*http://www.fda.gov/cder*). These clarifying revisions reflect our longstanding practice of relying upon the electronic version of the Orange Book (currently available at *http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm*), which is updated on a regular basis and can be accessed from FDA's Web site. We are proposing to delete the words ''current edition,'' ''any current supplement,'' and ''publication'' from the definition as these phrases imply reference to a printed version. As discussed in section II.B.3, the Agency no longer arranges for publication of an annual printed edition or monthly printed supplements to the Orange Book.

Although the format of the electronic version of the Orange Book may change with advances in technology, FDA intends to maintain a publicly available version of *the list* that includes, among other things: Approved NDAs and ANDAs; therapeutic equivalence evaluations (as applicable); exclusivity granted to a listed drug; patents submitted for listing by the NDA holder; use codes for method-of-use patents; requests to remove a patent from the list; and, upon request on a prospective basis, the date on which patents are received by FDA for listing.

II.A.2.ff. *Therapeutic equivalents.* We are proposing to define ''therapeutic equivalents'' as approved drug products that are pharmaceutical equivalents and for which bioequivalence has been demonstrated. Therapeutic equivalents can be expected to have the same clinical effect and safety profile when administered to patients under the conditions of use specified in the labeling. This proposed definition reflects the Agency's longstanding interpretation of this term as set forth in section 1.2 of the preface to the Orange Book (33rd Edition, 2013, at vii).

II.A.3. Proposed Amendments to Definitions in Current § 314.108

As discussed in sections II.A.1, II.A.2.f, and II.A.2.n, we are proposing to move the definitions of the terms ''active moiety'' and ''date of approval'' from § 314.108(a) to § 314.3(b). We are proposing to amend § 314.108 to state that the definitions in § 314.3 (in addition to other definitions in § 314.108) apply to § 314.108.

We also are proposing to add a definition of ''bioavailability study'' to § 314.108(a) to clarify the scope of this term as used in section 505(c)(3)(E)(iii), (c)(3)(E)(iv), (j)(5)(F)(iii), and (j)(5)(F)(iv) of the FD&C Act and § 314.108(b)(4) and (b)(5) regarding certain exclusivity determinations. The FD&C Act provides that a ''bioavailability study'' is not a type of ''new clinical investigations . . . essential to the approval of the application [or supplement] and conducted or sponsored by the applicant'' eligible for a 3-year period of exclusivity during which a 505(b)(2) application or ANDA may not be approved for the same conditions of approval (see section 505(c)(3)(E)(iii), (c)(3)(E)(iv), (j)(5)(F)(iii), and (j)(5)(f)(iv) of the FD&C Act; see also § 314.108(b)(4) and (b)(5)).

The proposed definition of ''bioavailability study'' means a study to determine the bioavailability or the pharmacokinetics of a drug. This definition incorporates by reference the revised definition of ''bioavailability'' proposed in § 314.3. This proposed revision is intended to clarify that a pharmacokinetic study, which generally is conducted in the same manner as a bioavailability study, also is not eligible for 3-year exclusivity. Although not specifically defined in part 314, the term ''pharmacokinetics'' is generally understood to refer to the way a drug is handled by the body, which is described by pharmacokinetic measures (such as area under the curve and concentration at the maximum) and other derived measures (such as clearance, half-life, and volume of distribution). The values of these measures reflect the absorption (A), distribution (D), and elimination (E) of a drug from the body. A drug can be eliminated by both metabolism (M) to one or more active and inactive metabolites and excretion of the unchanged drug. The overall set of processes is often referred to as ADME, which ultimately controls systemic exposure to a drug and its metabolites after drug administration.

II.A.4. Definitions in Current § 320.1

We are proposing to move the definitions in current § 320.1(a) through (g) to § 314.3(b). We are proposing this change for ease of reference because certain terms defined in current § 320.1 already are set forth in other parts of our regulations (*e.g.,* ''bioequivalence''). Proposed § 320.1 would simply state that the definitions in § 314.3(b) apply to part 320.

II.B. Submission of Patent Information (Proposed § 314.53)

II.B.1. General Requirements for Submission of Patent Information (Proposed § 314.53(b) and (c))

Section 314.53(b) of our regulations requires that an applicant submitting an NDA (including a 505(b)(2) application), an amendment to an NDA, or, except as provided in § 314.53(d)(2), a supplement to an approved application, submit the patent information described in § 314.53(c) on Forms FDA 3542a and 3542 with the filing or upon and after approval, respectively. The information provided in Form FDA 3542 for any patent which claims the drug or a method of using the drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug is published in the Orange Book after approval of the NDA or the supplement.

In the **Federal Register** of April 30, 2007 (72 FR 21266), we responded to comments submitted to FDA regarding FDA's request for an extension of approval of the collection of information related to patent submission and listing requirements involving Forms FDA 3542a and 3542 (April 2007 notice). At that time, we made certain revisions to Forms FDA 3542a and 3542 and the instructions for completing those forms to clarify acceptable practices in accordance with our existing regulations. Other proposed changes to Forms FDA 3542a and 3542 would have required revisions to the regulations upon which the requirements in Forms FDA 3542a and 3542 are based. In sections II.B.1.a and II.B.2.a, we propose certain revisions to the content of patent information submitted to FDA and the circumstances under which submission of patent information is required. These changes to the required submission of patent information are intended to clarify the basis for requiring certain information, revise and streamline our requirements, and describe acceptable approaches to compliance with applicable regulations.

Table 2 summarizes the proposed changes related to reporting requirements for submission of patent information:

TABLE 2—HIGHLIGHTS OF PROPOSED CHANGES REGARDING PATENT REPORTING REQUIREMENTS [1]

Current regulations	Proposed revisions to regulations
General Requirements (§ 314.53(c)(1)) Patent information will not be accepted unless it is complete and submitted on the appropriate forms (Form FDA 3542a or 3542).	*General Requirements (§ 314.53(c)(1))* • Patent information will not be accepted unless it is submitted on the appropriate forms (Form FDA 3542a or 3542) and contains the information required in § 314.53(c)(2).
Reporting Requirements (§ 314.53(c)(2)) The required information and verification in § 314.53(c)(2)(i) and (c)(2)(ii) includes: • Information on whether the patent has been submitted previously for the NDA. • Information on whether the patent is a re-issued patent of a patent submitted previously for listing for the NDA or supplement.	*Reporting Requirements (§ 314.53(c)(2))* The required information and verification in § 314.53(c)(2)(i) and (c)(2)(ii) includes: • Information on whether the drug substance patent claims a polymorph that is the same active ingredient that is described in the pending NDA or supplement, and, if so, has test data described in § 314.53(b)(2). • Information on whether the drug substance patent claims *only* a polymorph that is the same active ingredient that is described in the pending NDA or supplement, and, if so, has test data described in § 314.53(b)(2).
Method-of-Use Patents (§ 314.53(c)(2)(i)(O) and (c)(2)(ii)(P)) The required information and verification in § 314.53(c)(2)(i) and (c)(2)(ii) includes: • Information on each method-of-use patent including the following: (*2*) Identification of the specific section of the proposed labeling for the drug product that corresponds to the method of use claimed by the patent submitted (*3*) The description of the patented method of use as required for publication.	*Method-of-Use Patents (§ 314.53(c)(2)(i)(O) and (c)(2)(ii)(P))* The required information and verification in § 314.53(c)(2)(i) and (c)(2)(ii) includes: • Information on each method-of-use patent including the following: (*2*) Identification of the specific section(s) of the proposed labeling for the drug product that corresponds to the method of use claimed by the patent submitted (if the scope of the method-of-use claim(s) of the patent does not cover every use of the drug, the applicant must identify only the specific portion(s) of the indication or other condition of use claimed by the patent); (*3*) The description of the patented method of use as required for publication (which must contain adequate information to assist 505(b)(2) and ANDA applicants in determining whether a listed method-of-use patent claims a use for which the 505(b)(2) or ANDA applicant is not seeking approval).
[No corresponding regulation]	*Exceptions to Required Submission of Patent Information (§ 314.53(c)(2)(i)(S) and 314.53(c)(2)(ii)(T))* • If the applicant submits information for a patent that claims the drug substance (active ingredient) and meets the requirements for listing on that basis, then the applicant is not required to provide information on whether that patent also claims the drug product (composition/formulation). • If the applicant submits information for a patent that claims the drug product (composition/formulation) and meets the requirements for listing on that basis, then the applicant is not required to provide information on whether that patent also claims the drug substance (active ingredient).

TABLE 2—HIGHLIGHTS OF PROPOSED CHANGES REGARDING PATENT REPORTING REQUIREMENTS [1]—Continued

Current regulations	Proposed revisions to regulations
	• However, an applicant that submits information for a method-of-use patent must also submit information regarding whether that patent also claims either the drug substance or the drug product.

[1] These highlights describe important proposed revisions to our regulations, but should not be relied upon in place of the proposed regulation.

II.B.1.a. *Drug substance (active ingredient) and drug product (formulation or composition) patents.* We are proposing to revise § 314.53(c)(1) to clarify that FDA accepts patent information submitted on Form FDA 3542a or 3542, as appropriate, as long as the form contains the information required in § 314.53(c). The statement in our current regulations that FDA ''will not accept the patent information unless it is complete . . .'' has generated confusion in some cases, particularly where a portion of the specific information requested in a section on FDA Form FDA 3542a or 3542 was not applicable to the patent for which the form was submitted. By proposing to revise § 314.53(c)(1) to state that we will not accept the patent information unless it ''contains the information required in paragraph (c)(2) of this section,'' we are clarifying that FDA will accept a submission of patent information on Form FDA 3542a or 3542, as appropriate, that omits patent information requested on the form where that omission is permitted under an exception in § 314.53(c)(2).

We are proposing to add § 314.53(c)(2)(i)(S) and (c)(2)(ii)(T) to describe exceptions to the required submission of patent information. Proposed § 314.53(c)(2)(i)(S)(*1*) and (c)(2)(ii)(T)(*1*) state that if a patent claims the drug substance that is the active ingredient in the drug product for which approval is sought or has been granted, respectively, and is eligible for listing in the Orange Book, it is not necessary for an applicant to provide information on whether the patent also claims the drug product. Similarly, we are proposing to add § 314.53(c)(2)(i)(S)(*2*) and (c)(2)(ii)(T)(*2*) to provide that if a patent claims the drug product for which approval is sought or has been granted, respectively, and is eligible for listing in the Orange Book, it is not necessary for an applicant to provide information on whether the patent also claims the drug substance that is the active ingredient in the drug product. These proposed revisions to our regulations provide that an applicant need only satisfy the requirements for patent listing set forth in section 505(b)(1) and (c)(2) of the FD&C Act and, subject to § 314.53(c)(2)(i)(O)(*3*) and (c)(2)(ii)(P)(*4*), discussed in this section of the document, need not identify each basis on which the patent claims the drug. The designation of a patent as claiming the drug substance and/or drug product for purposes of listing in the Orange Book is not intended to define the scope of the patent claims that an NDA holder or patent owner may assert against a 505(b)(2) or ANDA applicant based on a listed patent.

Whether or not the applicant provides information stating that the patent claims the drug substance or the drug product, an applicant must submit information regarding whether the patent claims one or more methods of using the drug product for which approval is sought or has been granted (method-of-use patent). We are proposing to add § 314.53(c)(2)(i)(O)(*3*) and (c)(2)(ii)(P)(*4*) to confirm that the proposed exceptions to required submission of patent information do not alter the requirements for submission of method-of-use patent information. The information regarding method-of-use patents is required for implementation of the patent certification and statement provisions of the FD&C Act. Section 505(b)(2)(B) and (j)(2)(A)(viii) of the FD&C Act provide that a 505(b)(2) and ANDA applicant, respectively, may submit a statement for a method-of-use patent which does not claim a use for which the applicant is seeking approval, instead of a patent certification under section 505(b)(2)(A)(iii) or 505(j)(2)(A)(vii)(III) of the FD&C Act (paragraph III certification) or a paragraph IV certification to the listed patent. Information on whether a patent claims the drug substance or drug product in addition to whether the patent claims one or more methods of use is required because a 505(b)(2) or ANDA applicant that avails itself of the statutory provision that permits it to not seek approval of a method of use claimed by the patent (and carve out from product labeling the method-of-use information claimed by the patent) would still be required to submit a patent certification with respect to any drug substance or drug product claims covered by the same listed patent (see Letter from Janet Woodcock, M.D., Director, CDER, to Rosemarie R. Wilk-Orescan, Novo Nordisk Inc., and James F. Hurst, Winston & Strawn LLP, dated December 4, 2008, regarding Docket Nos. FDA–2008–P–0343–0009 and FDA–2008–P–0411–0006, available at *http://www.regulations.gov*) (Repaglinide Citizen Petition Response). For example, a 505(b)(2) or ANDA applicant may submit a statement under section 505(b)(2)(B) or 505(j)(2)(A)(viii), respectively, of the FD&C Act for a method-of-use patent that does not claim a use for which the applicant is seeking approval and a paragraph IV certification for any remaining drug substance, drug product, or other method-of-use claims covered by the same patent. This approach is sometimes described as a ''split certification'' to the patent.

We note that a 505(b)(2) or ANDA applicant that submitted a paragraph IV certification in addition to a statement under section 505(b)(2)(B) or 505(j)(2)(A)(viii) of the FD&C Act must comply with the notice requirements for a paragraph IV certification and may be subject to a 30-month stay of approval if patent infringement litigation is initiated within the statutory timeframe. An ANDA applicant that submitted a paragraph IV certification and a statement pursuant to section 505(j)(2)(A)(viii) of the FD&C Act to a listed patent also may be eligible for 180-day exclusivity based on its paragraph IV certification if the applicant is a ''first applicant'' and meets other statutory and regulatory requirements.

II.B.1.b. *Drug substance patents that claim only a polymorph of the active ingredient.* Section 314.53(c)(2)(i)(M)(*2*) and (c)(2)(ii)(N)(*2*) currently require submission of information on whether the patent claims a polymorph (generally, a drug substance with a different crystalline (including solvates and hydrates) or amorphous form of the same drug substance) that is the same active ingredient as that described in the pending NDA, amendment, or supplement. We explained in the preamble to the June 2003 final rule that ''it would be consistent to interpret 'drug substance' for patent submission and listing purposes as including certain drug substances having different physical forms if they would be

considered the same active ingredient for ANDA approval purposes'' (68 FR 36676 at 36678).

We are proposing to revise these regulations to state that an applicant is only required to provide information on whether the patent claims a polymorph that is the same active ingredient described in the pending NDA, amendment, or supplement if the only basis on which the patent is eligible for listing is that it claims the polymorph. Based on comments received from industry on this issue (see April 2007 notice) and inquiries from applicants regarding completion of Forms FDA 3542a and 3542, we have tentatively concluded that our regulations need to be modified. With respect to a patent that claims the drug substance or drug product described in the pending NDA, amendment, or supplement *and* one or more polymorphic forms of the drug substance, an applicant is not required to provide information on whether the patent claims a polymorph if the patent otherwise meets the statutory requirements for submission of patent information regarding the drug substance or drug product.

Similarly, we are proposing to make conforming revisions to § 314.53(b)(1), (b)(2), (c)(2)(i)(M)(*3*), and (c)(2)(ii)(N)(*3*) to provide that the applicant certification regarding test data required by § 314.53(b) applies only to patents that claim only a polymorph. This provision also had generated confusion, and we are proposing revisions for clarification.

II.B.1.c. *Method-of-use patents.* Section 314.53(b)(1) currently states that an applicant ''shall separately identify each pending or approved method of use and related patent claim.'' This text has been subject to differing interpretations by applicants as to whether our regulations require submission of patent information (and completion of Forms FDA 3542a and 3542) on a claim-by-claim basis. In the June 2003 final rule, we explained that we require identification of individual patent claims for method-of-use patents to assist 505(b)(2) and ANDA applicants in determining whether a listed method-of-use patent claims a use for which the 505(b)(2) or ANDA applicant is not seeking approval (see 68 FR 36676 at 36682 and 36685). In the April 2007 notice, we clarified that ''consistent with our regulations at § 314.53(b)(1), . . . an applicant may list together multiple patent claims for each pending or approved method of use. However, each pending or approved method of use must be separately identified and therefore will require separate listing(s) of method-of-use information in section 4 of Forms FDA 3542a and 3542. Therefore, if a patent claims one or more methods of use that apply to a pending application or approved product, each pending or approved method of use would need to be listed separately along with the patent claim number(s) for the patent claim(s) for the pending or approved method of use. A single Form FDA 3542a or Form FDA 3542, as appropriate, may be used to list a patent claiming more than one method of use, provided that each method of use is listed separately along with the patent claim number(s) for the patent claim(s) for the pending or approved method of use. This regulatory approach accomplishes the statutory objective of providing adequate information to permit ANDA and 505(b)(2) applicants to file statements which assert that the method-of-use patent does not claim a use for which the applicant is seeking approval'' (72 FR 21266 at 21268).

We are proposing to revise § 314.53(b)(1) by replacing the word ''claim'' with ''claim(s)'' in the phrase ''shall separately identify each pending or approved method of use and related patent claim.'' This proposed revision is intended to further clarify that an applicant may list together multiple patent claims for a pending or approved method of use on Forms FDA 3542a and 3542, respectively. However, each pending or approved method of use must be separately identified and therefore will require separate listing(s) of method-of-use information in section 4 of Forms FDA 3542a and 3542.

We also are proposing to revise § 314.53(b)(1), (c)(2)(i)(O)(*2*), (c)(2)(ii)(P)(*2*) and (c)(2)(ii)(P)(*3*) to enhance compliance by NDA applicants with the requirements for identifying the specific section(s) of product labeling that correspond to the method of use claimed by the patent and, upon approval, describing the approved method of use claimed by the patent, as required for publication in the Orange Book. Proposed § 314.53(b)(1) would expressly require that if the scope of the method-of-use claim(s) of a patent does not cover every use of the drug, the applicant must identify only the specific sections of product labeling that correspond to the specific portion(s) of the indication or other condition of use claimed by the patent. The specific product labeling that corresponds to the protected use may appear in sections of the labeling other than ''Indications and Usage.'' This proposed revision and conforming revisions to proposed § 314.53(c)(2)(i)(O)(*2*) and (c)(2)(ii)(P)(*2*) would address situations in which the scope of the method of use claimed by the patent is narrower than the indication or other condition of use described in product labeling. In such cases, the NDA applicant must identify only the specific sections of product labeling that correspond to the portion(s) of the indication or other condition of use claimed by the patent and not the broader indication or other condition of use in the product labeling which may include, but not be limited to, the use claimed by the patent. Accurate identification of the specific sections of product labeling that correspond to the use claimed by the patent is necessary to enable FDA to implement section 505(b)(2)(B) and (j)(2)(A)(viii) of the FD&C Act, which permit 505(b)(2) and ANDA applicants to omit protected conditions of use from labeling. This information regarding product labeling also is necessary for FDA to evaluate whether the omission of aspects of the listed drug's labeling protected by patent would render the proposed drug product less safe or effective than the listed drug for all remaining non-protected conditions of use and preclude approval (see § 314.127(a)(7); see also § 314.94(a)(8)(iv)).

Proposed § 314.53(c)(2)(ii)(P)(*3*) would codify our longstanding requirement that the NDA applicant's description of the patented method of use (the ''use code'') required for publication in the Orange Book must contain adequate information to assist FDA and 505(b)(2) and ANDA applicants in determining whether a listed method-of-use patent claims a use for which the 505(b)(2) or ANDA applicant is not seeking approval. If the scope of the method-of-use claim(s) of the patent does not cover every approved use of the drug, the NDA holder's ''use code'' must contain only the specific portion(s) of the indication or other method of use claimed by the patent. This requirement is necessary to effectively implement the statutory provisions that permit 505(b)(2) and ANDA applicants to submit a statement that the applicant is not seeking approval for the use claimed in the listed patent instead of a patent certification to the listed patent with respect to the method of use claim(s) (see section 505(b)(2)(B) and (j)(2)(C)(viii) of the FD&C Act, respectively). We require the NDA holder to submit an accurate description, subject to the verification requirements in § 314.53(c)(2)(ii)(R), of the method of use within the scope of the patent that claims an approved use of the drug to implement these statutory provisions. As the U.S. Supreme Court noted in *Caraco Pharm. Labs.* v. *Novo*

Nordisk A/S: ''An overbroad use code . . . throws a wrench into the FDA's ability to approve generic drugs as the statute contemplates'' (132 S. Ct. 1670, at 1684 (2012)).

II.B.1.d. *Patents previously submitted for listing.* We are proposing to revise §§ 314.53(c)(2)(i)(J) and (c)(2)(ii)(K) to remove the requirement that an applicant provide information regarding whether the patent has been submitted previously for the NDA or supplement. This requirement was intended to assist the Orange Book staff with their administrative listing responsibilities (see 68 FR 36676 at 36686). In response to a request for clarification of the purpose of this inquiry (see 72 FR 21266 at 21269) and to streamline the patent information submission requirements, we are proposing to revise §§ 314.53(c)(2)(i)(J) and (c)(2)(ii)(K) to request information on whether the patent is a reissuance of a patent submitted previously for listing in the Orange Book for the NDA or supplement, including the original patent number of the listed patent (see section II.B.1.e).

If a patent has been submitted previously for listing in the Orange Book, we currently request information on whether the expiration date is a new expiration date (§ 314.53(c)(2)(i)(K) and (c)(2)(ii)(L)). For example, a patent expiration date may be extended after NDA approval in response to a request for patent term restoration pursuant to 35 U.S.C. 156 (see proposed § 314.53(f)(2)(ii), discussed in section II.B.4.b). We are continuing to request this information.

We note that our proposed revisions to the patent information submission requirements for supplements to an approved NDA (see section II.B.2.a) are designed to identify, among other things, whether patents previously submitted for listing for the underlying NDA continue to claim the changed product as approved in the supplement.

II.B.1.e. *Reissued patents.* We are proposing certain revisions to our regulations to describe our requirements regarding submission of information related to patents that have been reissued by the PTO. Generally, a patent may be reissued to correct certain errors in the scope of claims or defects in a specification or drawing that otherwise would have invalidated, in whole or in part, the patent (see 35 U.S.C. 251). Accordingly, a reissued patent may affect both the patent certification or statement submitted by a 505(b)(2) or ANDA applicant and the infringement claims that could be asserted by the patent owner or NDA holder.

Although we recognize that the original patent is surrendered upon patent reissuance (see 37 CFR 1.178(a)), we are proposing to treat the original patent and the reissued patent as a ''single bundle'' of patent rights, albeit patent rights that may have changed with reissuance, for purposes of administering the patent certification requirements of the FD&C Act and any 30-month stay of approval or 180-day exclusivity that relates to a paragraph IV certification to the original patent (see discussion in section II.E.4). FDA's role in listing patents remains ministerial (see 59 FR 50338 at 50349, October 3, 1994 (1994 final rule); 68 FR 36676 at 36687 (June 2003 final rule)); however, we are mindful of the implications of reissued patents in fulfilling our statutory obligations regarding implementation of the patent certification and statement, 30-month stay, 180-day exclusivity, and tentative approval provisions of the FD&C Act. We are proposing these revisions to describe the responsibilities of an NDA applicant associated with listing a reissued patent. The requirements for a 505(b)(2) or ANDA applicant to provide an appropriate patent certification or statement to a reissued patent are discussed in section II.E.4).

We currently receive submissions of patent information for reissued patents and list those patents that are eligible for listing in the Orange Book. Reissued patents are identified by the PTO with the letters ''RE'' preceding the patent number and, because a patent is reissued for the unexpired part of the term of the original patent, have the same expiration date as the original patent. If the scope of claims was narrowed or broadened upon reissuance, the NDA applicant or holder may submit a reissued patent for listing in the Orange Book with a revised designation of whether the patent claims the drug substance, drug product, and/or a method or use, or with a revised use code.

Proposed § 314.53(c)(2)(i)(J) and (c)(2)(ii)(K) would provide that an NDA applicant or holder is required to include information on whether a patent submitted for listing is a reissuance of a patent previously submitted for listing for the NDA or supplement. Submission of patent information for reissued patents is subject to the 30-day timeframe for timely filed patent information set forth in section 505(c)(2) of the FD&C Act. As discussed further in section II.B.2.b, the timely filing of patent information for a reissued patent (including a reissued patent with a broadened scope of claims) does not alter the patent certification obligations of a 505(b)(2) or ANDA applicant whose application was pending when the original patent was filed by the holder of an approved application for listing more than 30 days after patent issuance (''late listed''). In other words, if a 505(b)(2) or ANDA applicant is not required to provide a patent certification or statement to the original patent pursuant to § 314.50(i)(4) or § 314.94(a)(12)(vi) because the patent was late listed, the 505(b)(2) or ANDA applicant would not be required to provide a patent certification or statement to the reissued patent even if timely filed following reissuance. This approach recognizes that the original and reissued patents comprise a ''single bundle'' of patent rights, which first became relevant to approval of 505(b)(2) applications and ANDAs with the submission of the patent information prior to reissuance. As described in section II.E.3, the date of submission of the original patent information also determines the availability of a 30-month stay arising from patent infringement litigation resulting from notice of a paragraph IV certification to the original or reissued patent (see section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act).

An original patent that has been reissued would remain listed in the Orange Book until FDA determined that any first ANDA applicant is no longer eligible for 180-day exclusivity or the 180-day exclusivity period has expired (see section II.E.4). We intend to designate original patents that have been reissued and remain listed in the Orange Book for this reason with the suffix ''*RE'' based on information submitted by the NDA applicant or holder in accordance with § 314.53(c)(2)(ii)(K). In the absence of this designation, an applicant that submits an ANDA after a reissued patent is listed in the Orange Book may not provide a patent certification or statement with respect to the original patent. Instead, the ANDA applicant must provide a patent certification or statement to the reissued patent.

Should the scope of a reissued patent be narrowed such that it is no longer eligible for listing under section 505(b)(1) or 505(c)(2) of the FD&C Act, the NDA holder is required to request that the patent or patent information be removed from listing in the Orange Book (''patent delisting''), subject to the exceptions set forth in proposed § 314.53(f)(2) (see discussion in section II.B.4.b).

II.B.2. When and Where To Submit Patent Information (Proposed § 314.53(d))

Table 3 summarizes the proposed changes regarding when and where to submit patent information:

TABLE 3—HIGHLIGHTS OF PROPOSED CHANGES REGARDING SUBMISSION OF PATENT INFORMATION [1]

Current regulations	Proposed revisions to regulations
Supplements (§ 314.53(d)(2)(i))	*Supplements (§ 314.53(d)(2)(i)).*
• Applicant must submit patent information required under § 314.53(c) for a patent that claims the drug, drug product, or method of use for which approval is sought in a supplement:	• Applicant must submit patent information required under § 314.53(c) for a patent that claims the drug substance, drug product, or method of use for which approval is sought in a supplement:
(A) to change the formulation;	(A) to change the dosage form or route of administration;
(B) to add a new indication or other condition of use;	(B) to change the strength; or
(C) to change the strength;	(C) to change the drug product from prescription to OTC use.
(D) to make any other patented change regarding the drug, drug product, or method of use..	
Supplements (§ 314.53(d)(2)(ii))	*Supplements (§ 314.53(d)(2)(ii)).*
If an applicant submits a supplement for a change described in § 314.53(d)(2)(i), the following patent information submission requirements apply:	If an applicant submits a supplement for a change other than one described in § 314.53(d)(2)(i), the following patent information submission requirements apply:
• If previously submitted patent information claims the changed product, the applicant must submit a certification with the supplement identifying the patents that claim the changed product.	• If previously submitted patent information claims the changed product, the applicant is not required to resubmit this patent information unless the description of the patented method of use would change upon approval of the supplement, and FDA will continue to list this patent information for the product;
• If no patents, including previously submitted patents, claim the changed product, it must so certify.	• If previously submitted patent information no longer claims the changed product, the applicant must submit a request to remove that patent information from the list at the time of approval of the supplement;
	• If one or more existing drug substance, drug product, or method-of-use patents claim the changed drug product for which approval is sought in the supplement and such patent information has not been submitted to FDA, the applicant must submit the patent information required under § 314.53(c).
Patent information deadline (§ 314.53(d)(3))	*Newly issued patents (§ 314.53(d)(3)).*
• If a patent is issued for a drug, drug product, or method of use after an application is approved, the applicant must submit to FDA the required patent information within 30 days of the date of patent issuance.	• If a patent is issued for a drug substance, drug product, or method of use after an NDA is approved, the applicant must submit to FDA the required patent information within 30 days of the date of patent issuance.
	• If the required patent information is not submitted within 30 days of patent issuance, FDA will list the patent, but patent certifications will be governed by the provisions regarding untimely filed patents at §§ 314.50(i)(4) and (i)(6) and 314.94(a)(12)(vi) and (a)(12)(viii).
Late submission of patent information (§§ 314.50(i)(4) and 314.94(a)(12)(vi)).	*Untimely filing of patent information (§§ 314.50(i)(4) and 314.94(a)(12)(vi)).*
• [Provision directed to submission of required patent information in general.].	• Except as provided in § 314.53(f)(1), an NDA holder's amendment to the description of the approved method(s) of use claimed by the patent will be considered untimely filing of patent information if:
	—the amendment is submitted more than 30 days after patent issuance and it is not related to a corresponding change in approved product labeling; or
	—the amendment is submitted more than 30 days after a corresponding change in approved product labeling.
Copies (§ 314.53(d)(4))	*Submission of Forms FDA 3542a and 3542 (§ 314.53(d)(4)).*
• Applicant must submit an archival copy and a copy for the chemistry, manufacturing, and controls (CMC) section of the review copy to the CDER Central Document Room.	• Applicant must submit patent information required by § 314.53(c)(1) and (c)(2)(i), § 314.50(h), or § 314.70(f) on Form FDA 3542a to the CDER Central Document Room at the address identified on FDA's Web site.
	○ Form FDA 3542a should not be submitted to the Orange Book Staff in the Office of Generic Drugs.
• Applicant must submit patent information by letter separate from, but at the same time as, submission of the supplement.	• Applicant must submit patent information required by § 314.53(c)(1) and (c)(2)(ii) on Form FDA 3542 to the Office of Generic Drugs, Document Room, Attention: Orange Book Staff.
Submission date (§ 314.53(d)(5))	*Submission date (§ 314.53(d)(5)).*
• Patent information will be considered submitted to FDA as of the date the information is received by the Central Document Room.	• Patent information will be considered submitted to FDA for purposes of § 314.53(d)(3) as of the earlier of the date the information submitted on Form FDA 3542 is date-stamped by the Office of Generic Drugs, Document Room, or officially received electronically by FDA through the Electronic Submissions Gateway.

[1] These highlights describe important proposed revisions to our regulations, but should not be relied upon in place of the proposed regulation.

II.B.2.a. *Submission of patent information for NDA supplements (proposed § 314.53(d)(2)).* We are proposing to revise the requirements for submission of patent information for NDA supplements to reduce duplicative submissions of patent information and enhance efficiency.

Section 314.53(c) requires submission of patent information for certain types of supplements that relate to the drug product or a method of using the drug product, namely those supplements that seek approval to change the formulation, add a new indication or other condition of use, change the strength, or make any other patented change regarding the drug, drug product, or any method of use (see § 314.53(d)(2)(i)(A) through (d)(2)(i)(D)). This approach avoided unnecessary resubmission of patent information with supplements that did not involve a change to the drug product or a method of using the product or involved a change that could not be patented (see 54 FR 28872 at 28910, July 10, 1989; and 59 FR 50338 at 50344). We are proposing to eliminate certain of these patent information submission requirements for supplements that seek approval for a change to an approved product and for which existing patents listed in the Orange Book for the specific drug product that is the subject of the supplement continue to claim the changed product (see proposed § 314.53(d)(2)(ii)(A)). These proposed revisions to our regulations also address a comment submitted by an association representing research-based pharmaceutical and biotechnology companies that ''submission of Forms FDA 3542a and 3542 with submission and upon approval, respectively, of an NDA supplement is redundant where the information has not changed since the form last was filed, imposes a burden on sponsors, and serves no statutory purpose'' (72 FR 21266 at 21270).

Our proposed revisions to § 314.53(d)(2) would create two broad categories of supplements for purposes of patent information submission based on whether the supplement is a type for which approval would result in a new entry in the Orange Book. For supplements that seek approval for a change that will result in a new entry in the Orange Book (*e.g.,* a change to the dosage form, route of administration, strength (including changes to concentration or total drug content), or prescription drug status (*i.e.,* change the drug product from prescription use to over-the-counter (OTC) use)), an applicant must continue to submit patent information required under § 314.53(c) with submission of the supplement and following approval, respectively. Although these types of changes may not necessarily result in a submission of different patent information, by requiring an NDA holder to submit complete patent information for a supplement that, if approved, would result in a new entry in the Orange Book, we ensure that patent information listed for the new entry clearly expresses the NDA holder's view regarding which patent(s) claim the drug or a method of using the drug as approved in the supplement. For example, different strengths of a drug product may have different patent coverage with respect to method-of-use patents that claim a dosing regimen or indication. In such a case, patent information would be required to be submitted with the filing of the NDA supplement and would be required to be submitted upon approval of the NDA supplement. This submission of patent information on Forms FDA 3542a and 3542 would, among other things, identify with specificity the new method of use claimed by the patent with reference to the proposed or approved labeling, respectively, for the drug product. If the patents listed for the approved NDA also claim the drug or method of using the drug for which approval is sought in the NDA supplement, we will permit an applicant to submit a statement declaring that the patents currently listed for a specific NDA (identified by NDA number and product number as listed in the Orange Book) also claim the drug or method of using the drug for which approval is sought in the NDA supplement, if this statement is accompanied by the signed patent declaration verification required by § 314.53(c)(2)(i)(Q) and (c)(2)(ii)(R) and if patent information required by § 314.53(c)(2)(ii) previously was submitted (see June 2003 final rule (68 FR 36676 at 36681)). This proposed approach fulfills the statutory requirements for patent listing set forth in section 505(b)(1) and (c)(2) of the FD&C Act and ensures that patents listed for separate entries for drug products in the Orange Book are supported by an unambiguous submission of applicable patent information.

It should be noted that proposed § 314.53(d)(2)(i)(A) is intended to encompass only the types of changes in dosage form or route of administration that may be submitted as an NDA supplement and does not apply to proposed changes in dosage form or route of administration that should be submitted as a separate application (see guidance for industry entitled ''Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees'' (December 2004), available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079320.pdf*) (Separate Marketing Application Guidance). Similarly, we note that proposed § 314.53(d)(2)(i)(C) describes supplements to change the drug product from prescription use to OTC status for all conditions of use, because a separate marketing application would be required for a change to OTC status for fewer than all conditions of use.

Our proposal would eliminate the automatic requirement for submission of patent information with a supplement seeking approval for a change in formulation or new indication or other condition of use (except for those conditions of use described in § 314.53(d)(2)(i)). However, new submission of patent information would still be required if the patent(s) that claim the product as changed by the supplement differ from the patent(s) currently listed for the drug product. For supplements that seek approval for a change to a listed product that would not result in a new entry in the Orange Book (*i.e.,* a change other than one of the changes described in proposed § 314.53(d)(2)(i)), an applicant needs to evaluate whether each patent for which information is currently listed in the Orange Book for the drug product continues to claim the changed product. If existing patents listed for the product approved in the original application claim the product as changed by the supplement, the applicant is not required to resubmit this patent information unless the description of the method of use claimed by a patent would change upon approval of the supplement (see proposed § 314.53(d)(2)(ii)(A)). (In this regard, we note that an untimely filed patent that claims the product approved in the original application cannot be transformed into a timely filed patent with submission of a supplement.)

If, however, a listed patent no longer claims the product as changed by the supplement (*e.g.,* a new formulation is no longer claimed by a patent listed for the original formulation of the drug product), then the applicant must submit a request to correct or remove the patent information from the list in accordance with proposed § 314.53(f)(2) at the time of approval of the supplement. Correspondingly, if one or more existing patents claim the product

as changed by the supplement (*e.g.,* a supplement seeking approval for a new indication) and this patent information has not been submitted to FDA, the applicant must submit the patent information with the supplement and following approval. The requirement in proposed § 314.53(d)(2)(ii)(C) also would apply to submission of patent information for a patent currently listed for the drug as approved in the original application that claims the drug approved in the supplement in a new way (*e.g.,* a new or additional method of use) and for which the patent information would be required to be submitted under § 314.53(c). In this case, the applicant would be required to comply with § 314.53(c) and submit patent information describing the new or additional method of use claimed by the patent with the supplement and following approval.

As noted previously in this section of the document, the Agency has received comments criticizing as redundant the requirement for submission of Forms FDA 3542a and 3542 with submission and upon approval, respectively, of an NDA supplement where the information has not changed since the form last was filed (see April 2007 notice). Section 505(b)(1) of the FD&C Act requires the submission of patent information with the filing of a supplement to an NDA. To the extent that patents currently listed for the drug product continue to claim the product as changed by the supplement, we interpret the statute to not require resubmission of duplicative patent information. In circumstances other than those described in proposed § 314.53(d)(2)(ii)(A), an applicant or sponsor must submit required patent information with submission and upon approval of a supplement. This requirement facilitates the prompt listing of patent information postapproval by requiring applicants to complete their initial assessment of relevant patents with submission of their application and during the pendency of its review.

We are proposing a conforming revision to § 314.70(f) to clarify that an applicant that submits a supplement to an NDA (including a 505(b)(2) application) also must comply with the patent information requirements under § 314.53.

II.B.2.b. *Untimely filing of patent information (proposed §§ 314.53(d)(3), 314.50(i)(4), and 314.94(a)(12)(vi)).* We are proposing to supplement § 314.53(d)(3) to expressly describe our longstanding practice with respect to listing untimely filed patents. Proposed § 314.53(d)(3) states that if the required patent information is not submitted within 30 days of the issuance of the patent, FDA will list the patent, but patent certifications will be governed by the provisions regarding untimely filed patents in §§ 314.50(i)(4) and (i)(6) and 314.94(a)(12)(vi) and (a)(12)(viii) of this part. We also are proposing to revise §§ 314.50(i)(4) and 314.94(a)(12)(vi) to include certain amendments to the description of the approved method(s) of use claimed by the patent within the category of untimely filed patent information.

Section 505(c)(2) of the FD&C Act requires an NDA holder to file patent information for a patent issued after the date of approval of the application within 30 days of patent issuance. (As clarified in proposed § 314.53(c)(2)(ii), this statutory requirement for timely filing does not apply to patent information submitted prior to approval of an NDA or supplement, even if the patent information is submitted to FDA more than 30 days after the patent is issued by the PTO.)

Section 505(c)(2) of the FD&C Act further directs the Agency to publish information on the newly-issued patent upon its submission, and we have interpreted this statutory provision to require listing in the Orange Book irrespective of whether the patent information has been timely filed. Although we list untimely filed patents pursuant to section 505(c)(2) of the FD&C Act, we generally do not require an applicant with a pending 505(b)(2) application or ANDA to provide a patent certification to a patent for which the NDA holder failed to comply with the statutory timeframe for submission of patent information after approval. Accordingly, the untimely filed patent will neither delay approval of a pending 505(b)(2) application or ANDA until patent expiration nor necessitate a carve-out of information related to a patented method of use.

Although an applicant with a pending 505(b)(2) application or ANDA that references the drug product generally would not be required to submit a patent certification to an untimely filed patent that was late-listed as to the pending 505(b)(2) application or ANDA, we would permit an applicant to submit and maintain a patent certification (including a paragraph IV certification) or a statement pursuant to section 505(b)(2)(B) or 505(j)(2)(B)(viii) of the FD&C Act, if desired. For example, a 505(b)(2) or ANDA applicant may wish to submit a paragraph IV certification to challenge the late-listed patent and obtain patent certainty (*i.e.,* determine whether the NDA holder or patent owner will initiate a patent infringement action against the applicant) instead of possibly marketing at risk.

We also are proposing to revise §§ 314.50(i)(4) and 314.94(a)(12)(vi) to state that, except as provided in § 314.53(f)(1), an NDA holder's amendment to the description of the approved method(s) of use claimed by the patent will be considered untimely filing of patent information if:

- The amendment is submitted more than 30 days after patent issuance and it is not related to a corresponding change in approved product labeling or
- the amendment is submitted more than 30 days after a corresponding change in approved product labeling.

This proposed revision is consistent with the objective of ensuring that prospective 505(b)(2) and ANDA applicants have timely notice of changes to the asserted patent coverage for a listed drug. In addition, proposed §§ 314.50(i)(4) and 314.94(a)(12)(vi) would complement proposed revisions to § 314.53 that are intended to enhance NDA holders' compliance with the requirement to accurately identify the specific sections of product labeling that correspond to the use claimed by the patent (see section II.B.1.c). If an amendment to change the patent use code is not related to a corresponding change in approved product labeling and is submitted more than 30 days after patent issuance (or patent reissuance), then the patent information is properly considered untimely filed. In accordance with §§ 314.50(i)(4) and 314.94(a)(12)(vi), an untimely filed method-of-use patent does not require a patent certification or statement and would not delay approval of a pending 505(b)(2) application or ANDA. Similarly, if an amendment to change the patent use code is submitted more than 30 days after a corresponding change in approved product labeling, then the amendment lacks a clear temporal or substantive link to the specific section(s) of approved product labeling claimed by the patent, and the patent information is untimely filed.

An applicant with a pending 505(b)(2) application or ANDA that seeks to confirm that a newly listed patent was untimely filed (and may not require a patent certification in accordance with § 314.50(i)(4) or § 314.94(a)(12)(vi)) should contact the Orange Book staff. Irrespective of whether the patent was untimely filed (and thus late-listed as to the pending 505(b)(2) application or ANDA) or timely filed (and thus ''later listed'' as to the pending 505(b)(2) application or ANDA), a paragraph IV certification submitted for a patent filed with FDA after the date on which a

505(b)(2) application or ANDA (that is later determined to be substantially complete) was submitted will not give rise to a 30-month stay (see section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act and section II.G).

We note, however, that a 505(b)(2) application or ANDA submitted after the untimely filed patent is listed in the Orange Book is required to submit an appropriate patent certification or statement to the patent. As we explained in the 1994 final rule, ''[t]he approach adopted by the Agency as best embodying the compromise adopted by Congress requires that if an NDA applicant submits required patent information on an approved drug product more than 30 days after issuance of the patent, FDA will publish the untimely information, but will not require ANDA and 505(b)(2) applicants with pending applications that have previously submitted a certification, *i.e.* those applicants that would be prejudiced by the late submission, to recertify to the new patent. Only applicants that initially submit ANDA's or 505(b)(2) applications after the submission of the patent information or whose pending applications do not contain a valid certification at the time of submission would be required to submit a certification as to that patent. . . . While this could result in two categories of ANDA's for a pioneer drug, those without certifications for the late-filed patent and those with certifications for that patent, this approach is the best means for discouraging manipulation of the patent filing scheme and providing optimum notice of applicable patents'' (59 FR 50338 at 50340, response to comment 7).

We remind NDA holders that patents issued after approval of a drug under section 505(c) of the FD&C Act include reissued patents (see section II.B.1.e) as well as patents that claim a drug product listed in the discontinued section of the Orange Book. With reference to the latter category, we note that a 505(b)(2) or ANDA applicant may rely upon a drug product listed in the discontinued section of the Orange Book to the extent that the product was not withdrawn for reasons of safety or effectiveness (see § 314.151 with respect to ANDAs). Accordingly, we encourage NDA holders to ensure that they continue to comply with the statutory requirements for patent listing for products that have been discontinued from marketing.

We also are proposing to revise § 314.50(i)(4) to remove an incorrect reference to the possible submission of a certification under § 314.50(i)(1)(ii) after the NDA holder's untimely filing of patent information. If a 505(b)(2) applicant is required to submit a patent certification to untimely filed patent information as provided in proposed § 314.50(i)(4), a ''no relevant patents'' statement under § 314.50(i)(1)(ii) would not be an acceptable patent certification.

Finally, we are proposing to revise the heading for § 314.53(d)(3) to ''newly issued patents'' to better characterize the text and emphasize its applicability to patents issued after approval of an NDA or supplement. We also are proposing to revise the heading for proposed §§ 314.50(i)(4) and 314.94(a)(12)(vi) to ''untimely filing of patent information'' and to make conforming revisions to the text of these sections for consistent use of terminology.

II.B.2.c. *Where to send submissions of Forms FDA 3542a and 3542 (proposed § 314.53(d)(4)).* We are proposing to require that patent information filed on Form FDA 3542 upon and after approval of an NDA or supplement be submitted directly to the Orange Book staff through the OGD Document Room. The Orange Book staff will send an archival copy of this patent information to CDER's Central Document Room for filing with the NDA.

Our proposal to require that NDA holders submit post-approval patent information directly to the Orange Book staff is intended to facilitate prompt listing of patent information in the Orange Book after Form FDA 3542 has been officially received by the Agency. Currently, many NDA holders submit a duplicate or courtesy copy of Form FDA 3542 to the Orange Book staff electronically or via facsimile at the time of their submission of Form FDA 3542 to CDER's Central Document Room. This patent information is listed in the Orange Book upon receipt by the Orange Book staff, and the Orange Book explains that the date on which patent information is published ''may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).'' However, this practice may result in publication of patent information prior to receipt by the official repository identified in our regulations and cause confusion for prospective first applicants and applicants with a pending 505(b)(2) application or ANDA seeking to determine whether or not the patent is late-listed. Proposed § 314.53(d)(4) designates the OGD Document Room as an official repository for submissions of Form FDA 3542, and proposed § 314.53(d)(5) (see section II.B.2.d) clarifies that the submission date of patent information provided by an NDA holder after approval of an application is the earlier of the date on which Form FDA 3542 is date-stamped by the OGD Document Room or officially received electronically by FDA though the Electronic Submissions Gateway. These proposed revisions to the regulations are intended to enhance efficiency and ensure that patent information is promptly listed after its receipt.

We note, however, that patent information submitted on Form FDA 3542a with the filing of an NDA, amendment, or supplement, and prior to approval of the application must continue to be submitted directly to the NDA as required by § 314.50(h) or § 314.70(f), as appropriate. An applicant should not submit a copy of Form FDA 3542a to the Orange Book staff; the Orange Book staff should only receive patent information submitted after approval of the NDA or supplement. An applicant should not submit a copy of the patent to FDA with submission of Form FDA 3542a or 3542.

II.B.2.d. *Submission date of patent information (proposed § 314.53(d)(5)).* We are proposing to revise § 314.53(d)(5) to clarify, for purposes of § 314.53(d)(3), that the submission date of patent information provided by an NDA holder after approval of an application is the earlier of the date on which Form FDA 3542 is date-stamped by the OGD Document Room or officially received electronically by FDA though the Electronic Submissions Gateway (*i.e.,* at the completion of electronic transmission). Our current regulations state that the information shall be considered submitted to FDA on the date it is received by the Central Document Room. We note that patent information sent to another location at FDA is not considered received by FDA for purposes of § 314.53(d)(3) on timely filing and a 505(b)(2) or ANDA applicant's patent certification obligations pursuant to § 314.50(i)(4) and (i)(6) or § 314.94(a)(12)(vi) and (a)(12)(viii), respectively, unless it is sent to the official repository identified in the regulation.

These proposed revisions are intended to remove any ambiguity about the date of submission in light of the implications of untimely filing of patent information on the patent certification obligations of 505(b)(2) applicants and ANDA applicants that rely upon the listed drug (see §§ 314.50(i)(4) and 314.94(a)(12)(vi)). In this regard, we note that the patent certification obligations of a 505(b)(2) or ANDA applicant arise upon the receipt by the official repository at FDA of the NDA holder's submission of patent information for a listed drug rather than the timing of publication of the patent

information in the Orange Book (see section 505(b)(2)(A) and (j)(2)(A)(vii) of the FD&C Act; see also *Teva Pharms., USA, Inc.* v. *Leavitt,* 548 F.3d 103, at 108 (D.C. Cir. 2008) (noting that FDA ''has consistently required ANDA applicants to certify to patents recently submitted to FDA, even if FDA had not yet published the patent in any version of the Orange Book'')).

However, for purposes of eligibility for 180-day exclusivity, an ANDA applicant is not permitted to submit a paragraph IV certification to a patent (*e.g.,* a recently issued patent that claims the RLD) before the first working day after the day the patent is listed in the Orange Book (see section II.D.1.b.ii and II.E.4).

In addition, proposed § 314.53(d)(5) would change the addressee to whom submission of Form FDA 3542 should be sent from the Central Document Room to the OGD Document Room or the Electronic Submissions Gateway, consistent with proposed § 314.53(d)(4) discussed in section II.B.2.c.

II.B.3. Public Disclosure of Patent Information (Proposed § 314.53(e))

We are proposing to delete the reference in § 314.53(e) to monthly supplements to the Orange Book because the Agency no longer arranges for publication of monthly printed supplements to the Orange Book. Patent information listed in the Orange Book, which may be accessed from the Agency's Web site, has been updated on a daily basis for several years. This correction to § 314.53(e) is consistent with our proposed revision of the definition of ''the list'' in § 314.3(b) to mean the list of approved drug products published in FDA's current ''Approved Drug Products With Therapeutic Equivalence Evaluations'' available electronically on FDA's Web site at *http://www.fda.gov/cder.*

Section 314.53(e) provides that copies of the patent information submitted on Form FDA 3542 may be requested from FDA's Freedom of Information Staff. We are proposing to revise § 314.53(e) to replace the reference to a request for copies of the ''file'' to copies of the ''submitted patent information.'' This revision is proposed for clarity and does not represent a substantive change. We note, for example, that some prospective 505(b)(2) or ANDA applicants have requested copies of the patent information submitted on Form FDA 3542 for patents listed for a listed drug in the Orange Book to determine the scope of the labeling identified by the NDA holder as relating to the use claimed by the patent. Copies of Form FDA 3542 also have been requested to obtain address information for the agent or representative authorized to receive notice of patent certification if the patent owner or NDA holder does not reside or have a place of business in the United States. We anticipate additional requests for the information submitted on Form FDA 3542 and may elect to proactively post on FDA's Web site a copy of Form FDA 3542 for patents listed in the Orange Book in advance of a request under the Freedom of Information Act (see Presidential Documents, Memorandum for the Heads of Executive Departments and Agencies on Transparency and Open Government (January 21, 2009) (74 FR 4685, January 26, 2009); see also Office of the Attorney General, Memorandum for the Heads of Executive Departments and Agencies on The Freedom of Information Act (March 19, 2009), available at *http://www.usdoj.gov/ag/foia-memo-march2009.pdf*).

II.B.4. Correction or Change of Patent Information (Proposed § 314.53(f))

We are proposing to revise § 314.53(f) to differentiate the procedure for correction or change of patent information by the NDA holder (proposed § 314.53(f)(2)) from the procedure for requests by persons other than the NDA holder. Proposed § 314.53(f) also would address certain issues that have arisen regarding method-of-use patents and enhance FDA's response to challenges to the accuracy or relevance of submissions of this patent information to the Agency. We are proposing to redesignate the current text of § 314.53(f) as § 314.53(f)(1). We are proposing to add new § 314.53(f)(2) to implement section 505(j)(5)(D)(i)(I)(bb)(CC) of the FD&C Act, as added by the MMA, and to make other changes for the efficient enforcement of the FD&C Act.

Table 4 summarizes the proposed changes related to correction or change of patent information:

TABLE 4—HIGHLIGHTS OF PROPOSED CHANGES REGARDING CORRECTION OR CHANGE OF PATENT INFORMATION [1]

Current regulations	Proposed revisions to regulations
Correction of patent information errors (§ 314.53(f))	*Correction or change of patent information—Requests by persons other than the NDA holder (§ 314.53(f)(1)).*
• If any person disputes the accuracy or relevance of patent information submitted to FDA under § 314.53 and published by FDA in the list, that person must first notify FDA (OGD Document Room, Attn: Orange Book Staff) in writing stating the grounds for disagreement. FDA then will request that the NDA holder confirm the correctness of the patent information..	• If any person disputes the accuracy or relevance of patent information submitted to FDA under § 314.53 and published by FDA in the list, that person must first notify FDA (OGD Document Room, Attn: Orange Book Staff) in a written or electronic communication titled ''314.53(f) Patent Listing Dispute'' that states the grounds for disagreement. FDA then will request that the NDA holder confirm the correctness of the patent information within 30 days. • For listed patents that claim an approved method of using the drug product, FDA will request that the NDA holder confirm the correctness of the ''Use Code'' in the Orange Book, and provide information on the specific approved use claimed by the patent that enables FDA to make a determination in accordance with section 505(b)(2)(B) or (j)(2)(C)(viii) of the FD&C Act.
• Unless the NDA holder withdraws or amends its patent information in response to FDA's request to confirm the correctness of the patent information, FDA will not change the patent information in the list.	• Unless the NDA holder withdraws or amends its patent information in response to FDA's request to confirm the correctness of the patent information, FDA will not change the patent information in the list. —If there is insufficient information to make a determination in accordance with section 505(b)(2)(B) or (j)(2)(C)(viii) of the FD&C Act and the NDA holder has confirmed the correctness of its description of the specific approved use claimed by the patent, the Agency will review the proposed labeling for the 505(b)(2) application or ANDA with deference to the 505(b)(2) or ANDA applicant's interpretation of the scope of the patent.

TABLE 4—HIGHLIGHTS OF PROPOSED CHANGES REGARDING CORRECTION OR CHANGE OF PATENT INFORMATION [1]—Continued

Current regulations	Proposed revisions to regulations
	Correction or change of patent information—Requests by the NDA holder (§ 314.53(f)(2)). • If the NDA holder determines that a patent or patent claim no longer meets the statutory requirements for listing, the NDA holder must promptly notify FDA to withdraw the patent information and request that the patent information be removed from the list. • If the NDA holder is required by court order to amend patent information or withdraw a patent from the list, it must submit a copy of the order to FDA (OGD Document Room, Attn: Orange Book Staff) within 14 days of order entry. FDA will remove a patent from the list if there is no first applicant eligible for 180-day exclusivity or upon the expiration of the 180-day period. • If the term of a listed patent is extended under 35 U.S.C. 156(e), the NDA holder must submit on Form FDA 3542 a correction to the patent expiration date within 30 days of receipt of a certificate of extension or documentation of an extension of the patent term. • Corrections or changes to previously submitted patent information, other than withdrawal of a patent and requests to remove a patent from the list (delisting requests), must be submitted on Form FDA 3542 or 3542a, as appropriate. • Withdrawal of a patent and delisting requests must be submitted as described in § 314.53(d)(4), except it need not be submitted on Form FDA 3542. The patent withdrawal and delisting request must contain the NDA number, each product to which the request applies, and the patent number.

[1] These highlights describe important proposed revisions to our regulations, but should not be relied upon in place of the proposed regulation.

II.B.4.a. *Requests by persons other than the NDA holder—patents that claim an approved method of using the drug product (proposed § 314.53(f)(1)).* To efficiently implement the statutory provisions in section 505(b)(2)(B) and (j)(2)(C)(viii) of the FD&C Act, we are proposing to enhance the mechanism for challenging the accuracy or relevance of information with respect to method-of-use patents submitted to the Agency under § 314.53 and listed in the Orange Book.

In the preamble to the June 2003 final rule on patent submission and listing requirements, we discussed our longstanding position, codified in § 314.53(b) and (c)(2), that ''only method-of-use patents that claim a use of the drug product in the pending or approved application must be submitted'' (68 FR 36676 at 36681). The June 2003 final rule further explained: ''The declarant must describe each individual method of use for which a patent is submitted for listing, and identify the corresponding language found in the labeling of the approved NDA that corresponds to that method of use. This information will expedite our review of ANDA and 505(b)(2) applications that do not seek approval for all the approved uses. In determining whether an ANDA applicant can 'carve out' the method of use, rather than certify to the listed patent, we will rely on the description of the approved use provided by the NDA holder or patent owner in the patent declaration and listed in the Orange Book'' (68 FR 36676 at 36682).

An NDA holder or patent owner must provide adequate information in its submission of patent information to enable potential 505(b)(2) and ANDA applicants to avail themselves of the statutory provision that permits a 505(b)(2) or ANDA applicant to not certify to a patent by stating that it is not seeking approval for the method of use claimed by the listed patent (see section 505(b)(2)(B) and (j)(2)(C)(viii) of the FD&C Act, respectively) and carving out from product labeling the corresponding use information. Our July 2007 revision of Forms FDA 3542a and 3542 clarifies, in its instructions, that ''[t]he use code designates a method of use patent that claims the approved indication or use of a drug product. Each approved use claimed by the patent should be separately identified in this section and contain adequate information to assist 505(b)(2) and ANDA applicants in determining whether a listed method of use patent claims a use for which the 505(b)(2) or ANDA applicant is not seeking approval'' (Form FDA 3542, section 4.2b).

Section 314.53(f) currently provides that, upon notification of the grounds for a disagreement with the accuracy or relevance of the patent submission, FDA will request that the NDA holder confirm the correctness of the patent information or omission of patent information. Proposed § 314.53(f)(1) would establish a 30-day timeframe in which the NDA holder is required to respond to FDA's request in order to facilitate timely resolution of the patent listing dispute.

Proposed § 314.53(f)(1) also would further specify that, in response to notification of a patent listing dispute for a listed patent that claims an approved method of using the drug product, FDA will request that the NDA holder confirm the correctness of its description of the approved indication or method of use that has been included as the ''use code'' in the Orange Book, and provide information on the specific approved use claimed by the patent that enables the Agency to make a determination in accordance with section 505(b)(2)(B) or (j)(2)(C)(viii) of the FD&C Act. If the patent has been listed and the NDA holder confirms the accuracy of the patent information, fails to timely respond to FDA's request under § 314.53(f), or submits a revision to the use code that does not provide adequate clarity for FDA to determine whether the scope of the proposed labeling carve-out would be appropriate based on the NDA holder's use code and approved labeling, FDA is proposing to review a proposed labeling carve-out(s) for the 505(b)(2) application or ANDA with deference to the 505(b)(2) or ANDA applicant's interpretation of the scope of the patent. In determining whether a proposed omission of use information

from labeling is appropriate, the Agency will consider the use code and labeling information submitted by the NDA holder on Form FDA 3542, the history of labeling changes related to approval of an indication(s) for the drug product, the 505(b)(2) or ANDA applicant's interpretation of the scope of the patent, the need for consistent labeling among products approved under section 505(j) of the FD&C Act, and the requirements of §§ 314.94(a)(8)(iv) and 314.127(a)(7), as appropriate.

The following hypothetical example illustrates our approach under proposed § 314.53(f)(1) to determining whether an ANDA applicant's proposed labeling carve-out would be appropriate: The NDA holder submits Form FDA 3542 to the Office of Generic Drugs, Document Room, Attention: Orange Book Staff, within 30 days after issuance of the '321 patent claiming a method of using the drug product Gaindrolone. The NDA holder provided the use code ''to promote weight gain after weight loss in certain types of patients'' for each patent that it submitted for listing in the Orange Book, but did not specifically identify the approved use(s) (*e.g.,* patient population(s)) claimed by the patent. In section 4.2a of Form FDA 3542, the NDA holder further identified the patented method of use claimed in patent claims 8, 9, and 10 of the '321 patent with specific reference to the following sections of the approved labeling for the drug product: Indications and Usage (''indicated as adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections, or severe trauma'') and Dosage and Administration. Applicant A submits an ANDA that cites Gaindrolone as the basis for ANDA submission and contains a 505(j)(2)(A)(viii) statement with respect to the '321 patent. Applicant A also notifies the Agency in a written communication titled ''314.53(f) Patent Listing Dispute'' that the use code listed in the Orange Book for the '321 patent is overbroad as Applicant A interprets the scope of the '321 patent to be limited to ''adjunctive therapy to promote weight gain after weight loss following chronic infections.'' Applicant A contends that other approved patient populations are not within the scope of the '321 patent. FDA subsequently provides the NDA holder with the Applicant A's basis for disagreement with the accuracy of the listed patent information and requests that the NDA holder confirm the correctness of the description of the specific approved use claimed by the patent or revise the description within 30 days. The NDA holder confirms the use code ''to promote weight gain after weight loss in certain types of patients'' and thus does not provide adequate clarity for the Agency to make a determination in accordance with section 505(j)(2)(A)(viii) of the FD&C Act on whether Applicant A could carve out the patented use in ''certain types of patients'' and seek approval for the remaining uses. Accordingly, FDA reviews the proposed ANDA labeling with deference to Applicant A's interpretation of the scope of the patent and approves the ANDA for ''adjunctive therapy to promote weight gain after weight loss following extensive surgery or severe trauma.'' As noted in the June 2003 final rule, ''the claim-by-claim listing of method-of-use patents will permit ANDA and 505(b)(2) applicants to assess whether they are seeking approval for a use claimed in the listed patent, and thus determine whether to submit a patent certification or a section viii statement. Additionally, we [FDA] can verify that the certification or statement is correct, and that only the appropriate methods of use are included in the proposed labeling for the ANDA or 505(b)(2) drug product'' (68 FR 36676 at 36685). Applicant A has a strong incentive to interpret the scope of the patent correctly to avoid being subject to patent infringement litigation following ANDA approval and potentially enjoined from marketing its product. The use code submitted by the NDA holder remains listed in the Orange Book (compare June 2003 final rule (68 FR 36676 at 36683) (''[u]se codes are intended to alert ANDA and 505(b)(2) applicants to the existence of a patent that claims an approved use. They are not meant to substitute for the applicant's review of the patent and the approved labeling'').

In the same example above, we note that if the NDA holder had responded to FDA's request by revising the description of the specific approved use claimed by the patent in a manner that provided sufficient information for the Agency to make a determination in accordance with section 505(j)(2)(A)(viii) of the FD&C Act on whether Applicant A could carve out the patented use, FDA would have no occasion to review the proposed ANDA labeling with deference to Applicant A's interpretation of the scope of the patent. For example, if the NDA holder submitted a revised Form 3542 that provided a revised use code (hypothetically ''to promote weight gain after weight loss following chronic infections or severe trauma'') and specifically referred to the corresponding portion of the approved labeling, there would be sufficient information for the Agency to make a determination in accordance with section 505(j)(2)(A)(viii) of the FD&C Act. Accordingly, there would be no ambiguity that would warrant review of the proposed ANDA labeling with deference to Applicant A's interpretation of the scope of the patent, even if Applicant A's interpretation differed from that of the NDA holder.

As previously discussed in the June 2003 final rule, we reiterate that the Agency's role in patent listing is ministerial and does not involve substantive review of patents (see 68 FR 36676 at 36683). Rather, our proposed revisions to the regulations in 314.53(f) are intended to provide the Agency with the information necessary to implement section 505(b)(2)(B) and (j)(2)(C)(viii) of the FD&C Act. FDA believes that enhancing the mechanism for challenging overbroad use codes listed in the Orange Book may cause NDA holders to be more circumspect in their original submission of patent information to FDA. Accordingly, we expect that there will rarely be a need for the Agency to review the proposed labeling for the 505(b)(2) application or ANDA with deference to the 505(b)(2) or ANDA applicant's interpretation of the scope of the patent. However, we invite comment on this proposed approach to enhancing FDA's response to challenges to the accuracy or relevance of submissions of patent information to the Agency, while maintaining the Agency's ministerial role in patent listing.

II.B.4.b. Requests by NDA Holder To Remove Patent Information From the List (Proposed § 314.53(f)(2))

II.B.4.b.i. *Patents or patent claims that no longer meet the statutory requirements for listing.* Section 1102(a)(2) of the MMA amends section 505(j)(5)(D)(i)(I) of the FD&C Act to define certain events that constitute forfeiture of 180-day exclusivity. As noted in section I, we are implementing the 180-day exclusivity provisions of the MMA directly from the statute and will determine if additional rulemaking is necessary in the future. Where a novel issue of interpretation is raised by a particular factual scenario regarding forfeiture of 180-day exclusivity, we may open a public docket or otherwise seek comment from affected parties in advance of taking action (see section I.D). However, we are proposing at this time to add § 314.53(f)(2) regarding requests by an NDA holder to remove patent information from the list to implement section 505(j)(5)(D)(i)(I)(bb)(CC) of the FD&C

Act (forfeiture of 180-day exclusivity due to failure to market where the patent or patent information that qualified the first applicant for 180-day exclusivity is withdrawn by the NDA holder), and to clarify our current practice with respect to withdrawal of a patent or patent information by an NDA holder.

Under proposed § 314.53(f)(2), if the NDA holder determines that a patent or patent claim (*e.g.,* a method-of-use claim) no longer meets the statutory requirements for listing, the NDA holder is required to promptly notify FDA to withdraw the patent or patent information and request that the patent or patent information be removed from the list. Circumstances under which a patent or patent claim no longer meets the statutory requirements for listing include, but are not limited to, a judicial finding of invalidity or unenforceability for a listed patent, from which no appeal has been or can be taken, or a court order to amend patent information or withdraw a patent from the list. We note that an NDA applicant that determined that a patent or patent claim submitted on Form FDA 3542a no longer met the statutory requirements for listing prior to NDA approval would ''withdraw'' the patent or patent claim by not including the patent or patent claim in its submission of Form FDA 3542 upon approval of the NDA or NDA supplement. There is no need to submit a request to remove the patent or patent claim from the list because such patent information is listed in the Orange Book only upon approval of the NDA or NDA supplement.

The FD&C Act does not provide an independent cause of action for a 505(b)(2) or ANDA applicant seeking an order requiring an NDA holder to correct or delete patent information listed in the Orange Book (see section 505(c)(3)(D)(ii)(II) and (j)(5)(C)(ii)(II) of the FD&C Act; see also *Mylan Pharmaceuticals, Inc.* v. *Thompson,* 268 F.3d 1323 (Fed. Cir. 2001) (holding that the pre-MMA statutory scheme did not recognize a cause of action for delisting a patent from the Orange Book, and that ''such an action would be a private right of action barred by the [act]'')). If a 505(b)(2) or ANDA applicant successfully asserts a counterclaim to a patent infringement action to obtain an order requiring the NDA holder to amend or withdraw patent information from the list (see section 505(c)(3)(D)(ii)(I) and (j)(5)(C)(ii)(I) of the FD&C Act), the NDA holder must withdraw the patent or patent information and request that the patent or patent information be removed from the list. The Agency will not remove the patent or patent information in response to a request, accompanied by a copy of the court order, from the 505(b)(2) or ANDA applicant or on its own. We are proposing to require an NDA holder to submit a copy of a court order requiring amendment or withdrawal of patent information to the Orange Book Staff through the Office of Generic Drugs Document Room within 14 calendar days of the date on which the order was entered. By providing a 14-day timeframe within which an NDA holder must notify FDA of this type of court order, the proposed regulation would facilitate the NDA holder's compliance with obligations under the FD&C Act and applicable regulations and ensure that pending 505(b)(2) applications or ANDAs that have provided a patent certification to the amended or withdrawn patent are not inappropriately delayed if they are otherwise eligible for approval. The Orange Book Staff subsequently will forward a copy of the court order to the NDA through the CDER Central Document Room.

We recognize that for patents that meet the statutory criteria for listing in the Orange Book, fewer than all of the patent claims may be the subject of litigation against a particular 505(b)(2) or ANDA applicant. In such a case, a judicial finding of invalidity for certain patent claims and withdrawal of that patent information by submission of an amended Form FDA 3542 may not necessarily be reflected in the Orange Book (unless, for example, all drug product claims were invalidated and only a method-of-use claim remained). Accordingly, it would be prudent for current and prospective 505(b)(2) and ANDA applicants to be aware of relevant court decisions in patent litigation (see also the 1994 final rule (59 FR 50338 at 50346) (noting the prudence of conducting patent searches to identify patents that may be ineligible for listing in the Orange Book but that may be infringed by a proposed product)).

Consistent with our current practice, proposed § 314.53(f)(2) states that we will remove a patent from the Orange Book when the NDA holder has informed us that the patent no longer meets the statutory requirements for listing if there is no first applicant eligible for 180-day exclusivity or upon the expiration of the 180-day exclusivity period of a first applicant.

Proposed § 314.53(f)(2) also applies to amendment of the patent information to remove a claim (drug substance, drug product, or method of use) from the list. For example, if a patent is listed in the Orange Book as claiming the drug product and a method of use, and an NDA holder withdrew only the drug product claim and requested that the drug product claim be removed from the list, we would remove the drug product claim from the Orange Book if there is no first applicant eligible for 180-day exclusivity or upon the expiration of the 180-day exclusivity period of a first applicant. This provision is intended to address scenarios in which an ANDA applicant has submitted a paragraph IV certification with respect to the drug substance or drug product claim and a 505(j)(2)(C)(viii) statement with respect to a method-of-use claim for a single patent.

When an NDA holder has withdrawn a patent and submitted to FDA a request to remove the patent from the Orange Book, we currently identify this request in a separate column in the Orange Book titled ''Delist Requested.'' If an NDA holder withdraws a patent claim (*e.g.,* a method-of-use claim in a patent that also claims the drug product) and submits to FDA a request to remove the patent claim from the Orange Book, we intend to identify this request with a symbol (*e.g.,* an asterisk) in the column for that claim. These notations signal that the patent or patent claim remains listed in the Orange Book only to preserve a first applicant's eligibility for 180-day exclusivity for their pending ANDA or during the period of 180-day exclusivity after approval of the first applicant's ANDA. While the patent or patent claims remain listed in the Orange Book, subsequent ANDA applicants must submit or maintain an appropriate patent certification or statement with respect to the patent or patent claims for which the delisting request has been submitted. This requirement is consistent with preservation of a first applicant's eligibility for 180-day exclusivity because the 180-day exclusivity period bars approval of subsequent ANDAs for the same drug product that also contain a paragraph IV certification to the patent (see section 505(j)(5)(B)(iv)(I) of the FD&C Act). However, a 505(b)(2) applicant is not required to certify or maintain a previous certification to the patent for which a request to remove the patent from the list has been submitted, because such a patent remains listed in the Orange Book only for purposes of preserving a first ANDA applicant's eligibility for 180-day exclusivity.

An applicant can determine that a patent or patent claim has been removed from the Orange Book if it no longer appears in the Orange Book patent listings for the drug product at issue. In addition, FDA maintains a separate Web page linked from the ''search by patent''

option on the Orange Book Web page that identifies patents that have been recently delisted (currently located at *http://www.accessdata.fda.gov/scripts/cder/ob/docs/delist.cfm*).

II.B.4.b.ii. *Patent term restoration.* Proposed § 314.53(f)(2)(ii) directs NDA holders to submit a correction to the expiration date of their listed patent if the term of the patent is extended under the patent term restoration provisions of 35 U.S.C. 156, and sets a timeframe for compliance. With respect to patents eligible for listing in the Orange Book, the Hatch-Waxman Amendments generally provide that the terms of certain patents may be extended for a period of up to 5 years if the patent claims a product or method of using a product that has been subject to a defined regulatory review period before commercial marketing or use (see 35 U.S.C. 156(a)). We are proposing to require the NDA holder to submit the correction to the patent expiration date on Form FDA 3542 within 30 calendar days of receipt of a certificate of extension as described in 35 U.S.C. 156(e)(1) or documentation of an extension of the term of the patent as described in 35 U.S.C. 156(e)(2). The 30-day timeframe within which an NDA holder must notify FDA of the patent term extension is consistent with the statutory timeframe set forth in section 505(c)(2) of the FD&C Act for filing with FDA the patent number and patent expiration date of any patent that claims the drug or method of using the drug and is issued after NDA approval. Although extension of the patent term of a previously issued patent is not explicitly within the scope of section 505(c)(2) of the FD&C Act, the proposed 30-day timeframe for submission of a correction of the patent expiration date is consistent with the objective of ensuring that prospective 505(b)(2) and ANDA applicants have timely notice of changes to the asserted patent coverage for a listed drug.

II.B.4.b.iii. *Submissions to FDA.* Proposed § 314.53(f)(2)(iii) would require that corrections or changes to previously submitted patent information (other than withdrawal of a patent or requests to remove a patent from the list) must be submitted on Form FDA 3542a or 3542, as appropriate. This proposed requirement is intended to facilitate listing of patent information in the Orange Book and ensure that patent information is accompanied by the patent declaration verification required by § 314.53(c)(2)(i)(Q) and (c)(2)(ii)(R) and set forth in the certification requirements of Form FDA 3542a or 3542, respectively. We note that we will not accept corrections or changes that are not submitted on the appropriate forms. However, an NDA holder may elect to submit a cover letter highlighting the corrections or changes made in the accompanying Form FDA 3542. An NDA holder's withdrawal of fewer than all of a previously submitted patent's claims (*e.g.,* withdrawal of the method of use claim(s) for a patent that also claims the drug product) would be considered a correction or change to patent information for purposes of proposed § 314.53(f)(2)(iii) because the patent would remain listed in the Orange Book.

However, proposed § 314.53(f)(2)(iv) clarifies that an NDA holder's withdrawal of a patent and request to remove a patent from the Orange Book is not required to be submitted on Form FDA 3542a (with respect to pre-approval withdrawal of a patent) or FDA Form FDA 3542. The withdrawal of a patent must be submitted as an amendment to the NDA if the application has not been approved. After NDA approval, the withdrawal of a patent must be submitted to the Orange Book Staff through the OGD Document Room and must specify the patent number, the application number, and each product(s) approved in the application to which the request applies. The Orange Book Staff subsequently will forward a copy of the patent withdrawal to the NDA through the CDER Central Document Room.

II.C. Patent Certification (Proposed §§ 314.50(i) and 314.94(a)(12))

II.C.1. Method-of-Use Patents (Proposed §§ 314.50(i)(1)(iii) and 314.94(a)(12)(iii))

We are proposing to revise §§ 314.50(i)(1)(iii) and 314.94(a)(12)(iii) to clarify that a 505(b)(2) or ANDA applicant that is not seeking approval for any indications or other conditions of use that are covered by a method-of-use patent for the listed drug(s) relied upon or RLD, respectively, and has omitted corresponding labeling from its proposed product may submit a statement under section 505(b)(2)(B) or 505(j)(2)(A)(viii), respectively, instead of a patent certification with respect to any method-of-use claims. The proposed addition of the phrase ''or other conditions of use'' to §§ 314.50(i)(1)(iii) and 314.94(a)(12)(iii) reflects that a method-of-use patent that claims a use other than an indication may be submitted for listing in the Orange Book and may be the subject of a statement under section 505(b)(2)(B) or 505(j)(2)(A)(viii) with an accompanying labeling carve-out. This proposed revision is intended to conform with current Agency practice.

II.C.2. Method-of-Manufacturing Patents (Proposed Deletion of §§ 314.50(i)(2) and 314.94(a)(12)(iv))

The current regulations in §§ 314.50(i)(2) and 314.94(a)(12)(iv) state that a 505(b)(2) or ANDA applicant, respectively, is not required to make a patent certification with respect to any patent that claims only a method of manufacturing the drug product (method-of-manufacturing patent). This has been incorrectly interpreted by certain applicants to mean that a manufacturer could elect to submit such a patent for listing. In 2003, § 314.53(b) was amended to state, among other things, that process patents (*i.e.,* method-of-manufacturing patents) must not be submitted to FDA (68 FR 36676 at 36679). Therefore, we are proposing that current §§ 314.50(i)(2) and 314.94(a)(12)(iv) be removed (and reserved) to ensure consistency and clarity in our regulations.

II.C.3. Licensing Agreement (Proposed § 314.50(i)(3))

We are proposing to revise § 314.50(i)(3) regarding licensing agreements to remove the references to an ''immediate effective date'' and clarify that the patent owner with whom the applicant has a licensing agreement may consent to approval of the 505(b)(2) application (if otherwise justified) as of a specific date. These proposed revisions reflect that there may be barriers to approval other than the patent that is the subject of the licensing agreement. In addition, the proposed revision acknowledges that a patent owner may consent to approval as of a specific date.

This proposed revision does not alter the current requirements for a 505(b)(2) (or ANDA) applicant that submits a paragraph IV certification to a patent that claims the listed drug relied upon and for which the applicant has a licensing agreement with the patent owner (see proposed §§ 314.50(i)(3) and 314.94(a)(12)(v)). A 505(b)(2) or ANDA applicant must comply with the statutory requirements for sending notice of paragraph IV certification under section 505(b)(3) and (j)(2)(B) of the FD&C Act, respectively, with respect to each listed patent for which it has submitted a paragraph IV certification notwithstanding the applicant's statement that it has been granted a patent license.

II.D. Notice of Paragraph IV Certification (Proposed §§ 314.52 and 314.95)

II.D.1. Timing of Notice

A 505(b)(2) or ANDA applicant submitting a paragraph IV certification is required to give notice of the patent challenge to the holder of the NDA for the listed drug(s) relied upon or RLD, respectively, and each owner of the patent that is the subject of the certification within a specified timeframe (see section 505(b)(3) and (j)(2)(B) of the FD&C Act). We are proposing to revise our regulations to clearly delineate the two limitations on the timeframe within which notice can be provided to the NDA holder and each patent owner of a paragraph IV certification to a listed patent: (1) The date before which notice may not be given and (2) the date by which notice must be given. The MMA amended the FD&C Act to establish the date by which notice of a paragraph IV certification must be given to the NDA holder and each patent owner. Table 5 summarizes the proposed changes related to the timing of providing notice of a paragraph IV certification.

TABLE 5—HIGHLIGHTS OF PROPOSED CHANGES REGARDING TIMING OF NOTICE OF PARAGRAPH IV CERTIFICATION [1]

Current regulations	Proposed revisions to regulations
Sending the notice (§§ 314.52(b) and 314.95(b))	*Sending the notice (§§ 314.52(b)(1) and (b)(2) and 314.95(b)(1) and (b)(2))*
• 505(b)(2) applicant must send notice required by § 314.52(a) when it receives from FDA an acknowledgment letter stating that its 505(b)(2) application has been filed.	• Except as provided in § 314.52(d), a 505(b)(2) applicant must send notice required by § 314.52(a) on or after the date it receives from FDA a paragraph IV acknowledgment letter, but not later than 20 days after the date of the postmark on the paragraph IV acknowledgment letter. • Any required notice is invalid if it is sent before the 505(b)(2) applicant's receipt of a paragraph IV acknowledgment letter. The applicant will not have complied with § 314.52(b) until it sends valid notice.
• ANDA applicant must send notice required by § 314.95(a), when it receives from FDA an acknowledgment letter stating that its ANDA is sufficiently complete to permit a substantive review.	• Except as provided in § 314.95(d), an ANDA applicant must send notice required by § 314.95(a) on or after the date it receives from FDA an acknowledgment letter or a paragraph IV acknowledgment letter, but not later than 20 days after the date of the postmark on the acknowledgment letter or paragraph IV acknowledgment letter. • Any required notice is invalid if it is sent before the ANDA applicant's receipt of an acknowledgment letter or a paragraph IV acknowledgment letter, or before the first working day after the day the patent is published in the list. The applicant will not have complied with § 314.95(b) until it sends valid notice. • The 20-day clock begins on the day after the date of the postmark on the paragraph IV acknowledgment letter. When the 20th day falls on Saturday, Sunday, or a Federal holiday, the 20th day will be the next day that is not a Saturday, Sunday, or Federal holiday.
Sending the notice (§§ 314.52(b) and 314.95(b))	*Sending the notice (§§ 314.52(b)(3) and 314.95(b)(3)*
• At the same time, the 505(b)(2) or ANDA applicant must amend its application to include a statement certifying that notice of paragraph IV certification has been provided to each person identified under § 314.52(a) or § 314.95(a), respectively, and that notice met the content requirement under § 314.52(c) or § 314.95(c), respectively.	• At the same time the 505(b)(2) or ANDA applicant sends the notice required by § 314.52(a) or § 314.95(a), respectively, it must submit an amendment to its 505(b)(2) application that includes a statement certifying that the notice of paragraph IV certification has been provided to each person under § 314.52(a) or § 314.95(a), respectively, and that notice met the content requirement under § 314.52(c) or § 314.95(c), respectively.

[1] These highlights describe important proposed revisions to our regulations, but should not be relied upon in place of the proposed regulation.

II.D.1.a. *Date before which notice may not be given.* We are proposing to clarify the text of our regulations to reflect our longstanding practice that notice of a paragraph IV certification may not be sent by a 505(b)(2) or ANDA applicant unless and until we have notified the applicant that its application has been filed or received, as appropriate, in an acknowledgment letter or a paragraph IV acknowledgment letter (see proposed §§ 314.52(b)(1) and 314.95(b)(1)).

Sections 314.52(b) and 314.95(b) currently require that a 505(b)(2) and ANDA applicant, respectively, send notice of a paragraph IV certification when it receives from FDA an acknowledgment letter stating that the application is sufficiently complete to permit a substantive review. An NDA, including a 505(b)(2) application, is deemed sufficiently complete to permit a substantive review if it is filed by the 60th day after submission (see § 314.101(a)(1) and proposed § 314.101(a)(2)). An ANDA is received when FDA has made a threshold determination that the ANDA is substantially complete and has sent the ANDA applicant an acknowledgment letter or paragraph IV acknowledgment letter (see § 314.101(b)). We previously have explained that notice of a paragraph IV certification is to be sent only after the 505(b)(2) or ANDA applicant has received acknowledgment from FDA that its application has been determined to be acceptable for review because such notice subjects the 505(b)(2) or ANDA applicant to the risk that it will be sued for patent infringement (see ''Abbreviated New Drug Application Regulations''; proposed rule (54 FR 28872; July 10, 1989) (1989 proposed rule); see also 35 U.S.C. 271(e)(2)). The receipt of notice of a paragraph IV certification by a patent owner or the NDA holder (or their representatives) begins a 45-day period within which the NDA holder or patent owner must initiate a patent infringement action against the 505(b)(2) or ANDA applicant in order to obtain, in certain cases, a statutory 30-month stay of approval of the application while the patent infringement litigation is pending (section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act).

The FD&C Act requires that a notice of paragraph IV certification must state

that the 505(b)(2) application or ANDA containing the certification ''has been submitted'' (see section 505(b)(3)(D)(i) and (j)(2)(B)(iv)(I) of the FD&C Act). As we noted in the preamble to the 1989 proposal to implement the Hatch-Waxman Amendments, however, ''[t]he statute and legislative history of Title I [of the Hatch-Waxman Amendments] demonstrate that Congress did not intend incomplete application submissions to trigger legal action by a patent owner or approved application holder'' (1989 proposed rule, 54 FR 28872 at 28887). By requiring that a 505(b)(2) application has been filed or an ANDA has been received before notice of a paragraph IV certification can be given, we ensure that the NDA holder and patent owner do not needlessly expend resources to initiate litigation with respect to an application that is incomplete and therefore may not be reviewed by the Agency (see 1989 proposed rule, 54 FR 28872 at 28887 and 1994 final rule, 59 FR 50338 at 50349–50350). Accordingly, our current regulations require that a 505(b)(2) or ANDA applicant's notice of a paragraph IV certification must include a statement that FDA has filed the NDA (in the case of a 505(b)(2) application) or has received the ANDA (see §§ 314.52(c)(1) and 314.95(c)(1)).

Despite the language in our existing regulations and the preamble to the 1989 proposed rule, we have continued to receive inquiries from the public regarding whether notice of paragraph IV certification may be sent before the filing of a 505(b)(2) application or receipt of an ANDA. Some have expressed uncertainty after enactment of the MMA because the FD&C Act requires that notice be sent ''not later than 20 days after the date of the postmark on the notice with which [FDA] informs the applicant'' that its 505(b)(2) application or ANDA has been filed, without explicitly establishing a date earlier than which notice may not be provided (see section 505(b)(3)(B)(i) and (j)(2)(B)(ii)(I) of the FD&C Act).

We are proposing to amend §§ 314.52(b) and 314.95(b) by revising and redesignating the current text as paragraphs (b)(1) and (b)(3) and adding a new paragraph (b)(2). Proposed § § 314.52(b)(2) and 314.95(b)(2) state that any notice sent before the receipt of an FDA acknowledgment letter or paragraph IV acknowledgment letter is invalid (and thus does not trigger either the 45-day period in which the NDA holder and each patent owner may initiate a patent infringement action and obtain a 30-month stay or the beginning of any related 30-month period) and will not be considered to comply with the FD&C Act's notice requirement until valid notice is sent. We also are proposing to revise § 314.95(b)(2) to state that any notice sent before the first working day after the day the patent is published in the Orange Book (the list) is invalid and will not be considered to comply with the FD&C Act's notice requirement (see discussion in section II.D.1.b.ii).

An applicant that prematurely sends notice of a paragraph IV certification must resend notice within the required timeframe in order to satisfy the notice requirement of the FD&C Act and, in the case of a first applicant, qualify for 180-day exclusivity. To help ensure that notices of paragraph IV certifications are not sent prematurely, we also are proposing to amend § § 314.52(c)(3) and 314.95(c)(3) to require that each 505(b)(2) or ANDA applicant include, in any notice of paragraph IV certification related to its application, a statement that it has received an acknowledgment letter or paragraph IV acknowledgment letter. We recognize that this proposed requirement may have the effect of delaying the provision of notice of paragraph IV certification by a 505(b)(2) applicant (but not an ANDA applicant) by approximately 2 weeks after the 505(b)(2) application is filed, because an NDA is considered filed 60 days after submission, but our proposed definition of a ''paragraph IV acknowledgment letter'' for a 505(b)(2) application is the filing communication that is generally mailed by the 74th day after the date of submission of the 505(b)(2) application in accordance with the performance goal established under the current reauthorization of the prescription drug user fee program in FDASIA (see section II.D.3.b). We recognize that this would potentially delay the initiation of patent infringement litigation by an NDA holder or patent owner and any corresponding 30-month stay of approval of the 505(b)(2) application by approximately 2 weeks. We invite comment on this approach to premature notice of a paragraph IV certification for a 505(b)(2) application, especially with respect to notice sent after a 505(b)(2) application is filed (60th day after submission) and before a paragraph IV acknowledgment letter (generally sent by the 74th day after submission) is received.

There have been some instances in which an applicant seeks to submit an amendment containing a paragraph IV certification to its 505(b)(2) application or ANDA prior to filing or receipt of the application as described in § 314.101(a) and (b), respectively, and receipt of an acknowledgment letter or a paragraph IV acknowledgment letter. For example, an applicant may seek to amend its ANDA to add a new strength of the drug product (see § 314.95(d)(3)). We are proposing to revise §§ 314.52(d)(2) and 314.95(d)(2) to clarify that an applicant submitting an amendment containing a paragraph IV certification must comply with the timeframes set forth in §§ 314.52(b) and 314.95(b) and wait until it has received an acknowledgment letter or a paragraph IV acknowledgment letter before sending notice of its paragraph IV certification to the NDA holder and each patent owner. This approach ensures that a notice of paragraph IV certification is not sent before we have accepted for substantive review the underlying application to which the notice relates (*i.e.,* before we have filed the 505(b)(2) application or received the ANDA). As one Federal district court observed in upholding FDA's interpretation of the statute in this scenario, ''[i]f an ANDA applicant could send Paragraph IV notice when amending an ANDA that has not yet been accepted as received, the applicant could accelerate the timing provisions and litigation process well beyond the framework that Congress intended'' (*SB Pharmco Puerto Rico, Inc.* v. *Mutual Pharmaceutical Co.,* 552 F. Supp. 2d 500, 510 (E.D. Pa.), *appeal dismissed,* 2008 U.S. App. LEXIS 27672 (Fed. Cir. 2008) (holding that notice of a paragraph IV certification sent concurrent with submission of an amendment to an ANDA that had not yet been accepted for filing ''was not valid or timely'' under section 505(j)(2)(B)(ii)(II) of the FD&C Act)).

Thus, if an ANDA applicant submits an amendment containing a paragraph IV certification before it has received an acknowledgment letter or a paragraph IV acknowledgment letter advising that the ANDA has been received for substantive review, the applicant is required to send notice of its paragraph IV certification within 20 days after the date of the postmark on the acknowledgment letter or paragraph IV acknowledgment letter, as applicable. It is important to note that the relevant date for purposes of determining first applicant eligibility for 180-day exclusivity based upon submission of a paragraph IV certification contained in an amendment is the date of submission of the amendment (*i.e.,* the date on which the amendment was officially received (date-stamped) by the OGD Document Room) even though the acknowledgment letter or paragraph IV acknowledgment letter may state that the ANDA was received for substantive review on the date on which the original ANDA was submitted (*i.e.,* the date on

which the ANDA was officially received (date-stamped) by the OGD Document Room) or, in the case of an ANDA that OGD initially refused to receive under § 314.101(d) or (e), the date on which the deficiencies were resolved.

II.D.1.b. *Date by which notice must be given.* The MMA amended the FD&C Act to require that 505(b)(2) and ANDA applicants provide notice of a paragraph IV certification to the NDA holder and each patent owner in accordance with the following timeframes:

- If the paragraph IV certification is included in an original 505(b)(2) application or ANDA, or in an amendment to such application that is submitted before the applicant receives an acknowledgment letter or paragraph IV acknowledgment letter, not later than 20 days after the date of the postmark on the notice from FDA informing the applicant that its application has been filed or received (see section 505(b)(3)(B)(i) and (j)(2)(B)(ii)(I) of the FD&C Act), or
- If the paragraph IV certification is included in any other amendment or in a supplement, at the time the applicant submits the amendment or supplement (see section 505(b)(3)(B)(ii) and 505(j)(2)(B)(ii)(II) of the FD&C Act).

II.D.1.b.i. *Determining the timeframe for sending notice after receipt of an acknowledgment letter or a paragraph IV acknowledgment letter.* We are proposing to revise §§ 314.52(b)(1) and 314.95(b)(1) to require that an applicant must send notice of a paragraph IV certification contained in a 505(b)(2) application or ANDA on or after the date on which it receives an acknowledgment letter or a paragraph IV acknowledgment letter, but not later than 20 days after the date of the ''postmark'' (see proposed definition below) on the acknowledgment letter or paragraph IV acknowledgment letter. As discussed in sections II.A.2.u and II.A.2.y, we are proposing a broader definition of the term ''postmark'' and, as applied to paragraph IV acknowledgment letters for 505(b)(2) applications, an alternate interpretation of the term ''postmark'' to reflect current OND practice regarding the mailing of filing communications. For purposes of proposed § 314.52(b) and (c) only, the ''date of the postmark'' on the paragraph IV acknowledgment letter for a 505(b)(2) application is considered to be 4 calendar days after the date on which the filing communication is signed by the signatory authority (generally the Division Director or designee in OND) unless OND sends the filing communication to the applicant via electronic transmission. If OND sends the filing communication via electronic transmission, then our proposed definition of ''postmark'' in § 314.3(b) would apply. We recognize that issuance of the filing communication within 14 days after the 60-day filing date described in § 314.101(a)(1) and (a)(2) represents a performance goal under the current reauthorization of the prescription drug user fee program in FDASIA. Accordingly, an applicant that has submitted a 505(b)(2) application containing a paragraph IV certification and has received neither a refuse-to-file letter within 60 days nor a filing communication within 74 days after FDA receives the 505(b)(2) application should contact FDA to request issuance of the filing communication. We invite comment on whether an alternate approach should be taken. With reference to an acknowledgment letter or a paragraph IV acknowledgment letter for an ANDA, we recognize that there may be scenarios in which the postmark on the envelope containing an acknowledgment letter or a paragraph IV acknowledgment letter is illegible or inadvertently absent. We invite comment on the interpretation of the term ''postmark'' in the context of an acknowledgment letter or a paragraph IV acknowledgment letter for a 505(b)(2) application or an ANDA, and whether our regulations should be amended to define differently the specific date on which the 20-day notice period begins.

The MMA does not specify how the 20-day period for providing notice of a paragraph IV certification is to be calculated. We are proposing in §§ 314.52(b)(1) and 314.95(b)(1) to calculate this notice period in the same way that we calculate the 45-day period within which each patent owner and NDA holder may initiate a patent infringement action (which may, if other applicable requirements are satisfied, trigger a 30-month stay of approval of a 505(b)(2) application or ANDA) following receipt of notice of a paragraph IV certification (see § 314.107(f)). Specifically, we propose that the first day of the 20-day period begin on the day after the date of the postmark on the acknowledgment letter or paragraph IV acknowledgment letter. The 20-day period is proposed to include all calendar days, except that if the 20th day falls on a Saturday, Sunday, or Federal holiday, the last day of the 20-day period will be considered to be the next day that is not a Saturday, Sunday, or Federal holiday. This approach reflects the most conservative interpretation of the statute and is the calculation method currently used by most ANDA applicants.

There will be no regulatory benefit or consequence for applicants based on when they provide notice of a paragraph IV certification contained in an original application, as long as notice is provided within the 20-day timeframe required by the MMA. An ANDA applicant that does not comply with the statutory timeframe in section 505(j)(2)(B)(ii)(I) and (j)(2)(B)(ii)(II) of the FD&C Act for providing notice of its paragraph IV certification will be subject to administrative consequences (see section II.D.5).

II.D.1.b.ii. *Determining the timeframe for sending notice of a paragraph IV certification upon submission of an amendment or supplement.* We are proposing to revise §§ 314.52(d) and 314.95(d) to implement section 505(b)(3)(B)(i), (b)(3)(B)(ii), (j)(2)(B)(ii)(I), and (j)(2)(B)(ii)(II) of the FD&C Act and for the efficient enforcement of the FD&C Act. Our proposed revisions clarify the applicable timeframe in which a 505(b)(2) or ANDA applicant must send notice of a paragraph IV certification submitted in an amendment or supplement to its 505(b)(2) application or ANDA, respectively. We are proposing to revise and redesignate the current text of §§ 314.52(d) and 314.95(d) as paragraph (d)(1) to accommodate the proposed inclusion of additional paragraphs to §§ 314.52(d) and 314.95(d). Table 6 summarizes the proposed changes related to the timing of providing notice of paragraph IV certification(s) submitted in an amendment or supplement to a 505(b)(2) application or ANDA.

TABLE 6—HIGHLIGHTS OF PROPOSED CHANGES REGARDING TIMING OF NOTICE OF PARAGRAPH IV CERTIFICATION IN AN AMENDMENT OR SUPPLEMENT [1]

Current regulations	Proposed revisions to regulations
Amendment to an application or an abbreviated application (§§ 314.52(d) and 314.95(d))	*Amendment or supplement to a 505(b)(2) application or an ANDA (§§ 314.52(d)(1) and 314.95(d)(1))*

TABLE 6—HIGHLIGHTS OF PROPOSED CHANGES REGARDING TIMING OF NOTICE OF PARAGRAPH IV CERTIFICATION IN AN AMENDMENT OR SUPPLEMENT [1]—Continued

Current regulations	Proposed revisions to regulations
• If an application or abbreviated application is amended to include the certification described in §§ 314.50(i) or 314.94(a)(12)(i)(A)(*4*), respectively, the applicant must send the notice required by §§ 314.52(a) or 314.95(a), respectively, at the same time the amendment is submitted to FDA	*After receipt of an acknowledgment letter or paragraph IV acknowledgment letter:* • If an applicant submits an amendment or supplement to its 505(b)(2) application or ANDA that includes a paragraph IV certification, the applicant must send notice required by § 314.52(a) or § 314.95(a), respectively, at the same time the amendment is submitted to FDA. • Notice of paragraph IV certification is required regardless of whether notice already has been provided for another paragraph IV certification contained in the application or in an amendment or supplement to the application. *Amendment to a 505(b)(2) application or an ANDA (§§ 314.52(d)(2) and 314.95(d)(2))* *Before receipt of an acknowledgement letter or paragraph IV acknowledgment letter:* • If an applicant submits a paragraph IV certification in an amendment to a 505(b)(2) application or ANDA, the applicant must send notice required by § 314.52(a) or § 314.95(a), respectively, in accordance with the procedures in § 314.52(b) or § 314.95(b). • If an ANDA applicant timely provides notice of paragraph IV certification in accordance with § 314.95(b), FDA will base its determination of whether the applicant is a first applicant on the date of submission of the amendment containing the paragraph IV certification. *Amendment to a 505(b)(2) application or an ANDA (§§ 314.52(d)(3) and 314.95(d)(3))* • An applicant that submits an amendment or supplement to its 505(b)(2) application or ANDA to seek approval of a new strength must provide notice of any paragraph IV certification in accordance with §§ 314.52(d)(1) and (d)(2) or §§ 314.95(d)(1) and (d)(2), as applicable.

[1] These highlights describe important proposed revisions to our regulations, but should not be relied upon in place of the proposed regulation.

We are proposing to revise §§ 314.52(d) and 314.95(d) (redesignated as §§ 314.52(d)(1) and 314.95(d)(1), respectively) to require that an applicant send notice of a paragraph IV certification contained in an amendment to an application that has been received for substantive review or in a supplement to an approved application at the same time that the amendment or supplement is submitted to FDA. Our proposed revisions clarify the requirement in our current regulations for an applicant to send notice of a paragraph IV certification at the same time that the amendment is submitted to FDA by distinguishing between: (1) Amendments submitted after the application has been received for substantive review as indicated by the receipt of an acknowledgment letter (if, as to an ANDA, the original application did not contain a paragraph IV certification) or paragraph IV acknowledgment letter and (2) amendments submitted before an application has been received for substantive review (see proposed §§ 314.52(d)(2) and 314.95(d)(2) and section II.D.1.b.i.). The MMA amended the FD&C Act to require that notice of a paragraph IV certification contained in a supplement to an approved 505(b)(2) application or ANDA be sent at the same time that the supplement is submitted to FDA, and our proposed revision to §§ 314.52(d)(1) and 314.95(d)(1) incorporates this requirement (see section 505(b)(3)(B)(ii) and (j)(2)(B)(ii)(II) of the FD&C Act).

In proposed §§ 314.52(d)(1) and 314.95(d)(1), we reiterate the statutory requirement that notice of a paragraph IV certification in an amendment or supplement must be provided regardless of whether the applicant has already given notice with respect to another paragraph IV certification contained in the 505(b)(2) application or ANDA or in an amendment or supplement to the 505(b)(2) application or ANDA. The phrase ''another paragraph IV certification'' may refer to a previous paragraph IV certification to a different listed patent for the listed drug relied upon or RLD or, for certain amendments and supplements (see section II.F), a previous paragraph IV certification to the same listed patent. For example, if an ANDA applicant submitted a paragraph IV certification to the '246 patent (a listed patent claiming the drug product for the listed drug relied upon) in its original application, and subsequently submitted an amendment to its pending ANDA to change the formulation, the ANDA applicant would be required to provide a new patent certification to the '246 patent (see proposed § 314.96(d)(1) and section II.F.1). If this ANDA applicant submitted a paragraph IV certification to the '246 patent in its amendment, the ANDA applicant would be required to send notice of its second paragraph IV certification to the '246 patent to the NDA holder and each patent owner at the same time the amendment to the ANDA is submitted to FDA.

If an applicant submits an amendment containing a paragraph IV certification to its 505(b)(2) application or ANDA before the applicant has received an acknowledgment letter (if, as to an ANDA, the original application did not contain a paragraph IV certification) or a paragraph IV acknowledgment letter, proposed §§ 314.52(d)(2) and 314.95(d)(2) require that the applicant send notice of its paragraph IV certification in accordance with the procedures described in §§ 314.52(b) and 314.95(b), respectively. In this circumstance, the 505(b)(2) or ANDA applicant must send notice of the paragraph IV certification contained in

its amendment on or after the date it receives an acknowledgment letter or paragraph IV acknowledgment letter, but not later than 20 days after the date of the postmark on the letter. This requirement reflects our longstanding policy that notice of a paragraph IV certification may not be sent unless and until we have notified the applicant that its application has been filed or received, as appropriate (see section II.D.1.a).

It should be noted that a paragraph IV certification submitted in an amendment after the 505(b)(2) application or ANDA is submitted but before the applicant receives a paragraph IV acknowledgment letter is considered part of the original 505(b)(2) application or ANDA solely for the purpose of determining the appropriate timeframe for sending notice of paragraph IV certification. The availability of a 30-month stay for patent infringement litigation initiated within the statutory timeframe in response to a paragraph IV certification submitted in an amendment to a 505(b)(2) application or an ANDA continues to be determined by whether the patent at issue was filed with FDA before the date on which the original 505(b)(2) application or ANDA (excluding an amendment or supplement) was submitted (see section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act; see also proposed § 314.107(b)(2) and section II.M.2.b). For purposes of determining an ANDA applicant's eligibility for 180-day exclusivity and the date from which a first ANDA applicant's compliance with section 505(j)(5)(D)(i)(IV) of the FD&C Act is assessed, the date of the submission of the paragraph IV certification is the date on which the amendment was submitted. An amendment seeking approval for a different strength of a drug product thus may have a different submission date than the original ANDA submission for purposes of evaluating an ANDA applicant's eligibility for 180-day exclusivity for that new drug product and the date from which a first ANDA applicant's compliance with section 505(j)(5)(D)(i)(IV) of the FD&C Act is assessed.

Proposed §§ 314.52(d)(3) and 314.95(d)(3) require that an applicant that submits an amendment or supplement to a 505(b)(2) application or ANDA that contains a paragraph IV certification and seeks approval for a different strength of the drug product must adhere to the timing requirements for notice in §§ 314.52(d)(1) or (d)(2) and 314.95(d)(1) or (d)(2), as applicable. Unlike other amendments and supplements to a 505(b)(2) application or ANDA, an amendment or supplement seeking approval of a different strength may refer to a different listed drug than the listed drug identified in the original 505(b)(2) application or ANDA (see section 505(b)(4)(B) and (j)(2)(D)(ii) of the FD&C Act). Accordingly, we have separately described this type of amendment or supplement to clarify applicable regulatory requirements.

There are a few situations in which the relationship between an acknowledgment letter or paragraph IV acknowledgment letter and the timing of notice for a paragraph IV certification contained in an amendment or supplement to a 505(b)(2) application or ANDA may seem complicated. For example, in the case of a 505(b)(2) or ANDA applicant that submits an original application containing a paragraph III certification to a listed patent and receives an acknowledgment letter (as distinguished from a paragraph IV acknowledgment letter) indicating that the 505(b)(2) application or ANDA has been received for substantive review, if the applicant subsequently submits an amendment containing a paragraph IV certification to a listed patent, the applicant need not wait to receive a paragraph IV acknowledgment letter before sending notice in accordance with § 314.52(d)(1) or § 314.95(d)(1).

Also, we note that FDA may send an acknowledgment letter for certain types of supplements (*e.g.,* a supplement to an ANDA seeking approval for a new strength of a drug product; a 505(b)(2) supplement to an NDA seeking approval for a new indication, new dosage regimen, new route of administration, or a change from prescription use to OTC status for all conditions of use). However, this practice would not alter the 505(b)(2) or ANDA applicant's statutory obligation to send notice of a paragraph IV certification at the time the supplement is submitted to FDA (and not at the time the paragraph IV acknowledgment letter for the supplement may be received).

We interpret the requirement in proposed § 314.52(d)(1) or § 314.95(d)(1) to send notice of a paragraph IV certification at the same time that the amendment or supplement to the application is submitted to FDA to mean that notice to the NDA holder and each patent owner must be sent on the same day that the amendment or supplement to the application is submitted to FDA. It should be noted that the controlling date for purposes of first applicant eligibility is the date on which the amendment or supplement to the ANDA containing a paragraph IV certification is submitted (*i.e.,* officially received (date-stamped) by the OGD Document Room) as long as notice is timely provided in accordance with the statute. Due to a technical difference in the method by which FDA determines the date of submissions to FDA (using a date of receipt rule) and the date on which an applicant sends notice of a paragraph IV certification to the NDA holder and each patent owner (using a date of mailing rule), these dates may differ. For example, Applicant A submits an amendment containing a paragraph IV certification to its ANDA on August 2 and sends notice of the paragraph IV certification to the NDA holder and each patent owner on that same day. The amendment to the ANDA is date-stamped by the OGD Document Room on August 3. Applicant A has complied with the statutory requirement to send notice of its paragraph IV certification at the same time the amendment or supplement to the ANDA is submitted despite the difference in the date on which the amendment was officially received and the date on which the notice of paragraph IV certification was sent because both the amendment and notice(s) were actually sent on the same day.

If an ANDA applicant does not provide notice of a paragraph IV certification on the same day that an amendment or supplement is submitted, FDA will consider the paragraph IV certification to be effective only as of the date that the applicant has both submitted the amendment or supplement containing the paragraph IV certification and sent the notice (see *Purepac Pharmaceutical Co.* v. *Thompson,* 354 F.3d 877 (D.C. Cir. 2004)).

To qualify as a first applicant eligible for 180-day exclusivity under section 505(j)(5)(B)(iv)(II)(bb) of the FD&C Act, an applicant must, among other things, submit a paragraph IV certification on the ''first day on which a substantially complete application containing a [paragraph IV certification] is submitted.'' Because daily electronic updates to the Orange Book generally do not occur until the afternoon (Eastern Standard Time), the opportunity to be a first applicant with respect to a patent that is newly listed in the Orange Book (*i.e.,* to submit an amendment to the ANDA containing a paragraph IV certification and send notice of the paragraph IV certification on that same day) could be affected by, among other things, the time zone in which the ANDA applicant resides. To ensure that all ANDA applicants (irrespective of time zone) have a reasonable opportunity to be a first applicant with respect to a newly listed patent, we are proposing that any notice of paragraph

IV certification is invalid if it is sent before the first working day after the day the patent is listed in the Orange Book (see proposed §§ 314.95(b)(2) and 314.94(a)(12)(viii)(C)(*1*)(*ii*), discussed in section II.E.4). The term ''working day'' has the meaning provided in 21 CFR 1.377 (''any day from Monday through Friday, excluding Federal holidays''). This approach is intended to promote equity among ANDA applicants and reduce the burden on industry and on the Agency associated with serial submissions of amendments and multiple notices of paragraph IV certifications related to a newly-issued patent. When a new patent is issued by the PTO, the NDA holder has 30 days within which to submit the patent information to FDA for listing. An ANDA applicant does not know if or when the patent may be submitted to FDA, and when it is submitted, there may be a delay in the patent's appearance in the Orange Book. Therefore, if an ANDA applicant reasonably believes a patent could be listed for an RLD, it will often submit a paragraph IV certification to FDA and send notice to the NDA holder and patent owner each day during the 30-day period after issuance of the new patent. ANDA applicants have adopted this practice in an attempt to satisfy the certification and notice requirements on the first date on which the patent is listed in the Orange Book and thus qualify as a first applicant. FDA's proposal is intended to eliminate the need for these burdensome serial certifications.

The following example illustrates our approach: The NDA holder submits Form FDA 3542 to the Office of Generic Drugs, Document Room, Attention: Orange Book Staff, within 30 days after issuance of the '123 patent claiming the drug product Litigatolol. Form FDA 3542 is date-stamped by the OGD Document Room on Friday, August 5 and listed in the Orange Book, which is updated at 3 p.m. Eastern Standard Time on that date. Applicant B and Applicant C have submitted ANDAs for Litigatolol and have received acknowledgment letters indicating that their ANDAs have been received for substantive review. Applicant B is located in California and submits an amendment to its ANDA containing a paragraph IV certification to the '123 patent and sends notice to the NDA holder and each patent owner late in the afternoon, Pacific Time, on Friday, August 5. Applicant C is located in New Jersey and would have been unable to submit an amendment to its ANDA containing a paragraph IV certification to the '123 patent and send notice to the NDA holder and each patent owner before the end of the working day on Friday, August 5. Applicant C submits the amendment and sends notice on Monday, August 8. Prior to these amendments, no ANDA had contained a paragraph IV certification to a patent listed for Litigatolol. Applicant B prematurely submitted its amendment containing a paragraph IV certification, and its notice of paragraph IV certification is invalid because it was sent before the first full working day after the patent is listed in the Orange Book. Only Applicant C has submitted the first substantially complete ANDA containing a paragraph IV certification for purposes of first applicant eligibility.

It should be noted that if there is a delay between FDA's receipt of new patent information and publication of the patent information in the Orange Book, the actual date of publication of the patent information in the Orange Book provides the date from which the validity of the ANDA applicant's notice of paragraph IV certification will be assessed for purposes of first applicant eligibility (compare section II.D.3 regarding determination of a 505(b)(2) or ANDA applicant's patent certification obligations and the availability of a 30-month stay based on patent information in FDA's possession).

II.D.1.c. *Certification of provision of notice.* We are proposing to amend §§ 314.52(b) and 314.95(b) by revising and redesignating certain text as new paragraph (b)(3). Proposed §§ 314.52(b)(3) and 314.95(b)(3) describe the current requirement for 505(b)(2) and ANDA applicants, respectively, to amend their applications at the time that they provide notice of a paragraph IV certification to include a statement certifying that notice has been provided to the NDA holder and each patent owner as required by §§ 314.52(a) and 314.95(a) and has met the content requirements for notice of a paragraph IV certification as described in §§ 314.52(c) and 314.95(c). We are proposing to clarify that a copy of the notice of paragraph IV certification itself does not need to be submitted to FDA in the amendment.

We describe acceptable methods for delivery of notice of paragraph IV certification and documentation of timely delivery and receipt of such notice in section II.D.4.

II.D.2. Notice Required for All Paragraph IV Certifications

The MMA requires applicants submitting 505(b)(2) applications and ANDAs to provide notice for *all* paragraph IV certifications submitted to FDA on or after August 18, 2003, regardless of whether the applicant had previously given notice of a paragraph IV certification contained in its application or an amendment or supplement to the application (see section 505(b)(3)(B) and (j)(2)(B)(ii) of the FD&C Act).

We are proposing to require a 505(b)(2) or ANDA applicant to provide a new notice of paragraph IV certification to a patent for which it previously had provided notice if the applicant submits an amendment or supplement to the 505(b)(2) application or ANDA for certain changes to the proposed product that should be accompanied by a new patent certification (see section II.F).

II.D.3. Contents of Notice

We are proposing to revise §§ 314.52(c) and 314.95(c) regarding the contents of notice of a paragraph IV certification to incorporate requirements added by the MMA and to support the efficient enforcement of our regulations. We note, however, that the Agency neither assesses the adequacy of the contents of a 505(b)(2) or ANDA applicant's notice of paragraph IV certification nor the applicant's stated basis for certifying that a listed patent is invalid, unenforceable, or will not be infringed by its proposed drug product. In our final rule implementing the patent and exclusivity provisions of the Hatch-Waxman amendments, we stated that ''the agency does not have the expertise or the desire to become involved in issues concerning patent law and sufficiency of notice. . . . Disputes involving the sufficiency of the notice [*i.e.,* the detailed statement of the factual and legal basis behind the applicant's opinion that the patent is invalid, unenforceable, or not infringed] must be resolved by the applicant, patent owner, and holder of the approved application rather than by action on the part of FDA'' (59 FR 50338 at 50349, October 3, 1994).

We also are revising §§ 314.52(c) and 314.95(c) to require the 505(b)(2) or ANDA applicant to cite section 505(b)(3)(D) and (j)(2)(B)(iv), respectively, as amended by the MMA, in the notice of paragraph IV certification.

Table 7 summarizes the proposed changes related to content of a notice of paragraph IV certification.

TABLE 7—HIGHLIGHTS OF PROPOSED CHANGES REGARDING CONTENT OF A NOTICE OF PARAGRAPH IV CERTIFICATION [1]

Current regulations	Proposed revisions to regulations
Content of a notice (§§ 314.52(c)) and 314.95(c)) • The 505(b)(2) or ANDA applicant must cite section 505(b)(3)(B) or 505(j)(2)(B)(ii) of the FD&C Act, as appropriate, and the notice must also include, but not be limited to, the following information: —(1) A statement that a 505(b)(2) application submitted by the applicant has been filed by FDA; or a statement that FDA has received an ANDA submitted by the applicant containing any required bioavailability (BA) or bioequivalence (BE) data or information. —(2) The NDA or ANDA number. —(3) The established name, if any, of the proposed drug product. —(4) The active ingredient, strength, and dosage form of the proposed drug product. —(5) The patent number and expiration date, as submitted to the Agency or as known to the applicant, of each patent alleged to be invalid, unenforceable, or not infringed. —(6) A detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed. —(7) If the applicant does not reside or have a place of business in the U.S., the name and address of an agent in the U.S. authorized to accept service of process for the applicant.	*Content of a notice (§§ 314.52(c)) and 314.95(c))* • The 505(b)(2) or ANDA applicant must cite section 505(b)(3)(D) or 505(j)(2)(B)(iv) of the FD&C Act, as appropriate, and the notice must also include, but is not limited to, the following information: —(1) A statement that a 505(b)(2) application that contains any required BA or BE data has been submitted by the applicant and filed by FDA; or a statement that FDA has received an ANDA submitted by the applicant containing any required BA or BE data or information. —(2) The NDA or ANDA number. —(3) A statement that the applicant has received the acknowledgment letter or paragraph IV acknowledgment letter for the 505(b)(2) application or ANDA. —(4) The established name, if any, of the proposed drug product. —(5) The active ingredient, strength, and dosage form of the proposed drug product. —(6) The patent number and expiration date of each patent on the list alleged to be invalid, unenforceable, or not infringed. —(7) A detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed. —(8) If the applicant alleges that the patent will not be infringed and may later decide to file a civil action for declaratory judgment in accordance with section 505(c)(3)(D) and 505(j)(5)(C) of the FD&C Act, then the notice must be accompanied by an offer of confidential access to the 505(b)(2) application or ANDA for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the paragraph IV certification. —(9) If the applicant does not reside or have a place of business in the U.S., the name and address of an agent in the U.S. authorized to accept service of process for the applicant.

[1] These highlights describe important proposed revisions to our regulations, but should not be relied upon in place of the proposed regulation.

II.D.3.a. *Statement that any required bioavailability or bioequivalence studies for a 505(b)(2) application have been submitted.* The MMA amended the FD&C Act to require that the notice of paragraph IV certification for a 505(b)(2) application include a statement that ''an application that contains data from bioavailability or bioequivalence studies'' has been submitted to FDA (section 505(b)(3)(D)(i) of the FD&C Act). This statutory provision parallels the content requirements for notice of paragraph IV certification for an ANDA (see section 505(j)(2)(B)(iv)(I) of the FD&C Act). Consistent with our previous implementation of the statutory requirement for ANDAs in § 314.95(c), proposed § 314.52(c)(1) requires that a notice of a paragraph IV certification for a 505(b)(2) application state that data from ''any *required* bioavailability or bioequivalence studies'' (emphasis added) have been submitted. This qualifier reflects that FDA may exercise its scientific judgment to determine what bioavailability and bioequivalence studies may be needed for certain 505(b)(2) applications and ANDAs (see, *e.g.,* § 314.54(a)(1) and (a)(2) (citing §§ 314.50(d)(3) and 320.21(a)(2) and (f)); compare § 320.21(b)(2)).

A 505(b)(2) application may seek to rely upon non-product-specific published literature or other studies necessary for approval for which the applicant has no right of reference or use. This type of 505(b)(2) application generally would not require studies showing relative bioavailability or bioequivalence because the 505(b)(2) application is not relying upon the Agency's finding of safety and/or effectiveness for a listed drug. In the absence of a listed drug, there is not likely to be a specific drug for use as a comparator in a relative bioavailability or bioequivalence study. However, such a 505(b)(2) application must establish that reliance on the studies described in the literature is scientifically appropriate. Further, a 505(b)(2) application that did not rely upon a listed drug would not require a patent certification or statement, and thus there would be no occasion for a notice of paragraph IV certification.

II.D.3.b. *Statement confirming receipt of an acknowledgment letter or a paragraph IV acknowledgment letter.* We are proposing to revise §§ 314.52(c)(3) and 314.95(c)(3) to add a new requirement for 505(b)(2) and ANDA applicants, respectively, to facilitate compliance with and enforcement of section 505(b)(3)(B)(i), (b)(3)(B)(ii), (j)(2)(B)(ii)(I), and (j)(2)(B)(ii)(II) of the FD&C Act regarding the timing of notice of paragraph IV certification. Proposed §§ 314.52(c)(3) and 314.95(c)(3) require a 505(b)(2) and ANDA applicant, respectively, to include a statement in its notice of paragraph IV certification that the applicant has received an acknowledgment letter or a paragraph IV acknowledgment letter for its 505(b)(2) application or ANDA. This requirement is intended to ensure that a notice of paragraph IV certification is not sent before FDA has determined that the 505(b)(2) application or ANDA containing the certification is acceptable for substantive review and has issued an acknowledgment letter or a paragraph IV acknowledgment letter (see section II.D.1.a).

II.D.3.c. *Documentation that paragraph IV certification was submitted and notice was sent only for patents listed in the Orange Book.* We are proposing to revise §§ 314.52(c)(6) and 314.95(c)(6) to specify that notice of a paragraph IV certification (and therefore the underlying paragraph IV certification as well) must only be sent for a patent that is listed in the Orange Book for the listed drug(s) relied upon

for a 505(b)(2) application or for the RLD for an ANDA. We are proposing to add the phase ''on the list'' to proposed §§ 314.52(c)(6) and 314.95(c)(6) to qualify the patents for which a notice of paragraph IV certification must be sent.

As discussed in section II.D.4.b, we are proposing to require an ANDA applicant to include a dated printout of the Orange Book entry for the RLD that includes the patent that is the subject of the notice of paragraph IV certification in its amendment certifying that notice of paragraph IV certification has been sent and documenting that notice has been received (see proposed § 314.95(e)). A 505(b)(2) applicant may elect to submit a copy of the Orange Book patent listing for the listed drug(s) relied upon with its 505(b)(2) application, amendment, or supplement containing a paragraph IV certification to describe the applicant's understanding of the most current patent information listed in the Orange Book at the time of submission. We note, however, that a 505(b)(2) or ANDA applicant's patent certification obligations and the availability of a 30-month stay under section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act are determined based on patent information in FDA's possession, even if such information is not accurately listed in the Orange Book (see *Teva Pharms., USA, Inc.* v. *Leavitt,* 548 F.3d 103, at 105 (D.C. Cir. 2008) (''FDA insists reality matters'')).

In addition, we are proposing to delete the phrase ''as submitted to the agency or as known to the applicant'' from §§ 314.52(c)(6) and 314.95(c)(6), as this phrase is over-inclusive. It does not accurately describe the universe of patents for which a paragraph IV certification may be submitted and thus is inapplicable to the content requirements for notice of a paragraph IV certification. Although an applicant may submit a certification pursuant to section 505(b)(2)(A)(i) or 505(j)(2)(A)(vii)(I) of the FD&C Act (''paragraph I certification'') with respect to patent information that has not been filed with FDA and is not listed in the Orange Book, such a patent could not be the basis for a paragraph IV certification.

II.D.3.d. *Offer of confidential access accompanying notice.* The MMA established conditions under which a 505(b)(2) or ANDA applicant may bring a declaratory judgment action to obtain ''patent certainty'' (*i.e.,* obtain a judicial determination of noninfringement, invalidity, or unenforceability) with respect to a listed patent for which it has given notice of a paragraph IV certification but has not been sued by the NDA holder or any patent owner within the statutory timeframe (see section 505(c)(3)(D) and (j)(5)(C) of the FD&C Act). As a precondition to filing an action for declaratory judgment to establish patent noninfringement (as distinguished from patent invalidity or unenforceability), the applicant must provide a document offering the NDA holder and each patent owner confidential access to the 505(b)(2) application or ANDA for the sole and limited purpose of assessing patent noninfringement (see section 505(c)(3)(D)(i)(III) and (j)(5)(C)(i)(III) of the FD&C Act). Because this offer of confidential access, if made, is required to accompany the notice of paragraph IV certification, we are proposing to revise §§ 314.52(c) and 314.95(c) to reference the statutory requirement for an offer of confidential access (see section 505(c)(3)(D)(i)(I)(cc) and (j)(5)(C)(i)(I)(cc) of the FD&C Act). Our proposed regulations do not otherwise address the offer of confidential access because the process for seeking a declaratory judgment does not involve FDA.

II.D.4. Documentation of Timely Sending and Receipt of Notice

We are proposing to revise §§ 314.52(e) and 314.95(e) to clarify the requirements for submission of an amendment to a 505(b)(2) application or ANDA, respectively, containing documentation of timely sending of notice of paragraph IV certification and confirmation of receipt of same by the NDA holder and each patent owner. In addition, we are proposing to revise §§ 314.52 and 314.95 to expand the list of acceptable delivery methods that may be used to send notice of paragraph IV certification to the NDA holder and each patent owner. These proposed revisions are intended to facilitate compliance with the statutory requirements regarding timing of notice of paragraph IV certification and related regulatory provisions.

Table 8 summarizes the proposed changes regarding documentation of timely sending and receipt of notice of paragraph IV certification:

TABLE 8—HIGHLIGHTS OF PROPOSED CHANGES REGARDING DOCUMENTATION OF TIMELY SENDING AND RECEIPT OF NOTICE OF PARAGRAPH IV CERTIFICATION [1]

Current regulations	Proposed revisions to regulations
Notice of certification (§§ 314.52(a) and 314.95(a))	*Notice of certification (§§ 314.52(a) and 314.95(a))*
• 505(b)(2) or ANDA applicant must send notice of paragraph IV certification by registered or certified mail, return receipt requested, to each patent owner and the NDA holder.	• 505(b)(2) or ANDA applicant must send notice of paragraph IV certification by registered or certified mail, return receipt requested, or by a designated delivery service, to each patent owner and the NDA holder. • 505(b)(2) or ANDA applicant may send notice by an alternative method only if FDA has agreed in advance that the method will produce an acceptable form of documentation.
Documentation of receipt of notice (§§ 314.52(e) and 314.95(e))	*Documentation of timely sending and receipt of notice (§§ 314.52(e) and 314.95(e))*
• Applicant must amend its 505(b)(2) application or ANDA to document the date of receipt of the notice of paragraph IV certification by each patent owner and NDA holder provided the notice.	• Applicant must amend its 505(b)(2) application or ANDA to provide documentation of the date of receipt of the notice of paragraph IV certification by each patent owner and NDA holder provided the notice.
• Applicant must include a copy of the return receipt or other similar evidence of the date the notification was received. —FDA will accept as adequate documentation of the date of receipt a return receipt or a letter acknowledging receipt by the person provided the notice.	—FDA will accept as adequate documentation of the date of receipt a return receipt, signature proof of delivery by a designated delivery service, or a letter acknowledging receipt by the person provided notice.
• An applicant may rely on another form of documentation only if FDA has agreed to such documentation in advance.	—Amendment must be submitted to FDA within 30 days after the last date on which notice was received by a patent owner or NDA holder.

TABLE 8—HIGHLIGHTS OF PROPOSED CHANGES REGARDING DOCUMENTATION OF TIMELY SENDING AND RECEIPT OF NOTICE OF PARAGRAPH IV CERTIFICATION [1]—Continued

Current regulations	Proposed revisions to regulations
	• Amendment also must include adequate documentation that notice was sent on a date that complies with the timeframe required by § 314.52(b) or (d) or § 314.95(b) or (d), as applicable. —FDA will accept a copy of the registered mail receipt, certified mail receipt, or receipt from a designated delivery service, as adequate documentation of the date of delivery. • An ANDA applicant's amendment must include a dated printout of the Orange Book entry for the RLD that includes the patent that is the subject of the paragraph IV certification. • An applicant may rely on another form of documentation only if FDA has agreed in advance.

[1] These highlights describe important proposed revisions to our regulations, but should not be relied upon in place of the proposed regulation.

II.D.4.a. *Acceptable methods of sending notice of paragraph IV certification.* A 505(b)(2) or ANDA applicant currently is required to send notice of a paragraph IV certification to the NDA holder and each patent owner by registered or certified mail, return receipt requested, unless FDA agrees in advance to another method of delivery (see §§ 314.52(a) and (e) and 314.95(a) and (e)). We are proposing to revise §§ 314.52(a) and (e) and 314.95(a) and (e) to provide applicants with the option of sending notice of paragraph IV certification by a designated delivery service, as defined in proposed §§ 314.52(g)(1) and 314.95(g)(1). Section 505(b)(2) and ANDA applicants often request permission to send notice of a paragraph IV certification by a major commercial delivery service instead of the U.S. Postal Service (for example, to send notice of a paragraph IV certification to a patent owner who resides outside of the United States). Because we routinely grant these requests, we are proposing to amend our regulations to provide the option to all 505(b)(2) and ANDA applicants to send notice of paragraph IV certification by the U.S. Postal Service or a designated delivery service. We propose to define a ''designated delivery service'' in §§ 314.52(g)(1) and 314.95(g)(1) to mean any delivery service provided by a trade or business that the Agency determines: (1) Is available to the general public throughout the United States; (2) records electronically to its database, kept in the regular course of its business, or marks on the cover in which any item referred to in this section is to be delivered, the date on which such item was given to such trade or business for delivery; and (3) provides overnight or 2-day delivery service throughout the United States.

This proposed definition is adapted from definition of ''designated delivery service'' in 26 U.S.C. 7502(f)(2) (governing timely mailing treated as timely filing and paying by the IRS). As noted in proposed §§ 314.52(g)(2) and 314.95(g)(2), FDA will periodically issue guidance describing designated delivery services that meet these criteria.

Our proposal to revise §§ 314.52(a) and (e) and 314.95(a) and (e) to provide applicants with the option of sending notice of paragraph IV certification by a designated delivery service, as defined in proposed §§ 314.52(g)(1) and 314.95(g)(1), differs from an earlier proposal to provide additional methods of sending notice of paragraph IV certification (see ''New Drugs for Human Use; Clarification of Requirements for Patent Holder Notification; Proposed Rule'' 63 FR 11174; March 6, 1998) (Patent Holder Notification proposed rule). The Patent Holder Notification proposed rule would have permitted a 505(b)(2) or ANDA applicant to send notice of paragraph IV certification ''by mail or personal delivery'' (including overnight delivery service, electronic mail, and facsimile) if the applicant obtained a verification of receipt. We received comments objecting to certain aspects of the Patent Holder Notification Proposed Rule—in particular, notice by electronic methods of delivery such as electronic mail or facsimile—and withdrew the proposed rule (see ''New Drugs for Human Use; Clarification of Requirements for Patent Holder Notification; Withdrawal'' 65 FR 12154; March 8, 2000) (Withdrawal of Patent Holder Notification proposed rule). With respect to notification by overnight delivery service, two comments on the Patent Holder Notification proposed rule supported this alternate method of delivery if a signed verification of receipt of notice by the NDA holder or each patent owner was provided (see Docket No. FDA–1997–P–0417–0011 and FDA–1997–P–0417–0012, available at *http://www.regulations.gov*). Another comment objected to notification by overnight delivery service because receipt of bulk deliveries (containing multiple envelopes and packages) to large corporations is acknowledged by a single signature. This commenter expressed concern that an overnight delivery service envelope containing a notice of paragraph IV certification may not ensure timely receipt by a responsible person. Given that receipt of notice of paragraph IV certification begins a statutory 45-day period within which a patent infringement action must be filed to obtain, under certain circumstances, a 30-month stay, a signature acknowledging receipt of the specific envelope was preferred by this commenter (see Docket No. FDA–1997–P–0417–0010, available at *http://www.regulations.gov*).

In light of the frequency with which FDA receives requests to send notice by overnight delivery services, we invite comment on our current proposal to provide applicants with the option of sending notice of paragraph IV certification by a designated delivery service, as defined in proposed §§ 314.52(g)(1) and 314.95(g)(1).

We also are proposing to add §§ 314.52(a)(4) and 314.95(a)(4) and revise §§ 314.52(e) and 314.95(e) to clarify that a 505(b)(2) or ANDA applicant may send notice of paragraph IV certification by an alternative method (*i.e.,* a method other than registered or certified mail, return receipt requested, or a designated delivery service) only if FDA has agreed in advance that the method will produce an acceptable form of documentation.

In addition, we are proposing to revise the introductory text of § 314.52(a) to refer to each patent that claims the listed drug or drugs relied upon or that claims a use for such listed drug or drugs and for which the applicant submits a paragraph IV certification. This revision is proposed

for clarity and does not represent a substantive change.

II.D.4.b. *Amendment documenting timely sending and confirmation of receipt of notice of paragraph IV certification.* We are proposing to revise §§ 314.52(e) and 314.95(e) to facilitate implementation of section 505(b)(3)(B)(i), (b)(3)(B)(ii), (j)(2)(B)(ii)(I), and (j)(2)(B)(ii)(II) of the FD&C Act and for the efficient enforcement of the FD&C Act.

A 505(b)(2) or ANDA applicant that has submitted one or more paragraph IV certifications currently must submit an amendment to its application documenting the date on which notice of paragraph IV certification was *received* by the NDA holder and each patent owner (see §§ 314.52(e) and 314.95(e)). As discussed in section II.D.1.b, the MMA amended the FD&C Act to require that a 505(b)(2) and ANDA applicant provide notice of a paragraph IV certification in accordance with the timeframes described in section 505(b)(3)(B)(i), (b)(3)(B)(ii), (j)(2)(B)(ii)(I), and (j)(2)(B)(ii)(II) of the FD&C Act (see proposed §§ 314.52(b) and (d) and 314.95(b) and (d)). Our proposed revisions to §§ 314.52(e) and 314.95(e) require a 505(b)(2) and ANDA applicant, respectively, to establish compliance with this statutory requirement by also submitting in its amendment documentation that the notice of paragraph IV certification was *sent* on a date that complies with the timeframe required by § 314.52(b) or (d) or § 314.95(b) or (d), as applicable. For administrative efficiency, we are proposing to require that a 505(b)(2) or ANDA applicant submit the amendment containing documentation of timely sending and receipt of notice of paragraph IV certification within 30 days after the last date on which notice was received by a person described in § 314.52(a) or § 314.95(a), respectively.

The proposed requirement for documentation that notice of paragraph IV certification was timely sent can be satisfied by submitting a copy of the registered mail receipt or certified mail receipt issued by the U.S. Postal Service that bears a postmark documenting the date of mailing or by submitting a copy of the receipt from a designated delivery service, as defined in proposed §§ 314.52(g) and 314.95(g). With respect to documentation of the date of receipt of notice of paragraph IV certification, we are proposing to revise §§ 314.52(e) and 314.95(e) to include acceptance of signature proof of delivery by a designated delivery service as adequate documentation. A single document may be adequate to document both timely sending and receipt of notice of paragraph IV certification if it contains the information required by proposed §§ 314.52(e) and 314.95(e).

In addition, we are proposing to require that ANDA applicants include in their amendment a dated printout of the Orange Book entry for the RLD that includes the patent that is the subject of the notice of paragraph IV certification. This requirement is intended to ensure that a paragraph IV certification that may qualify an ANDA applicant for 180-day exclusivity is submitted only for a listed patent and is not prematurely or inappropriately sent before the first working day after the day the patent is listed in the Orange Book (see proposed §§ 314.95(b)(2) and 314.94(a)(12)(viii)(C)(*1*)(*ii*)).

The following example illustrates our approach: The NDA holder timely submits Form FDA 3542 to the Office of Generic Drugs, Document Room, Attention: Orange Book Staff, at 4 p.m., Eastern Standard Time, on the 30th day after issuance of the '456 patent claiming the drug product Procrastinadipine. Form FDA 3542 is date-stamped by the Office of Generic Drugs, Document Room on Friday, October 1 and listed in the Orange Book on the afternoon of Monday, October 4. Applicant D and Applicant E have submitted ANDAs for Procrastinadipine and each has received an acknowledgment letter indicating that its ANDA has been received for substantive review.

Applicant D is aware that the '456 patent was issued by the PTO on September 1 and understands that for the '456 patent to be timely filed under section 505(c)(2) of the FD&C Act, the NDA holder must file the patent information with FDA no later than October 1. Applicant D submits an amendment to its ANDA containing a paragraph IV certification to the '456 patent and sends notice to the NDA holder and each patent owner on October 1 in an effort to have submitted the first substantially complete ANDA containing a paragraph IV certification to a patent listed for Procrastinadipine. However, Applicant D is unable to submit the required printout (see proposed § 314.95(b)(2)) of the Orange Book entry for the RLD that includes the patent that is the subject of the paragraph IV certification because the '456 patent has not yet been listed in the Orange Book. Applicant E submits on Tuesday, October 5 (*i.e.,* the first working day after the day the patent is listed in the Orange Book) an amendment to its ANDA containing a paragraph IV certification to the '456 patent and the required printout of the Orange Book entry and sends notice to the NDA holder and each patent owner on that same day.

Prior to these amendments, no ANDA had contained a paragraph IV certification to a patent listed for Procrastinadipine. Applicant D's notice of paragraph IV certification is premature and thus invalid because the '456 patent had not yet been listed in the Orange Book. Only Applicant E has submitted the first substantially complete ANDA containing a paragraph IV certification for purposes of first applicant eligibility.

II.D.5. Administrative Consequence for Late Notice

The MMA does not specify a consequence for 505(b)(2) or ANDA applicants that do not send notice of a paragraph IV certification within the timeframe required by the FD&C Act (*i.e.,* within 20 days after the date of the postmark on the paragraph IV acknowledgment letter or on the date that an amendment or supplement containing a paragraph IV certification is submitted to FDA). In response to our Request for MMA Comments, we received comments suggesting that we create an administrative consequence for late notice (see, *e.g.,* PhRMA MMA Comment at 1 to 2). In light of the importance of the timing of sending notice of paragraph IV certification to the statutory scheme, we agree that it is appropriate to propose an administrative consequence for ANDA applicants who are late in providing notice.

After considering several suggestions for administrative consequences, including those submitted to us in response to our Request for MMA Comments, we are proposing to address ANDA applicants that fail to timely provide notice of a paragraph IV certification by moving forward the date of submission of the ANDA by the number of days beyond the required time frame that the applicant delayed in sending its notice (see proposed § 314.101(b)(4)). Consequently, an ANDA applicant may lose its first applicant status and thus its eligibility for 180-day exclusivity as a result of providing late notice (see section 505(j)(5)(B)(iv) of the FD&C Act), if another applicant submits a substantially complete ANDA containing a paragraph IV certification on the same first day and provides timely notice. Also, an ANDA applicant that fails to timely provide notice of paragraph IV certification may experience a delay in the review queue for its ANDA consistent with the revised date of submission. We note that this proposed administrative consequence

would not reduce the 30-month timeframe set forth in section 505(j)(5)(D)(i)(I)(aa)(BB) and (j)(5)(D)(i)(IV) of the FD&C Act in the forfeiture calculus for a first applicant; rather, the 30-month period would begin on the revised date of submission.

We believe that the proposed administrative consequence for ANDA applicants appropriately balances the purposes served by the requirement for timely notice of paragraph IV certifications with the legislative goal of speeding the availability of lower cost alternatives to approved drugs. Certain options we considered as alternatives did not seem to provide as measured a balance. For example, we considered deeming paragraph IV certifications for which notice had been provided after the statutory timeframe to not be ''lawfully maintained'' (see section 505(j)(5)(B)(iv)(bb) of the FD&C Act). Under this interpretation, however, an ANDA applicant would certainly lose its eligibility for 180-day exclusivity as a result of sending late notice, regardless of the amount of time its notice was delayed (*e.g.,* even if its notice were one day late). We decline to adopt this approach because it seems disproportionately punitive.

We are not proposing a similar consequence for 505(b)(2) applicants that fail to timely provide notice of a paragraph IV certification because 505(b)(2) applicants are not eligible for 180-day exclusivity and we are unable to extend the review clock as an administrative consequence for an NDA (including a 505(b)(2) application) subject to the Prescription Drug User Fee Act Reauthorization Performance Goals and Procedures (see *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119243.htm;* see also 21 CFR 314.100). As described below, we considered other possible administrative consequences for any 505(b)(2) applicants that fail to provide notice of a paragraph IV certification within the statutory timeframe; however, we are declining to propose an administrative consequence at this time.

The implications of late notice of a paragraph IV certification by a 505(b)(2) applicant differ from those of an ANDA applicant that may otherwise be eligible for 180-day exclusivity. A 505(b)(2) application that contains a paragraph IV certification could not be approved until the 505(b)(2) applicant had provided notice of its paragraph IV certification to the NDA holder and each patent owner and the respective 45-day periods for each recipient of notice had expired without the filing of a legal action for patent infringement (see § 314.107(f)(2)). A 505(b)(2) applicant that provides late notice of a paragraph IV certification risks that the NDA holder or patent owner will file an action for patent infringement within the 45-day period after notice, and that any resultant 30-month stay will delay approval by a period of time commensurate with the 505(b)(2) applicant's delay in providing notice of its paragraph IV certification. We considered the suggestion, submitted in response to our Request for MMA Comments, that we ''creat[e] an automatic regulatory presumption which could be used by the court hearing the patent infringement action that the ANDA or 505(b)(2) applicant 'failed to reasonably cooperate in expediting the action' within the meaning of [section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act]'' (see PhRMA MMA Comment at 2). However, we decline to propose this approach because it is not necessary to properly implement the statutory goal of adequate notice and opportunity to defend certain intellectual property rights prior to approval.

II.E. Amended Patent Certifications (Proposed §§ 314.50(i)(6) and 314.94(a)(12)(viii))

We are proposing to revise §§ 314.50(i)(6) and 314.94(a)(12)(viii) regarding submission of amended patent certifications by 505(b)(2) and ANDA applicants, respectively, to reflect revisions to the FD&C Act made by the MMA and for the efficient enforcement of the FD&C Act. A 505(b)(2) or ANDA applicant would be required to submit an amended patent certification to provide, for example, a certification to a recently issued patent listed by the NDA holder after submission of a 505(b)(2) application or ANDA that relies upon the listed drug, or to change its certification to a patent for which the applicant had previously submitted a patent certification. As discussed in this section of the document, submission of an amended patent certification also would be required for a reissued patent and for a revision to a prior certification in the event that a patent or patent information has been withdrawn from listing in the Orange Book.

We are proposing to revise the introductory text of § 314.94(a)(12)(viii) to remove the provision that restricts an ANDA applicant from amending a paragraph IV certification to a paragraph III certification in certain circumstances. Currently, § 314.94(a)(12)(viii) provides that an ANDA applicant that has submitted a paragraph IV certification may not amend its patent certification to a paragraph III certification (delaying approval until the date on which such patent will expire) if a patent infringement action has been filed against another applicant that had submitted a paragraph IV certification. The current regulation provides that an ANDA applicant is permitted to amend its patent certification to a paragraph III certification in these circumstances only if the Agency has determined that no applicant is entitled to 180-day exclusivity or the patent expired while patent infringement litigation was pending or before the end of the 180-day exclusivity period. We have determined, however, that it is not necessary to restrict submission of an amended patent certification under these circumstances because 180-day exclusivity does not extend beyond patent expiry. Accordingly, an applicant that amended its paragraph IV certification to a paragraph III certification would not be eligible for approval until patent expiration and thus would not undermine a first applicant's 180-day exclusivity as to that patent. The MMA specifically provides that a first applicant's 180-day exclusivity would, in any event, terminate upon expiration of all of the patents as to which the applicant submitted a paragraph IV certification qualifying it for 180-day exclusivity (see section 505(j)(5)(D)(i)(VI) of the FD&C Act; see also § 314.94(a)(12)(viii)).

There are several circumstances in which amending to a paragraph III certification is appropriate, including when an applicant is no longer seeking approval before the patent expires or when required by the terms of a settlement agreement between parties in patent infringement litigation. This proposal would facilitate amendment of paragraph IV certifications to paragraph III certifications in such circumstances.

We also are proposing to revise §§ 314.50(i)(6)(i) and 314.94(a)(12)(viii) to require that a 505(b)(2) or ANDA applicant submit an amended patent certification as an amendment to its pending application (including a supplemental 505(b)(2) application or supplemental ANDA (see §§ 314.70(i) and 314.97(c), respectively)) and not by letter. This requirement will facilitate appropriate management of amended patent certifications.

Table 9 summarizes the proposed changes regarding amended patent certifications:

TABLE 9—HIGHLIGHTS OF PROPOSED CHANGES REGARDING AMENDED PATENT CERTIFICATIONS[1]

Current regulations	Proposed revisions to regulations
Amended Certifications (§§ 314.50(i)(6) and 314.94(a)(12)(viii)) • Amended patent certification must be submitted as an amendment to a pending 505(b)(2) application or ANDA or by letter to an approved application. *Amended Certifications (§ 314.94(a)(12)(viii) only)* • ANDA applicants restricted from amending a paragraph IV certification to a paragraph III certification in certain circumstances when another ANDA applicant has been sued for patent infringement.	*Amended Certifications (§§ 314.50(i)(6) and 314.94(a)(12)(viii))* • Amended patent certification must be submitted as an amendment to the 505(b)(2) application or ANDA and may no longer be submitted by letter. *Amended Certifications (§ 314.94(a)(12)(viii) only)* • Deletion of restriction on ANDA applicants from amending a paragraph IV certification to a paragraph III certification.
After a Finding of Infringement (§§ 314.50(i)(6)(i) and 314.94(a)(12)(viii)(A))	*After a Finding of Infringement (§§ 314.50(i)(6)(i) and 314.94(a)(12)(viii)(A))* • Change from paragraph IV certification to paragraph III certification required after a final judgment is entered finding the patent to be infringed. • Provision applies if patent infringement action initiated within 45 days of receipt of notice of paragraph IV certification. • Change from paragraph IV certification to paragraph III certification required after court enters final decision from which no appeal has been or can be taken, or signs settlement order or consent decree with a finding of infringement (unless the patent also is found invalid). An applicant may instead provide a statement under § 314.50(i)(1)(iii) or § 314.94(a)(12)(iii) with respect to a method-of-use patent if the 505(b)(2) application or ANDA is amended such that the applicant is no longer seeking approval for a method of use claimed by the patent. • Provision applies if patent infringement action initiated after receipt of notice of paragraph IV certification, irrespective of whether the action is brought within the 45-day period.
After Removal of a Patent from the List (§§ 314.50(i)(6)(ii) and 314.94(a)(12)(viii)(B)) • If a patent is removed from the list, any applicant with a pending application (including a tentatively approved application with a delayed effective date) who has made a certification with respect to such patent must amend its certification. • A patent that is the subject of a lawsuit under § 314.107(c) shall not be removed from the list until FDA determines either that no delay in effective dates of approval is required under that section as a result of the lawsuit, that the patent has expired, or that any such period of delay in effective dates of approval is ended. • Applicant must submit a ''no relevant patents'' certification or, if other relevant patents claim the drug, must amend the patent certification to refer only to those relevant patents.	*After Request to Remove a Patent or Patent Information from the List (§§ 314.50(i)(6)(ii) and 314.94(a)(12)(viii)(B))* • If the list reflects that an NDA holder has requested that a patent be removed from the list and: —no ANDA applicant is eligible for 180-day exclusivity based on a paragraph IV certification to that patent, the patent will be removed and any applicant with a pending 505(b)(2) application or ANDA (including a tentatively approved 505(b)(2) application or ANDA) who has certified to that patent must submit an amendment to withdraw the certification. —one or more first applicants are eligible for 180-day exclusivity based on a paragraph IV certification to that patent, the patent shall remain listed until any 180-day exclusivity is extinguished. • If one or more first applicants are eligible for 180-day exclusivity based on a paragraph IV certification to a patent that has been reissued, then the first applicant must submit a paragraph IV certification to the reissued patent within 30 days of listing to have lawfully maintained its paragraph IV certification for purposes of eligibility for 180-day exclusivity. • A 505(b)(2) applicant is not required to provide or maintain a certification to a patent that remains listed only for purposes of a first applicant's 180-day exclusivity. • After any applicable 180-day exclusivity period has ended, the patent will be removed and any pending ANDA (including a tentatively approved ANDA) that contains a certification to the patent must be amended to withdraw the certification. • If removal of a patent from the list results in no patents listed for the listed drug(s) identified in the 505(b)(2) application or ANDA, the applicant must submit an amended certification reflecting that there are no listed patents.
Late submission of patent information (§§ 314.50(i)(4) and 314.94(a)(12)(vi)) • If a patent on the listed drug is issued and the NDA holder for the listed drug does not submit the required information on the patent within 30 days of patent issuance, an applicant who submitted a 505(b)(2) application or an ANDA for that drug that contained an appropriate patent certification before the submission of the patent information is not required to submit an amended certification.	*Untimely filing of patent information (§§ 314.50(i)(4) and 314.94(a)(12)(vi))* • (see Table 3)

TABLE 9—HIGHLIGHTS OF PROPOSED CHANGES REGARDING AMENDED PATENT CERTIFICATIONS[1]—Continued

Current regulations	Proposed revisions to regulations
• An applicant whose 505(b)(2) application or ANDA is submitted after a late submission of patent information, or whose pending 505(b)(2) application or ANDA was previously submitted but did not contain an appropriate patent certification at the time of the patent submission, must submit a certification under (§ 314.50(i)(1)(i) or § 314.94(a)(12)(i) or a statement under § 314.50(i)(1)(iii) or § 314.94(a)(12)(iii) as to that patent.	
Patents Claiming the Drug Substance, Drug Product, or Method of Use (§§ 314.50(i)(1)(i)(A) and 314.94(a)(12)(i)(A))	*Patents Claiming the Drug Substance, Drug Product, or Method of Use (§§ 314.50(i)(1)(i)(A) and 314.94(a)(12)(i)(A))*
• A 505(b)(2) application and ANDA are required to contain a patent certification or statement for each patent issued by the PTO that, in the opinion of the applicant and to the best of its knowledge, claims the listed drug relied upon or RLD or that claims an approved use for such drug for which the applicant is seeking approval and for which information is required to be filed under section 505(b) and (c) of the FD&C Act and § 314.53.	• (No substantive revisions)
	Other Amendments (§§ 314.50(i)(6)(iii)(A)(2) and 314.94(a)(12)(viii)(C)(1)(ii))
	• Except as provided in §§ 314.50(i)(4) and (i)(6)(iii)(B) and 314.94(a)(12)(vi) and (a)(12)(viii)(C)(*2*)), an applicant must submit a patent certification or statement if, after submission of the 505(b)(2) application or ANDA, a new patent is issued by the PTO that, in the opinion of the applicant and to the best of its knowledge, claims the listed drug or RLD or that claims an approved use for such drug and for which information is required to be filed under section 505(b) and (c) of the FD&C Act and § 314.53.
	• For a paragraph IV certification, the certification must not be submitted earlier than the first working day after the day the patent is published in the list.
Other Amendments (§§ 314.50(i)(6)(iii)(A) and 314.94(a)(12)(viii)(C)(1))	*Other Amendments (§§ 314.50(i)(6)(iii)(A)(1) and 314.94(a)(12)(viii)(C)(1)(i))*
• [Amended patent certification required upon patent expiration under existing requirement for submission of amended certification if, at any time before approval, the submitted certification is no longer accurate.]	• [Upon patent expiration, FDA will consider the 505(b)(2) or ANDA applicant to have constructively changed its patent certification to a paragraph II certification.]
Other Amendments (§§ 314.50(i)(6)(iii)(B) and 314.94(a)(12)(viii)(C)(2))	*Other Amendments (§§ 314.50(i)(6)(iii)(B) and 314.94(a)(12)(viii)(C)(2))*
• An applicant is not required to amend a submitted certification in response to patent information submitted after approval of the 505(b)(2) application or ANDA (unless a patent certification is required with a supplement to the 505(b)(2) application or ANDA).	• An applicant is not required to submit a supplement to change a submitted certification in response to patent information submitted after approval of the 505(b)(2) application or ANDA (unless a patent certification is required with a supplement to the 505(b)(2) application or ANDA).

[1] These highlights describe important proposed revisions to our regulations, but should not be relied upon in place of the proposed regulation.

II.E.1. Amended Patent Certifications After a Finding of Infringement

We are proposing to amend §§ 314.50(i)(6)(i) and 314.94(a)(12)(viii)(A) to reflect changes to the FD&C Act made by the MMA that clarify the requirements for a 505(b)(2) or ANDA applicant, respectively, to amend their paragraph IV certification after a judicial finding of patent infringement. As further discussed in section II.M, the MMA amended section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act to specify the types of court decisions that will terminate a 30-month stay of approval, given that many patent infringement actions previously had been concluded without a ''final judgment'' regarding infringement being entered by a court. With respect to a 505(b)(2) or ANDA applicant that had submitted a paragraph IV certification resulting in a patent infringement action, the FD&C Act provides that if, before the expiration of the 30-month stay of approval, the district court hearing the patent infringement action decides that the patent has been infringed and the district court's judgment is either not appealed or is affirmed on appeal, the 505(b)(2) application or ANDA may be approved on the date specified by the district court that is not earlier than the date of expiration of the patent (including any patent extension) and of any applicable exclusivity (see section 505(c)(3)(C)(ii)(II) and (j)(5)(B)(iii)(II)(bb) of the FD&C Act and 35 U.S.C. 271(e)(4)(A)).

We are proposing to amend §§ 314.50(i)(6)(i) and 314.94(a)(12)(viii)(A) to require that a 505(b)(2) and ANDA applicant, respectively, submit an amendment to change its paragraph IV certification to a paragraph III certification (stating that the patent will expire on a specific date) or, if appropriate, to a statement under section 505(b)(2)(B) or (j)(2)(A)(viii) of the FD&C Act if a ''court enters a final decision from which no appeal has been or can be taken'' that the patent at issue has been infringed. After a final court decision of patent infringement from which no appeal has been or can be taken, a 505(b)(2) or ANDA applicant can no longer lawfully maintain a paragraph IV certification that the patent is invalid or will not be infringed by the manufacture, use, or sale of the drug for which the 505(b)(2) application or ANDA has been submitted (see, *e.g., Mylan Labs., Inc.* v. *Thompson,* 389 F.3d 1272, 1281 (D.C. Cir. 2004) (concluding that after the district court's finding of patent validity and infringement, the ANDA applicant's paragraph IV certification was ''at variance with the legal reality'' and ''no longer accurate'')). These proposed revisions to §§ 314.50(i)(6)(i) and

314.94(a)(12)(viii)(A) reflect a change to the current text requiring a 505(b)(2) or ANDA applicant to amend its paragraph IV certification if a ''final judgment'' has been entered finding the patent to be infringed.

Proposed §§ 314.50(i)(6)(i) and 314.94(a)(12)(viii)(A) also would require a 505(b)(2) and ANDA applicant, respectively, to submit an amendment to change its paragraph IV certification to a paragraph III certification or, if appropriate, to a statement under section 505(b)(2)(B) or 505(j)(2)(A)(viii) of the FD&C Act if a court signs a settlement order or consent decree in the action that includes a finding that the patent is infringed, unless the final decision, settlement order or consent decree also finds the patent to be invalid. For a first ANDA applicant, submission of an amendment that changes the paragraph IV certification that qualified the applicant for 180-day exclusivity to a paragraph III certification or a statement under section 505(j)(2)(A)(viii) of the FD&C Act has implications for continuing eligibility for 180-day exclusivity (see section 505(j)(5)(D)(i)(III) of the FD&C Act). We note, however, that if a settlement is reached without a finding of patent infringement or invalidity, then a paragraph IV certification may continue to be appropriate. For example, if the 505(b)(2) or ANDA applicant is granted a patent license such that the applicant would be permitted to obtain approval and commence marketing prior to patent expiration, the 505(b)(2) or ANDA applicant would maintain its paragraph IV certification with respect to the patent at issue and should submit an amendment pursuant to proposed §§ 314.50(i)(3) and 314.94(a)(12)(v) to advise the Agency of the patent licensing agreement. Such an amendment must include a written statement by the applicant that it has been granted a patent license and a written statement from the patent owner confirming the licensing agreement and consenting to approval of the application as of a specific date (see proposed §§ 314.50(i)(3) and 314.94(a)(12)(v)).

We are proposing to apply the requirement that a 505(b)(2) or ANDA applicant must submit an amendment to change its paragraph IV certification to a paragraph III certification or, if appropriate, to a statement under section 505(b)(2)(B) or 505(j)(2)(A)(viii) of the FD&C Act after a judicial finding of patent infringement irrespective of whether the patent infringement action was brought within 45 days of receipt of the notice of paragraph IV certification (see proposed §§ 314.50(i)(6)(i) and 314.94(a)(12)(viii)(A)). A patent infringement action initiated outside of the 45-day period following receipt of a notice of paragraph IV certification is not eligible for a 30-month stay of approval while the patent infringement litigation is pending (see § 314.107(b)(3)). However, the rationale for an amended patent certification in the event that the patent is found valid and infringed applies with equal force to a legal action for infringement of a listed patent that was brought outside of the 45-day period (see 35 U.S.C. 271(e)(4)). Thus, we are proposing to remove the phrase ''within 45 days of the receipt of notice sent under [§ 314.52 or § 314.95, respectively]'' from the description of the patent infringement action to which §§ 314.50(i)(6)(i) and 314.94(a)(12)(viii)(A) apply. This proposed revision would clarify, for example, that the approval of a 505(b)(2) application or ANDA that contained a paragraph IV certification but was not subject to a 30-month stay still may be delayed by the intervening grant of pediatric exclusivity under section 505A(b)(1)(B) of the FD&C Act after a judicial finding of infringement of the patent for which the paragraph IV certification had been submitted (see *Mylan Labs., Inc.* v. *Thompson,* 332 F. Supp. 2d 106 (D.D.C.), *aff'd,* 389 F.3d 1272 (D.C. Cir. 2004); see also proposed § 314.107(b)(4) and (e)(1)(vi)).

As explained in proposed §§ 314.50(i)(6)(i) and 314.94(a)(12)(viii)(A), an applicant may change its paragraph IV certification for a method-of-use patent to a statement under section 505(b)(2)(B) or 505(j)(2)(A)(viii) of the FD&C Act only if the applicant amends its 505(b)(2) application or ANDA, respectively, such that the applicant is no longer seeking approval for a method of use claimed by the patent (see §§ 314.50(i)(1)(iii) and 314.94(a)(12)(iii)).

II.E.2. Amended Certifications After Request by the NDA Holder To Remove a Patent or Patent Information From the List

We are proposing to revise §§ 314.50(i)(6)(ii) and 314.94(a)(12)(viii)(B) to clarify the circumstances and timeframe in which a 505(b)(2) or ANDA applicant, respectively, must submit an amended patent certification to its 505(b)(2) application or ANDA after an NDA holder has requested removal of a patent or patent information from the list (''patent delisting''). These proposed revisions also describe our current practice regarding patent delisting as it relates to the eligibility of one or more first ANDA applicants for 180-day exclusivity.

An NDA holder may request removal of a patent or patent information from the list in accordance with a court order or on its own initiative, if it determines that the patent or patent information no longer meets the statutory criteria for listing (see section 505(b)(1) and (c)(2) of the FD&C Act). Since April 18, 2008, FDA has identified in the Orange Book (the list) those patents for which an NDA holder has withdrawn the patent and submitted a request for removal of the patent from the list. We are proposing to revise §§ 314.50(i)(6)(ii) and 314.94(a)(12)(viii)(B) to state that if an NDA holder has requested removal of a patent or patent information from the list, the patent or patent information will be removed if no ANDA applicant has submitted a paragraph IV certification to the patent or no ANDA applicant is eligible for 180-day exclusivity. Upon removal of the patent or patent information from the list, any applicant with a pending 505(b)(2) application or ANDA (including a tentatively approved 505(b)(2) application or ANDA) must submit an amendment to its application to withdraw its certification to the patent.

However, if an NDA holder has requested removal of a patent or patent information from the list and one or more first ANDA applicants are eligible for 180-day exclusivity, FDA will not remove the patent or patent information from the list until we have determined that no first applicant still is eligible for 180-day exclusivity (see section 505(j)(5)(D) of the FD&C Act regarding forfeiture of 180-day exclusivity) or the 180-day exclusivity is extinguished (see proposed §§ 314.50(i)(6)(ii) and 314.94(a)(12)(viii)(B)). Otherwise, if the NDA holder withdrew the patent or patent information for which a first ANDA applicant had submitted the certification that qualified it for 180-day exclusivity and FDA immediately removed the patent or patent information from the list, the first applicant would be required to withdraw its patent certification and could not ''lawfully maintain'' its paragraph IV certification (as the ANDA would no longer be considered to be one containing a paragraph IV certification) (see section 505(j)(5)(B)(iv)(II)(bb) and (j)(5)(D)(i)(III) of the FD&C Act). In addition, if FDA immediately removed a patent or patent information from the list upon the NDA holder's request when one or more first applicants were eligible for 180-day exclusivity, it could result in ANDA applicants withdrawing corresponding patent certifications

prematurely and thus undermining a first applicant's 180-day exclusivity. We also are proposing to revise the heading for §§ 314.50(i)(6)(ii) and 314.94(a)(12)(viii)(B) by replacing the phrase ''after removal of a patent'' with ''after request to remove a patent or patent information'' to emphasize that FDA will not remove a patent or patent information from the list until we have determined that no first applicant is eligible for 180-day exclusivity.

An NDA holder's withdrawal of a patent or patent information is implicitly an acknowledgment that the standard for patent listing set forth in section 505(b) and (c) of the FD&C Act can no longer be met. Nevertheless, a patent for which the NDA holder has requested removal may remain listed for 180-day exclusivity purposes. For a patent that remains listed for purposes of 180-day exclusivity after an NDA holder has withdrawn the patent or patent information and requested that FDA remove the patent or patent information from the list, the requirements for providing a patent certification will differ between 505(b)(2) applicants and ANDA applicants. A 505(b)(2) applicant is neither eligible for nor blocked by 180-day generic drug exclusivity. Accordingly, we are proposing to revise § 314.50(i)(6)(ii) to exempt a 505(b)(2) applicant from the requirement to provide or maintain a certification to a patent that is identified in the Orange Book as remaining listed only for purposes of a first applicant's 180-day generic drug exclusivity. Because one or more ANDA applicants may be eligible for 180-day exclusivity, ANDA applicants are required to provide an appropriate patent certification to each patent listed in the Orange Book (except as provided in § 314.94(a)(12)(vi)), including to a patent that is listed with a notation indicating that the NDA holder has requested removal of the patent or patent information from the Orange Book. Once FDA has determined that no first applicant is eligible for 180-day exclusivity, or such exclusivity is extinguished, and has removed the patent information from the Orange Book, an ANDA applicant must submit an amendment to its pending ANDA to withdraw the certification.

We are proposing to delete the statement in current §§ 314.50(i)(6)(ii) and 314.94(a)(12)(viii)(B) regarding the timing of removal of a patent or patent information that is the subject of a patent infringement lawsuit under § 314.107(c). This statement would be replaced by the broader criterion, discussed earlier in this section, that a patent will not be removed from the list until FDA has determined that any 180-day exclusivity is extinguished. This proposed revision reflects our current practice.

We also are proposing to add a statement to emphasize that if a 505(b)(2) or ANDA applicant submits an amendment to withdraw a paragraph IV certification, the 505(b)(2) application or ANDA will no longer be considered to be one containing a paragraph IV certification to the patent. In addition, we are proposing a conforming revision to § 314.94(a)(12)(viii) to clarify that once an amendment is submitted to change a certification, the ANDA will no longer be considered to contain the prior certification. This is consistent with the Agency's practice for amended patent certifications for 505(b)(2) applications (see § 314.50(i)(6)).

Finally, we are proposing to relocate within §§ 314.50(i)(6)(ii) and 314.94(a)(12)(viii)(B) and revise the current statement regarding submission of an amended patent certification after removal of a patent from the list. This proposed revision is intended to clarify rather than substantively change our current requirements. If removal of a patent from the list results in there being no patents listed for the listed drug(s) identified in the 505(b)(2) application or the RLD identified in the ANDA, the applicant must submit an amended certification under § 314.50(i)(1)(ii) or § 314.94(a)(12)(ii), as appropriate, to reflect that there are no listed patents. We note, however, that if a 505(b)(2) or ANDA applicant fails to submit an amended patent certification after removal of a patent from the list, the Agency will consider the 505(b)(2) or ANDA applicant to have constructively withdrawn its patent certification to the delisted patent (compare *Ranbaxy Labs. Ltd.* v. *FDA,* 307 F. Supp. 2d 15, 21 (D.D.C.), *aff'd,* 2004 U.S. App. LEXIS 8311 (D.C. Cir. 2004); see also section II.E.4). With respect to any patents that remain listed for the listed drug(s) identified in the 505(b)(2) application or for the RLD identified in the ANDA, it is expected that the applicant would maintain an accurate patent certification consistent with current regulatory requirements (see §§ 314.50(i)(6)(iii) and 314.94(a)(12)(viii)(C)). We seek comment on this approach.

II.E.3. Amended Certifications Upon Patent Reissuance

In section II.B.1.e, we describe certain proposed revisions to our regulations to clarify our requirements regarding an NDA holder's submission of patent information related to reissued patents. Because the listing of a reissued patent may require submission of an amended patent certification by a 505(b)(2) or ANDA applicant under our current regulations, we are describing in this section of the document an applicant's patent certification obligations with respect to a reissued patent.

Sections 314.50(i)(6)(iii) and 314.94(a)(12)(viii)(C) require that a 505(b)(2) and ANDA applicant submit an amended patent certification if, at any time before approval of the 505(b)(2) application or ANDA, the applicant learns that the submitted certification is no longer accurate. As a general rule, we require a 505(b)(2) or ANDA applicant to provide an appropriate patent certification or statement with respect to a reissued patent, unless either the original patent or the reissued patent was not timely filed by the NDA holder for listing in the Orange Book (see §§ 314.50(i)(4) and 314.94(a)(12)(vi)). As noted in section II.B.1.e, if a 505(b)(2) or ANDA applicant is not required to provide a patent certification or statement to the original patent because it was untimely filed (and late-listed as to the pending 505(b)(2) application or ANDA), the 505(b)(2) or ANDA applicant would not be required to provide a patent certification or statement to the reissued patent even if timely filed following reissuance.

We require a 505(b)(2) or ANDA applicant to provide an amended patent certification or statement to the reissued patent, even though a patent certification or statement may already have been submitted for the original patent, because the scope of claims may be narrowed or, in certain circumstances, broadened upon reissuance of the patent (see 35 U.S.C. 251). A change in the scope of the patent claims may result in the reissued patent being listed in the Orange Book with a revised designation by the NDA holder regarding whether the patent claims the drug substance, drug product, and/or a method of use, or the reissued patent may be listed with a revised use code. Accordingly, submission of an amendment to a pending 505(b)(2) application or ANDA is necessary to provide an appropriate patent certification or statement to the reissued patent, even if the type of patent certification (*e.g.,* a paragraph III certification) does not differ from that submitted for the original patent.

If an ANDA applicant submitted a paragraph IV certification to the original listed patent and continues to opine that the reissued patent is invalid or will not be infringed by the manufacture, use, or sale of the drug for which the application is submitted, then we are

proposing that the applicant must submit an amendment to its pending ANDA that contained a paragraph IV certification to the reissued patent within 30 days of the date of listing of the reissued patent in the Orange Book to lawfully maintain its paragraph IV certification for purposes of eligibility for 180-day exclusivity (see proposed § 314.94(a)(12)(viii)(B)). Both 505(b)(2) and ANDA applicants are required to provide notice of the paragraph IV certification to the reissued patent and comply with other applicable regulatory requirements at the time of submission of the amendment containing the paragraph IV certification. We seek comment on this proposal.

An amended patent certification to the reissuance of an original patent for which a paragraph IV certification previously was submitted may have implications for the 30-month stay provisions of the FD&C Act:

- If a 505(b)(2) or ANDA applicant submitted a paragraph IV certification to the original patent and a patent infringement action was initiated within 45 days of its notice of the paragraph IV certification to the original patent, the resulting 30-month stay would not be affected solely by reissuance of the patent, recertification, and renotification and would continue subject to § 314.107.
- If a 505(b)(2) or ANDA applicant submitted a statement under section 505(b)(2)(B) or section 505(j)(2)(A)(viii) of the FD&C Act, respectively, or a paragraph III certification to the original patent and subsequently submitted a paragraph IV certification to the reissued patent, a 30-month stay would be available if a patent infringement action was initiated within 45 days of its notice of the paragraph IV certification to the reissued patent.
- If a 505(b)(2) or ANDA applicant had previously submitted a paragraph IV certification to the original patent and no patent infringement action was initiated within 45 days of receipt of notice, no subsequent patent infringement action with respect to the reissued patent can give rise to a 30-month stay.

This approach reflects our proposal to treat the original patent and the reissued patent as a ''single bundle'' of patent rights, albeit patent rights that have changed with reissuance, such that the patent information listed for the reissued patent would have been submitted under 505(b)(1) or 505(c)(2) of the FD&C Act at the time of listing of the original patent for purposes of section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act. Although we recognize that a reissued patent may have a broadened scope of claims if applied for within 2 years from the grant of the original patent (see 35 U.S.C. 251), our proposal to consider the original patent and reissued patent together for purposes of administering the patent certification requirements of the FD&C Act and any 30-month stay of approval or 180-day exclusivity that relates to a paragraph IV certification is intended to provide a consistent and predictable approach to implementation of the FD&C Act. If FDA were to propose a different approach to the availability of a 30-month stay based on a paragraph IV certification to a reissued patent with broadened claims, the implementation of such an approach would require resources and patent expertise that FDA currently does not possess and would be inconsistent with the Agency's ministerial role in patent listing. In any event, we do not expect that the scenario described here will occur frequently.

An amended patent certification to the reissuance of an original patent for which a paragraph IV certification previously was submitted also may have implications for the 180-day exclusivity provisions of the FD&C Act. As described previously in this section of the document, if a one or more first ANDA applicants is eligible for 180-day exclusivity based on a paragraph IV certification to the original patent and the patent is reissued, the first ANDA applicant would be required to submit a paragraph IV certification to the reissued patent within 30 days of listing to be considered by FDA to have lawfully maintained its paragraph IV certification for purposes of section 505(j)(5)(B)(iv)(II)(bb) and (j)(5)(D)(i)(III) of the FD&C Act. We note that the original patent, which qualified the first applicant for 180-day exclusivity, would remain listed in the Orange Book until FDA determined that any 180-day exclusivity is extinguished. Consistent with our current practice regarding requests for patent delisting, the original patent that qualified a first applicant for 180-day exclusivity also would remain listed in the Orange Book even if the scope of the reissued patent is narrowed such that the patent is no longer eligible for listing pursuant to section 505(b)(1) or 505(c)(2) of the FD&C Act and the NDA holder has requested, as required, that the patent be delisted from the Orange Book (see proposed § 314.53(f)(2) and section II.B.4.b). Given that FDA will continue to list a patent that qualified a first applicant for 180-day exclusivity under specified circumstances even if the patent has been withdrawn by the NDA holder on its own initiative or after a judicial finding of invalidity or unenforceability, the fact that the original patent technically is surrendered upon reissuance is not relevant to FDA's assessment of a first applicant's continued eligibility for 180-day exclusivity. However, in recognition of the surrender of the original patent upon reissuance, we require a first applicant to maintain a paragraph IV certification to the reissued patent. If a first applicant submitted only a paragraph III certification or a 505(j)(2)(A)(viii) statement to the reissued patent, we would consider the first applicant to have amended or withdrawn its paragraph IV certification to the patent for which it qualified for 180-day exclusivity under section 505(j)(5)(D)(i)(III) of the FD&C Act.

If no applicant had submitted a paragraph IV certification to the original patent, the first ANDA applicant to submit a paragraph IV certification to the reissued patent could be eligible for 180-day exclusivity, if no other applicant already has qualified as a first applicant based on an earlier paragraph IV certification to another listed patent. However, if a first applicant who qualifies as such based on a paragraph IV certification to the original patent forfeits 180-day exclusivity, 180-day exclusivity would not be available to a subsequent applicant that submitted a paragraph IV certification to the reissued patent (see section 505(j)(5)(D)(iii)(II) of the FD&C Act).

II.E.4. Other Amended Certifications

Sections 314.50(i)(6)(iii) and 314.94(a)(12)(viii)(C) require a 505(b)(2) and ANDA applicant, respectively, to amend a submitted certification if, at any time before approval of the application, the applicant learns that the submitted certification is no longer accurate. In *Dr. Reddy's Labs., Inc.* v. *Thompson,* the district court held that our regulations ''imposing a duty upon ANDA applicants to assure its certifications are accurate until the date of final approval is supported by [the] . . . express FDA authority [in section 505(j)(4)(J) and (K) of the FD&C Act]'' (302 F. Supp. 2d 340, 355 (D.N.J. 2003)) (see also section 505(e) of the FD&C Act).

Over the years, many 505(b)(2) and ANDA applicants have neglected to amend a previously submitted patent certification after the patent has expired. The Agency's longstanding position has been that a patent is relevant for purposes of 180-day exclusivity determinations ''until the end of the term of the patent or applicable 180-day

exclusivity period, whichever occurs first'' (1994 final rule, 59 FR 50338 at 50348). Section 505(j)(5)(D)(i)(VI) of the FD&C Act, added by the MMA, is consistent with FDA's longstanding position that 180-day exclusivity is extinguished upon expiration of the patent(s) on which exclusivity is based (see Docket No. FDA–2004–N–0062–0006 (comment submitted by PhRMA) at 5, available at *http://www.regulations.gov*).

Accordingly, we are proposing to codify our longstanding position that if an applicant that previously submitted a paragraph III certification, a paragraph IV certification, or a statement under section 505(b)(2)(B) or (j)(2)(A)(viii) of the FD&C Act with respect to a listed patent fails to amend its patent certification to a paragraph II certification upon patent expiration, the Agency will consider the 505(b)(2) or ANDA applicant to have constructively changed its patent certification to a paragraph II certification (see, *e.g., Ranbaxy Labs. Ltd.* v. *FDA,* 307 F. Supp. 2d 15, 21 (D.D.C.), *aff'd,* 2004 U.S. App. LEXIS 8311 (D.C. Cir. 2004) (finding that upon patent expiration an ANDA applicant's paragraph IV certifications ''became invalid, and either converted as a matter of law to Paragraph II certifications or became inaccurate, thereby creating both an obligation on [the ANDA applicant's] . . . part to amend its ANDAs to reflect patent expiry and an inability on the part of the FDA to approve the ANDAs in their inaccurate form'')). This approach also will clarify that any pediatric exclusivity will delay approval of a 505(b)(2) application or ANDA upon patent expiry under section 505A(b)(1)(B) and (c)(1)(B) of the FD&C Act, regardless of whether an applicant has amended its certification to a paragraph II certification.

We also are proposing to amend §§ 314.50(i)(6)(iii)(A) and 314.94(a)(12)(viii)(C)(*1*) by revising and redesignating the current text as paragraph (*1*) and paragraph (*i*), respectively, and adding a new paragraph (*2*) and paragraph (*ii*) to expressly codify the requirement for a 505(b)(2) and ANDA applicant to submit a patent certification to a newly issued patent. Proposed §§ 314.50(i)(6)(iii)(A)(*2*) and 314.94(a)(12)(viii)(C)(*1*)(*ii*) state that, except as provided in §§ 314.50(i)(4) and (i)(6)(iii)(B) and 314.94(a)(12)(vi) and (a)(12)(viii)(C)(*2*)), an applicant must submit a patent certification or statement if, after submission of the 505(b)(2) application or ANDA, a new patent is issued by the PTO that, in the opinion of the applicant and to the best of its knowledge, claims the listed drug or RLD or that claims an approved use for such drug and for which information is required to be filed under section 505(b) and (c) of the FD&C Act and § 314.53.

A 505(b)(2) and ANDA applicant currently are required to submit a patent certification or statement for each patent issued by the PTO that, in the opinion of the applicant and to the best of its knowledge, claims the listed drug or RLD or that claims an approved use for such drug for which the applicant is seeking approval and for which information is required to be filed under section 505(b) and (c) of the FD&C Act and § 314.53. Although the general requirement to submit a patent certification to a newly issued patent is established by §§ 314.50(i)(1)(i)(A) and 314.94(a)(12)(i)(A) and implicit in the exceptions for late submission of patent information, we are proposing to expressly codify the requirement to submit a patent certification to a newly issued patent in the section of the regulations directed to amended patent certification.

As discussed in section II.D.1.b.ii, we are proposing that a patent certification or statement by an ANDA applicant must not be submitted earlier than the first working day after the day the patent is published in the Orange Book (see proposed § 314.94(a)(12)(viii)(C)(*1*)(*ii*)). Thus, for a paragraph IV certification, the certification must not be submitted earlier than the first working day after the day the patent is published in the Orange Book. This proposal is intended to discourage burdensome serial submissions of paragraph IV certifications and ensure that all ANDA applicants (irrespective of time zone) have a reasonable opportunity to be a first applicant with respect to a newly listed patent (see also proposed § 314.95(b)(2)).

In addition, we are proposing to revise §§ 314.50(i)(6)(iii) and 314.94(a)(12)(viii)(C) to technically correct, but not substantively change, the reference to the lack of a requirement to ''amend'' a submitted patent certification after approval of a 505(b)(2) application or ANDA, respectively. We are proposing to correct this statement to indicate that an applicant is not required to submit a supplement solely to change a submitted patent certification after approval of the application. This revision also reflects that any changes to an application after approval would be made in a supplement to the application and not in an amendment, as the current regulation describes.

II.F. Patent Certification Requirements for Amendments and Supplements to 505(b)(2) Applications and ANDAs (Proposed §§ 314.60, 314.70, 314.96, and 314.97)

We are proposing to add §§ 314.60(f), 314.70(i), 314.96(d), and 314.97(c) to clarify and augment the patent certification requirements for amendments and supplements described in §§ 314.50(i)(6)(iii) and 314.94(a)(12)(viii)(C). Proposed §§ 314.60(f) and 314.96(d) would require an applicant to also submit a patent certification described in §§ 314.50(i) or 314.94(a)(12), as appropriate, if approval is sought for any of the following types of amendments to an original 505(b)(2) application or ANDA: (1) To add a new indication or other condition of use; (2) to add a new strength; (3) to make other than minor changes in product formulation; or (4) to change the physical form or crystalline structure of the active ingredient.

Currently, an applicant that submits an amendment to a pending 505(b)(2) application or supplement or a pending ANDA or supplement is required to amend its patent certification if, at any time before approval, the applicant learns that the previously submitted patent certification is no longer accurate with respect to the pending application or supplement, as amended (see §§ 314.50(i)(6)(iii) and 314.94(a)(12)(viii)(C), respectively, and section II.E.4). For example, an amendment to change the formulation of a proposed product in a 505(b)(2) application or ANDA would require a revised patent certification if, in the applicant's opinion and to the best of its knowledge, the new formulation would infringe a listed patent for which it previously had filed a paragraph IV certification.

Some NDA holders have expressed concern that a 505(b)(2) or ANDA applicant may change its proposed product in an amendment to a pending application, but not update its patent certification to correspond to the proposed product as changed by the amendment. For example, in 2003, FDA received a citizen petition submitted on behalf of Biovail Corporation requesting, among other things, that FDA require submission of a new patent certification upon amendment of the chemistry, manufacturing, and controls section of an ANDA (Docket No. FDA–2003–P–0519 (Biovail Petition), available at *http://www.regulations.gov;* see also PhRMA comment to Docket No. FDA–2002–N–0279–0061 at 9 to 10, available at *http://www.regulations.gov*). The

Biovail Petition recognized that even if the ANDA (or 505(b)(2)) applicant continued to assert that a paragraph IV certification was the appropriate patent certification for the changed product, the factual and legal basis of the applicant's opinion that the patent will not be infringed may have changed in light of the changes in product formulation (see Biovail Petition at 4 to 5). Biovail maintained that ''[r]equiring a new patent certification whenever the CMC portion of an ANDA is amended will allow the NDA holder and patent owner to ensure that the impact of the amendment on patent infringement issues is addressed promptly'' (Supplement to Biovail Petition at 1).

We agree that certain changes to a proposed product submitted in a 505(b)(2) application or ANDA should be accompanied by a new patent certification (see section II.F.2). To address these concerns and further clarify our requirements for submission of new patent certifications with an amendment to a 505(b)(2) application or ANDA, we are proposing to add §§ 314.60(f) and 314.96(d). If an applicant submits an amendment to a 505(b)(2) application or ANDA for any of the categories of changes described in these provisions and does not submit a new patent certification, the applicant will be required to verify that the proposed change described in the amendment is not the type of change for which a new patent certification is required (*e.g.,* the proposed formulation change meets the criteria for a ''minor'' formulation change). We seek comment on this proposal.

We also are proposing to add §§ 314.70(i) and 314.97(c), and make conforming revisions to §§ 314.50(i)(6)(iii)(B) and 314.94(a)(12)(viii)(C)(*2*), to clarify our requirements for submission of new patent certifications with a supplement to a 505(b)(2) application or ANDA. Proposed §§ 314.70(i) and 314.97(c) would require an applicant to also submit a patent certification described in § 314.50(i) or 314.94(a)(12), as appropriate, if approval is sought for either of the following types of supplements to a 505(b)(2) application or ANDA: (1) To add a new indication or other condition of use or (2) to add a new strength.

FDA is not proposing to require a patent certification with a supplement to change the formulation or to change the physical form or crystalline structure of the active ingredient of a product approved in a 505(b)(2) application or ANDA. It is not necessary for FDA to use its limited resources to require patent certifications under these circumstances because the NDA holder for a listed drug and any patent owner can monitor postapproval changes in the formulation or active ingredient of a marketed drug product and address any patent-related concerns without the involvement of FDA. With respect to NDA supplements, it should be noted that these patent certification requirements apply to 505(b)(2) supplements, irrespective of whether the original application to which the supplement was submitted was approved as a stand-alone 505(b)(1) application or a 505(b)(2) application. A supplement to a 505(b)(2) application of the type described in proposed § 314.70(i) is generally a 505(b)(2) supplement.

Table 10 summarizes the proposed changes related to patent certification requirements for amendments and supplements to 505(b)(2) applications and ANDAs:

TABLE 10—HIGHLIGHTS OF PROPOSED CHANGES REGARDING PATENT CERTIFICATION REQUIREMENTS FOR AMENDMENTS AND SUPPLEMENTS TO 505(b)(2) APPLICATIONS AND ANDAS [1]

Current regulations	Proposed revisions to regulations
Amended certifications—Other amendments (§§ 314.50(i)(6)(iii), 314.94(a)(12)(viii)(C)) • Except as otherwise provided, an applicant must amend a submitted certification if, at any time before approval of the 505(b)(2) application or ANDA, the applicant learns that the submitted certification is no longer accurate.	*Amended certifications—Other amendments (§§ 314.50(i)(6)(iii), 314.94(a)(12)(viii)(C))* • Except as otherwise provided, an applicant must amend a submitted certification if, at any time before approval of the 505(b)(2) application or ANDA, the applicant learns that the submitted certification is no longer accurate. *Patent certification requirements (§§ 314.60(f) and 314.96(d)).* • Except as provided below, an amendment to a 505(b)(2) application or ANDA is required to contain patent certifications described in §§ 314.50(i) or 314.94(a)(12), respectively, if approval is sought for any of the following types of amendments or supplements: —(1) To add a new indication or other condition of use; —(2) to add a new strength; —(3) to make other than minor changes in product formulation; or —(4) to change the physical form or crystalline structure of the active ingredient. *Patent certification requirements (§§ 314.70(i) and 314.97(c)).* • Except as provided below, a supplement to a 505(b)(2) application or ANDA is required to contain patent certifications described in §§ 314.50(i) or 314.94(a)(12), respectively, if approval is sought for either of the following types of supplements: —(1) To add a new indication or other condition of use; or —(2) to add a new strength. • A supplement to a 505(b)(2) application that seeks approval to add a new indication or other condition of use is required to contain patent certifications described in § 314.50(i) only for patents that are identified as claiming an approved use. If the method-of-use patent is identified as also claiming the drug substance or drug product, the patent certification also must address the drug substance and/or drug product claims.

[1] These highlights describe important proposed revisions to our regulations, but should not be relied upon in place of the proposed regulation.

We invite comment on this proposal and whether a new patent certification should be required with the submission of other types of amendments or supplements to a 505(b)(2) application or ANDA that may change the drug product in a manner that could be protected by patent.

II.F.1. Types of Amendments or Supplements for Which Patent Certification is Required

II.F.1.a. *Amendments or supplements to add a new indication or other condition of use.* Proposed §§ 314.60(f)(1), 314.70(i)(1)(i), 314.96(d)(1), and 314.97(c)(1) require a 505(b)(2) or ANDA applicant to submit a new patent certification with an amendment or supplement to add a new indication or other condition of use for the drug product that is the subject of the 505(b)(2) application or ANDA. Although most requests for approval of a different indication or condition of use by a 505(b)(2) applicant could not be made as an amendment to the 505(b)(2) application (see Separate Marketing Application Guidance at 4 to 5), there are certain scenarios in which an applicant may submit an amendment to a 505(b)(2) application (or ANDA) for a new indication or other condition of use. For example, a 505(b)(2) or ANDA applicant seeking approval for a drug product for which the indication has changed from prescription status to OTC use for the listed drug relied upon or RLD, as applicable, would be required to submit a new patent certification with an amendment or supplement to the application. These patent certification requirements are currently encompassed by §§ 314.50(i)(6)(iii) and 314.94(a)(12)(viii)(C). Proposed §§ 314.60(f)(1), 314.70(i)(1)(i), 314.96(d)(1), and 314.97(c)(1) would parallel the requirements for submission of patent information by an NDA applicant seeking approval of a supplement to add a new indication or other condition of use (see proposed § 314.53(d)(2)(ii)).

Currently, an applicant is required to submit a patent certification or statement with a 505(b)(2) supplement that seeks approval for a new indication or other condition of use (''efficacy supplement''). We are proposing to reduce the current patent certification requirements with respect to a supplement to a 505(b)(2) application that seeks approval for a new indication or other condition of use. Proposed § 314.70(i)(2) states that a supplement to a 505(b)(2) application that only seeks approval to add a new indication or other condition of use is required to contain patent certifications described in § 314.50(i) only for patents that are identified as claiming an approved use. This proposed change preserves the NDA holder's intellectual property rights without requiring the 505(b)(2) applicant to submit a duplicative certification to patents listed in the Orange Book for the listed drug relied upon that have not been identified by the NDA holder as claiming a method of use and would not be implicated by the efficacy supplement. We note, however, that if a method-of-use patent is identified as also claiming the drug substance or drug product, a statement under section 505(b)(2)(B) of the FD&C Act would not be sufficient. The 505(b)(2) applicant's patent certification also must address the drug substance and/or drug product claims in the patent.

II.F.1.b. *Amendments or supplements to add a new strength or change an existing strength.* Proposed §§ 314.60(f)(2), 314.70(i)(1)(ii), 314.96(d)(2), and 314.97(c)(2) would codify our current requirements with respect to an applicant's submission of a new patent certification with an amendment or supplement to add a new strength for the drug product that is the subject of the 505(b)(2) application or ANDA. As noted in section II.A.2.q, it is our longstanding practice to regard different strengths of a drug product as different drug products (see *Apotex, Inc.* v. *Shalala,* 53 F. Supp. 2d 454 (D.D.C.), *aff'd,* 1999 U.S. App. LEXIS 29571 (D.C. Cir. 1999)).

II.F.1.c. *Amendments to make other than minor changes in product formulation.* Proposed §§ 314.60(f)(3) and 314.96(d)(3) would require a 505(b)(2) or ANDA applicant to submit a new patent certification with an amendment to make other than minor changes in the formulation of the drug product that is the subject of the original 505(b)(2) application or ANDA. This enhanced patent certification requirement is intended to facilitate ongoing compliance with section 505(b)(2)(A) and (j)(2)(A)(vii) of the FD&C Act. An applicant that submits a 505(b)(2) application or ANDA containing a paragraph IV certification to a listed patent must reevaluate whether the patent certification continues to be accurate after a change to the formulation of the proposed product submitted in an amendment to the 505(b)(2) application or ANDA. By requiring a new patent certification and, with respect to a paragraph IV certification, a new notice of paragraph IV certification to be sent at the same time the amendment for the change in formulation is submitted to FDA, we aim to uphold the legislative balance of the Hatch-Waxman Amendments that facilitates the availability of generic drug products while protecting innovator intellectual property rights. We seek comment on this proposal.

This requirement would apply to all amendments to change the formulation of a proposed product in an original 505(b)(2) application or ANDA, except for minor changes in product formulation that FDA would regard as resulting in essentially the same product. A new patent certification would not be required if the new formulation in the amendment is qualitatively (Q1) the same as the previous formulation (*i.e.*, contains all of the same inactive ingredients) and quantitatively (Q2) essentially the same (*i.e.*, each inactive ingredient differs by no more than plus or minus 5 percent from the previous formulation). These limits correspond to the Agency's policy on products that generally can be regarded as essentially the same (see, *e.g.*, draft guidance for industry entitled ''Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action'' (April 2003) at 8, available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070111.pdf*; compare § 314.70(b)(2)(i)), and thus a change within these limits would not be likely to affect an applicant's patent certification. These limits also are similar to ''Level 1'' changes (those that are unlikely to have any detectable impact on formulation quality and performance) in components and composition of a drug product under the Agency's Scale-Up and Postapproval Changes guidance (see guidance for industry entitled ''Immediate Release Solid Oral Dosage Forms; Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls, *In Vitro* Dissolution Testing, and *In Vivo* Bioequivalence Documentation'' (November 1995) at 6 to 8, available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070636.pdf*).

It should be noted that an applicant seeking approval for an ANDA for a product intended for parenteral, ophthalmic, otic, or topical use must submit information to show that the proposed product contains the same inactive ingredients in the same concentration as the RLD, subject to exceptions specified in § 314.94(a)(9)(iii) through (a)(9)(v). Additional regulatory considerations related to changes to the formulation of a drug product proposed in an

amendment to an ANDA are discussed in section II.G.1 to II.G.2 and II.L.

II.F.1.d. *Amendments to change the physical form or crystalline structure of the active ingredient.* Proposed §§ 314.60(f)(4) and 314.96(d)(4) would require a 505(b)(2) or ANDA applicant to submit a new patent certification with an amendment to change the physical form (*e.g.*, different waters of hydration, solvates, and amorphous forms) or crystalline structure of the active ingredient of the drug product that is the subject of the 505(b)(2) application or ANDA. For example, a new patent certification would be required for an amendment to an ANDA that includes a change to the physical form of the active ingredient to conform with the physical form(s) of the active ingredient described in a final USP monograph.

These patent certification requirements apply to changes to the active ingredient that may be submitted as an amendment to a 505(b)(2) application or ANDA and do not alter the Agency's policy regarding the types of different active ingredients (*e.g.*, different salts, esters, and complexes of the same active moiety) that should be submitted in a separate application (see Separate Marketing Application Guidance; see also section II.G.3 to II.G.4). We note that the Agency has long considered different polymorphs to be the ''same active ingredient'' and pharmaceutical equivalents (see section 1.7 of the preface to the Orange Book (33rd Edition, 2013, at xv).

II.F.2. Requirements for Notice of Paragraph IV Certifications and Implications for 180-Day Exclusivity

There are additional regulatory considerations related to the submission of a paragraph IV certification by an applicant required to submit a new patent certification with its amendment or supplement to a 505(b)(2) application or ANDA. As a preliminary matter, we note that notice is required for all paragraph IV certifications, irrespective of whether the applicant previously provided notice of paragraph IV certification to the same patent or to another patent claiming the listed drug relied upon or RLD (see section 505(b)(3)(B) and (j)(2)(B)(ii) of the FD&C Act). If patent infringement litigation has been initiated in response to a previous notice of paragraph IV certification, a new paragraph IV certification submitted with an amendment or supplement to the 505(b)(2) application or ANDA still requires formal notice in accordance with §§ 314.52 and 314.95.

The new notice of paragraph IV certification must contain the information required by section 505(b)(3)(D) and (j)(2)(B)(iv) of the FD&C Act and §§ 314.52(c) and 314.95(c), updated to correspond to the proposed product as changed by the amendment or supplement. For example, the detailed statement of the factual and legal basis of the applicant's opinion that the patent is invalid, unenforceable, or will not be infringed by its proposed product must be updated, as necessary, by the 505(b)(2) or ANDA applicant to reflect the changes proposed in the amendment or supplement. The notice of paragraph IV certification also must clarify whether the amendment or supplement contains any required bioavailability or bioequivalence data that was necessary to support the proposed change to the 505(b)(2) application or ANDA.

With respect to any listed patent challenged by the applicant in an amendment or supplement to the 505(b)(2) application or ANDA for which the NDA holder or patent owner initiated patent infringement litigation within the statutory timeframe in response to notice of paragraph IV certification, the availability of a 30-month stay will depend upon whether the NDA holder filed information on the patent at issue with FDA prior to the date of submission of the 505(b)(2) application or the date of submission of the ANDA (which FDA later determined to be substantially complete) that refers to the listed drug claimed by the patent (see section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act). Accordingly, a 30-month stay may result from initiation of a patent infringement action in response to a second notice of paragraph IV certification provided at the time of submission of an amendment or supplement to a 505(b)(2) application or ANDA if the patent was listed prior to the date of submission of the original 505(b)(2) application or ANDA and, for example, the infringement action was warranted by the change proposed in the amendment or supplement.

A first applicant that submits an amendment to its pending ANDA or a supplement would be considered to have lawfully maintained a paragraph IV certification to the patent upon which eligibility for 180-day exclusivity was based if the amendment or supplement is accompanied by another paragraph IV certification to the patent and notice of paragraph IV certification is sent in accordance with § 314.95(d).

II.G. Amendments or Supplements to a 505(b)(2) Application for a Different Drug and Amendments or Supplements to an ANDA That Reference a Different Listed Drug (Proposed §§ 314.60, 314.70, 314.96, 314.97)

The MMA added section 505(b)(4)(A), (b)(4)(B), (j)(2)(D)(i), and (j)(2)(D)(ii) to the FD&C Act, which generally prohibit the submission of certain types of changes in an amendment or a supplement to a 505(b)(2) application or an ANDA, respectively. We interpret these provisions in the context of the MMA's amendment of section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act to restrict the availability of a 30-month stay of approval in certain circumstances involving amendments and supplements to a 505(b)(2) application or ANDA and seek comment on this approach.

Section 1101(a)(1)(A) of the MMA amended section 505(j) of the FD&C Act to generally prohibit an ANDA applicant from amending or supplementing an ANDA ''to seek approval of a drug referring to a different listed drug from the listed drug identified in the application as submitted [to FDA]'' (section 505(j)(2)(D)(i) of the FD&C Act). The textual reference in the statute to ''seek approval of a drug referring to a different listed drug'' is clearly understood in the context of section 505(j) of the FD&C Act and FDA's regulatory scheme for the approval of ANDAs. An applicant that submits an ANDA for a duplicate of a listed drug is required to identify and rely upon the listed drug designated by FDA as the RLD (see § 314.94(a)(3)). An applicant also may petition FDA to request permission to submit an ANDA that differs from a selected listed drug in route of administration, dosage form, or strength, or that has one different active ingredient in a combination drug product (see section 505(j)(2)(C) of the FD&C Act). Accordingly, we are proposing to add §§ 314.96(c) and 314.97(b) to state that an ANDA applicant may not amend or supplement an ANDA to seek approval of a drug referring to listed drug that is different from the RLD identified in the ANDA. An ANDA applicant that seeks to refer to a listed drug different from the RLD identified in the initial ANDA must submit a new ANDA (see section 505(j)(2)(D)(i) of the FD&C Act; see also section II.G.1 to II.G.2 of this document).

Section 1101(b)(1)(A) of the MMA amended section 505(b) of the FD&C Act to generally prohibit an applicant from amending or supplementing ''an application referred to in [section

505(b)(2)] to seek approval of a drug that is a different drug than the drug identified in the application as submitted to the Secretary.'' Although section 1101(a) and (b) of the MMA are parallel in structure, the statutory text restricting an applicant from amending or supplementing a 505(b)(2) application in certain circumstances differs from the corresponding restrictions for ANDAs. Section 505(b)(4)(A) prohibits an amendment or a supplement ''to seek approval of a *drug that is a different drug*'' (emphasis added) while section 505(j)(2)(D)(i) prohibits an amendment or supplement to an ANDA ''to seek approval of a *drug referring to a different listed drug*'' (emphasis added).

The MMA also amended section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act to permit a 30-month stay of approval of a 505(b)(2) application or ANDA only with respect to patents for which the NDA holder submitted information to FDA prior to the date of submission of the 505(b)(2) application or the date of submission of the ANDA (which FDA later determines to be substantially complete) that refers to the listed drug claimed by the patent. The ''date on which the application . . . was submitted'' specifically excludes the date of submission of an amendment or supplement to a 505(b)(2) application or ANDA. Given this limitation on the patents that may give rise to a 30-month stay, the MMA may have created an incentive for a 505(b)(2) or ANDA applicant to seek approval for a change to a drug, or to reference a different listed drug, through an amendment or a supplement, rather than by submitting a new application. To address this concern, section 505(b)(4)(A) and (j)(2)(D)(i) of the FD&C Act ensure that 505(b)(2) and ANDA applicants do not use the amendment or supplement process to evade the possibility of a 30-month stay of approval that otherwise would have applied if the 505(b)(2) applicant sought approval for a drug that is a different drug or if the ANDA applicant sought to refer to a different RLD in the original 505(b)(2) application or ANDA, respectively. Accordingly, we interpret section 505(b)(4)(A) of the FD&C Act in a manner that is consistent with the statutory text, accomplishes the statutory goal of preserving a meaningful opportunity for a single 30-month stay, and reflects, to the extent feasible, Congress' expressed intent to preserve rather than disrupt FDA processes regarding submission of amendments and supplements to 505(b)(2) applications and ANDAs.

We propose that a drug will be considered a ''different drug'' for purposes of section 505(b)(4)(A) of the FD&C Act if it has been modified to have a different active ingredient, different route of administration, or different dosage form. Similarly, a drug will be considered to be a different drug if it has been modified to have different excipients that require either a separate clinical study to establish safety or effectiveness or, for topical products, that requires a separate in vivo demonstration of bioequivalence (see proposed §§ 314.60(e) and 314.70(h)). Consistent with FDA's ''bundling'' policy in effect at the time of enactment of the MMA, an applicant may not seek approval for these types of changes to a drug through an amendment or supplement to the 505(b)(2) application; the applicant is required to submit a new 505(b)(2) application (see draft guidance for industry entitled ''Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees'' (describing FDA's bundling policy at the time of enactment of the MMA in 2003); see also Separate Marketing Applications Guidance). These changes to a drug product are significant enough that it is reasonable to assume that one or more patents for the listed drug might be implicated by the change and, if an action for patent infringement is brought in response to a paragraph IV certification to a listed patent, an opportunity for 30-month stay would be appropriate. Thus, FDA has concluded that these modifications to a drug would make the drug a ''different drug'' for purposes of section 505(b)(4)(A) of the FD&C Act. An applicant seeking marketing approval for a drug that has been modified in these ways must submit a separate marketing application for the different drug product, and not an amendment or supplement.

We considered possible alternative interpretations of the phrase ''to seek approval of a drug that is a different drug'' in section 505(b)(4)(A) of the FD&C Act. The narrowest reading of this text would preclude the submission of an amendment or a supplement to a 505(b)(2) application for *any* change (including labeling changes and manufacturing changes) that would arguably render the proposed product a ''different drug'' than the drug identified in the original submission of the application. If labeling changes, for example, could not be made through an amendment or a supplement to a 505(b)(2) application, each such change would require the submission of a separate 505(b)(2) application, with related regulatory and administrative burdens, and user fee and review cycle implications. We did not adopt this reading because it would have resulted in an unwarranted departure from FDA's previous practice for handling such changes.

In applying section 505(b)(4)(A) of the FD&C Act, we initially interpreted the phrase ''drug that is a different drug'' in section 505(b)(4)(A) in a manner that was influenced by and intended to be consistent with the phrase ''drug referring to a different listed drug'' in section 505(j)(2)(D)(i) of the FD&C Act. Under this interpretation, an applicant was not permitted to amend or supplement a 505(b)(2) application to seek approval of a drug that relied on the Agency's finding of safety and/or effectiveness for a listed drug that was different from the listed drug(s) identified in the original submission of the application. This approach assumed that the difference in phrasing between section 505(b)(4)(A) and (j)(2)(D)(i) of the FD&C Act was simply intended to reflect the different statutory frameworks for 505(b)(2) applications and ANDAs. This interpretation also was intended to ensure that a 505(b)(2) applicant did not circumvent the 30-month stay provisions of the FD&C Act by amending or supplementing a 505(b)(2) application to identify a new or additional listed drug upon which it relied for approval.

We found our initial approach to be overly restrictive in practice, however, as this interpretation required withdrawal and resubmission of a 505(b)(2) application to identify a new or additional listed drug even where there were no patents listed in the Orange Book for the new or additional listed drug, and thus there was no possibility of a 30-month stay.

Accordingly, we are proposing a narrower interpretation that is guided by Congress' expressed view that these provisions are intended to ''reflect the FDA's current practice regarding those changes and variations to both innovator and generic drugs that may be approved under amendments and supplements to previously filed NDAs and ANDAs . . .'' (see Conference Report on H.R. 1, November 20, 2003, at H12099).

Our interpretation of section 505(b)(4)(A), (b)(4)(B), (j)(2)(D)(i), and (j)(2)(D)(ii) of the FD&C Act seeks to preserve the legislative balance of the Hatch-Waxman Amendments with respect to facilitating the availability of drug products that meet the statutory requirements for approval while protecting innovator intellectual property rights (and allowing for an early resolution of any patent infringement litigation). We seek

comment on this proposal and potential alternatives to maintain the intended balance.

In the **Federal Register** of November 4, 2004 (69 FR 64314), FDA announced the availability of a draft guidance for industry, issued as required by section 505(j)(2)(D)(iii) of the FD&C Act, that defined the term ''listed drug'' for purposes of section 505(j)(2)(D) with respect to amendments and supplements to an ANDA (see draft guidance for industry entitled ''Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003'' (October 2004), available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072887.pdf*) (Draft Guidance on Listed Drugs). In the Draft Guidance on Listed Drugs, we advised that our definition of the term ''listed drug'' is set forth in § 314.3, and that we did not intend to amend that definition to implement section 505(j)(2)(D) of the FD&C Act. Although minor revisions to the definition of listed drug are proposed in this rulemaking (see section II.A.2.s), these proposed revisions do not substantively alter the definition for purposes of section 505(j)(2)(D) of the FD&C Act. We note that different strengths of an approved drug product continue to be regarded as different listed drugs. However, the FD&C Act expressly permits an applicant to amend or supplement a 505(b)(2) application or ANDA to seek approval of a different strength (see section 505(b)(4)(B) and (j)(2)(D)(ii) of the FD&C Act).

Table 11 summarizes the proposed changes related to amendments or supplements to a 505(b)(2) application or ANDA:

TABLE 11—HIGHLIGHTS OF PROPOSED CHANGES REGARDING AMENDMENTS OR SUPPLEMENTS TO A 505(B)(2) APPLICATION OR ANDA [1]

Current regulations	Proposed revisions to regulations
[No corresponding regulation]	*Amendments and Supplements—Different drug (§§ 314.60(e) and 314.70(h))* • Applicant may not amend a 505(b)(2) application to seek approval of a drug that is a different drug from the drug in the original submission of the 505(b)(2) application. • Applicant may not supplement a 505(b)(2) application to seek approval of a drug that is a different drug from the drug in the approved 505(b)(2) application. • For purposes of this section, a drug is a different drug if it has been modified to have a different active ingredient, different route of administration, different dosage form, or difference in excipients that requires either a separate clinical study to establish safety or effectiveness or, for topical products, that requires a separate in vivo demonstration of bioequivalence. • Approval of a different drug must be requested in a new 505(b)(2) application. • Notwithstanding the limitations described above, an applicant may amend or supplement the 505(b)(2) application to seek approval of a different strength.
[No corresponding regulation]	*Amendments and Supplements—Different listed drug (§§ 314.96(c) and 314.97(b))* • Applicant may not amend an ANDA to seek approval of a drug referring to a listed drug that is different from the RLD identified in the ANDA. —Applies if, at any time before ANDA approval, a different listed drug approved in an NDA is pharmaceutically equivalent to the product in the ANDA and is designated as an RLD. —Applies if changes are proposed in an amendment to the ANDA such that the proposed product is a pharmaceutical equivalent to a different listed drug than the RLD identified in the ANDA. • Applicant may not supplement an ANDA to seek approval of a drug referring to a listed drug that is different from the current RLD identified in the ANDA. —Applies if changes are proposed in a supplement to the ANDA such that the proposed product is a pharmaceutical equivalent to a different listed drug than the RLD identified in the ANDA. • A change of the RLD must be submitted in a new ANDA. • Notwithstanding the limitations described above, an applicant may amend or supplement the ANDA to seek approval of a different strength.

[1] These highlights describe important proposed revisions to our regulations, but should not be relied upon in place of the proposed regulation.

II.G.1. Amendments to an Unapproved ANDA (Proposed § 314.96(c))

We are proposing to revise § 314.96 regarding amendments to an unapproved ANDA by adding paragraph (c) to implement section 505(j)(2)(D)(i) and (ii) of the FD&C Act. Proposed § 314.96(c) states that an applicant may not amend an ANDA to seek approval of a drug referring to a listed drug that is different from the RLD identified in the ANDA. Two examples in proposed § 314.96(c) illustrate the application of this provision.

II.G.1.a. *Approval of a pharmaceutically equivalent drug product.* Proposed § 314.96(c) states that if at any time before approval of the ANDA, an NDA is approved for a drug product that is pharmaceutically equivalent to the product in the pending ANDA and that NDA is designated as an RLD, the applicant is not permitted to amend its pending ANDA to reference the new RLD. This change must be submitted in a new ANDA. As a preliminary matter, we note that the drug product designated as an RLD may not necessarily be the drug product identified in the Orange Book as the reference standard for bioequivalence studies, for example, for drug product lines with multiple strengths. An ANDA would not be ineligible for approval because it relied upon an RLD that was not the reference standard or because it relied upon one of two or more potential RLDs for a pharmaceutically equivalent product. FDA's policy on designating an additional RLD for multiple source products is set forth in the preamble to the 1992 final rule and also described in the preface to the Orange Book. In the 1992 final rule, we stated in relevant part: ''FDA recognizes that, for multiple source products, a product not designated as the listed drug and not shown bioequivalent to the listed drug may be shielded from direct generic competition. If an applicant believes that there are sound reasons for designating another drug as a reference listed drug, it should consult FDA'' (57 FR 17950 at 17958; see also Letter to Robert W. Pollock, Lachman Consultant Services, Inc., dated April 18, 2005, regarding Docket No. FDA–2004–P–0466 (requesting designation of DiaBeta as a second RLD for glyburide tablets, 5

mg), available at *http://www.regulations.gov*).

The scenario described in proposed § 314.96(c) arises, for example, when an ANDA is submitted after the grant of a suitability petition pursuant to section 505(j)(2)(C) of the FD&C Act for a new dosage form, route of administration, or new active ingredient (in a drug product containing more than one active ingredient) and another applicant obtains approval of an NDA (including a 505(b)(2) application) for the change described in the suitability petition before the ANDA is approved. Under these circumstances, it is FDA's longstanding position that an ANDA (including a tentatively approved ANDA) can no longer reference the approved suitability petition and the listed drug described therein as the basis for ANDA submission (see §§ 314.94(a)(3) and 314.127(a)(5), (a)(6), and (a)(12) and section II.I). Prior to enactment of the MMA, an applicant with a pending ANDA based upon an approved ''suitability petition'' (a petitioned ANDA) could have amended its ANDA to change the basis for submission (see § 314.94(a)(3)) to a pharmaceutically equivalent product that subsequently had been approved in an NDA and was designated by FDA as the RLD. However, the plain language of section 505(j)(2)(D)(i) of the FD&C Act (added by the MMA) prohibits an ANDA applicant from amending its ANDA to change the basis for submission to a pharmaceutically equivalent product subsequently approved in an NDA. Accordingly, for an ANDA applicant to obtain approval for a pharmaceutically equivalent product, the applicant would be required to submit a new ANDA that identifies the pharmaceutically equivalent product as its basis for ANDA submission under § 314.94 and meet applicable statutory and regulatory requirements (see, generally, discussion in the Letter from Janet Woodcock, M.D., Director, CDER, to Mark S. Aikman, Pharm.D., Osmotica Pharmaceutical Corp., dated November 25, 2008, regarding Docket No. FDA–2008–P–0329, available at *http://www.regulations.gov*) (Venlafaxine ER Citizen Petition Response).

FDA's policy is scientifically justified because an NDA (either a ''stand-alone'' NDA or 505(b)(2) application) approved for the change described in a suitability petition need not be bioequivalent to the listed drug identified in the suitability petition. For example, a 505(b)(2) applicant may develop a different dosage form of a drug product that is intentionally more bioavailable than a previously approved product (see § 314.54(b)). A 505(b)(2) applicant also may have relied upon a different listed drug in support of its 505(b)(2) application than the listed drug identified in the suitability petition. By ensuring that an ANDA has clearly demonstrated bioequivalence to a pharmaceutically equivalent drug product identified as the RLD, we enhance the utility and accuracy of FDA's therapeutic equivalence determinations. We previously have explained that ''this approach reduces the potentially confusing proliferation of pharmaceutically equivalent drug products that have not demonstrated therapeutic equivalence, and ensures that ANDAs . . . will be therapeutically equivalent and thus substitutable for the RLD'' (Venlafaxine ER Citizen Petition Response at 13).

FDA's requirement that an applicant with a pending ANDA must change its basis for ANDA submission upon approval of an NDA for the same drug product described in the suitability petition also is intended to ensure that ANDA applicants do not circumvent the patent certification requirements of section 505(j)(2)(A)(vii) and (j)(2)(A)(viii) of the FD&C Act through the suitability petition process. Otherwise, if a patent were listed for a drug product approved in an NDA and designated as the RLD and a pending ANDA submitted pursuant to an approved suitability petition were permitted to amend its application to refer to the new RLD, even a single 30-month stay would not be available should the NDA holder or patent owner initiate patent infringement litigation within the statutory timeframe in response to a paragraph IV certification for a patent listed after submission of the original ANDA that FDA later determined to be substantially complete. In addition, our policy appropriately protects any marketing exclusivity that has been granted to the newly approved RLD.

The Agency has rejected the argument that a pending ANDA submitted pursuant to an approved suitability petition may continue to reference the listed drug identified in the suitability petition after a pharmaceutically equivalent product has been approved in an NDA (including a 505(b)(2) application) and is designated as the RLD (see generally Venlafaxine ER Citizen Petition Response). This ''reflects the Agency's judgment that considerations regarding an ANDA's limited reliance on an approved suitability petition are outweighed by the need for a clear determination of therapeutic equivalence for a generic drug product and protection of intellectual property rights accorded an NDA holder'' (Venlafaxine ER Citizen Petition Response at 9). In section II.I, we describe our proposed revisions to § 314.93(e) and (f) to codify FDA's policy that the listed drug identified in an approved suitability petition can no longer be the basis for submission for an unapproved ANDA after a drug product is approved in an NDA for the change described in the petition.

In the case of a first applicant that had been eligible for 180-day exclusivity based on a paragraph IV certification to a patent listed in the Orange Book for the listed drug described in the suitability petition, we note that a new assessment of first applicant status would begin upon submission of a new ANDA. This reflects the fact that any ANDA that referenced the listed drug identified in the suitability petition after approval of a pharmaceutically equivalent product could not be approved. Further, an applicant that withdrew its ANDA would not have lawfully maintained its paragraph IV certification and would no longer be eligible for first applicant status.

II.G.1.b. *Changes to the drug product proposed in the ANDA.* The second example in proposed § 314.96(c) that illustrates the application of this provision involves one or more changes proposed in an amendment to an ANDA that would result in the proposed product being a pharmaceutical equivalent to a different listed drug than the RLD identified in the ANDA. This type of change must be submitted in a new ANDA that identifies the pharmaceutically equivalent product as the new RLD. In the Draft Guidance on Listed Drugs, we explained that ''[a]ll changes that would have the effect of seeking approval for a drug product different from the listed drug cited in the initial submission (*e.g.*, different active ingredient, dosage form, route of administration) should be made in a new application. When the Orange Book identifies as a separate listed drug a product with the characteristics (*e.g.*, active ingredient, dosage form, route of administration) for which the applicant is seeking approval, the applicant should submit a separate ANDA referencing the corresponding listed drug'' (Draft Guidance on Listed Drugs, at 3). This generally conforms with Agency practice before passage of the MMA with respect to certain types of changes (*e.g.*, a change in the dosage form or a change in the formulation that may significantly affect absorption of the active drug ingredient or active moiety) that should be submitted as a separate ANDA (see guidance for industry entitled ''Variations in Drug

Products that May Be Included in a Single ANDA'' (December 1998), available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072892.pdf*) (Guidance on Drug Product Variations). For example, we noted ''[g]enerally, when there is a separate NDA as a RLD for a specific drug product there should be a separate abbreviated application for that NDA'' (Guidance on Drug Product Variations, at 2).

Proposed § 314.96(c) clarifies that, notwithstanding these restrictions on amendments to an ANDA, an applicant is permitted to amend an ANDA to seek approval for a different strength of the drug product (see section 505(j)(2)(D)(ii) of the FD&C Act). As discussed in section II.A.2.bb, we interpret this exception for different strengths of the drug product to include changes to the concentration or to the total drug content of a parenteral drug product. We note that, unlike original ANDAs, not all amendments are subject to a filing review by the Office of Generic Drugs to determine whether the submission may be formally received for substantive review. Accordingly, it is possible that an ANDA applicant that submits an amendment not permitted by statute may be informed late in the review process that the proposed change to its ANDA must be submitted as a new ANDA. We encourage ANDA applicants with questions about whether a proposed amendment to an ANDA would be precluded by section 505(j)(2)(D)(i) of the FD&C Act to contact the Office of Generic Drugs for further guidance.

II.G.2. Supplements to an ANDA (Proposed § 314.97(b))

We are proposing to revise § 314.97 regarding supplements by designating the current text as paragraph (a) and by adding proposed paragraph (b) to implement section 505(j)(2)(D)(i) and (ii) of the FD&C Act. Proposed § 314.97(b) explains that an applicant may not supplement an ANDA to seek approval of a drug referring to a listed drug that is different from the current RLD identified in the ANDA. This restriction applies if changes are proposed in a supplement to the ANDA that would result in the proposed product being pharmaceutically equivalent to a different listed drug than the RLD identified in the underlying ANDA. This type of change must be submitted in a new ANDA that identifies the pharmaceutically equivalent product as the new RLD.

There are several types of changes that may be proposed in a supplement to an ANDA that would result in the proposed product being pharmaceutically equivalent to a different listed drug than the RLD identified in the underlying ANDA. For example, the scenario described in proposed § 314.97(b) may arise if the RLD for the drug product approved in an ANDA is subsequently changed from prescription use to OTC status for some or all conditions of use of the drug product. An ANDA holder for the drug product with the ''switched'' conditions of use would be required to seek approval of the drug product for OTC use because the FD&C Act does not permit a drug product to be marketed as prescription and OTC for the same conditions of use at the same time (see section 503(b) of the FD&C Act (21 U.S.C. 353(b)). However, if the NDA holder for the RLD obtained approval of the switch from prescription use to OTC status in a separate NDA (for example, if fewer than all conditions of use were switched to OTC status), then the NDA for OTC use would be considered a different RLD. Section 505(j)(2)(D)(i) of the FD&C Act does not permit an ANDA holder to refer to a different RLD in a supplement (or, with respect to a pending ANDA, an amendment) to its ANDA. This type of change must be submitted in a new ANDA that identifies the different NDA for OTC use as the RLD.

We note, however, that an ANDA holder may submit a supplement that seeks to demonstrate bioequivalence to a different listed drug when there are multiple RLDs (see, *e.g.,* Orange Book, 33rd Edition (2013) at xx to xxi (Description of Special Situations—levothyroxine sodium)). In this case, the submission of additional bioequivalence data in an ANDA supplement is not for the purpose of seeking approval of a drug referring to a different RLD, but rather to obtain an additional therapeutic equivalence rating. This type of change may continue to be submitted as a supplement to an ANDA.

Proposed § 314.97(b) clarifies that, notwithstanding these restrictions on supplements to an ANDA, an applicant is permitted to supplement an ANDA to seek approval for a different strength of the drug product (see section 505(j)(2)(D)(ii) of the FD&C Act). As discussed in section II.G.1.b, we interpret this exception for different strengths of the drug product to include changes to the concentration or to the total drug content of a parenteral drug product (see also section II.A.2.bb).

II.G.3. Amendments to an Unapproved 505(b)(2) Application (Proposed § 314.60(e))

We are proposing to revise § 314.60 regarding amendments to an unapproved 505(b)(2) application by adding proposed paragraph (e) to implement section 505(b)(4)(A) and (b)(4)(B) of the FD&C Act. Proposed § 314.60(e) states that an applicant may not amend a 505(b)(2) application to seek approval of a drug that is a different drug from the drug in the original submission of the 505(b)(2) application. For purposes of this section, a drug is a different drug if it has been modified to have a different active ingredient, different route of administration, different dosage form, or difference in excipients that requires either a separate clinical study to establish safety or effectiveness or, for topical products, that requires a separate in vivo demonstration of bioequivalence.

II.G.3.a. *Applications within the scope of section 505(b)(4)(A) of the FD&C Act.* Section 505(b)(4)(A) of the FD&C Act restricts certain types of amendments and supplements to a 505(b)(2) application. We interpret this statutory provision to apply to an NDA that was submitted as a 505(b)(2) application and to an NDA that was submitted as a stand-alone 505(b)(1) application but was misclassified by the applicant. A stand-alone 505(b)(1) application would be misclassified if, for example, the application relied, at least in part, on the Agency's finding of safety and/or effectiveness for one or more listed drugs or published literature. Such an NDA is considered to be a 505(b)(2) application even if the applicant failed to identify the listed drug(s) in accordance with § 314.54(a)(1)(iii) and comply with applicable regulatory requirements. It would be inconsistent with the statutory scheme, as amended by the MMA, to permit an applicant to circumvent the restrictions on amendments to a 505(b)(2) application and the potential implications for the availability of a 30-month stay of approval pursuant to section 505(c)(3)(C) of the FD&C Act merely by incorrectly characterizing the original submission as a stand-alone 505(b)(1) application.

We note, however, that reliance on a listed drug pursuant to section 505(b)(2) of the FD&C Act generally assumes that the drug the applicant is referencing is one for which it is not the application holder and for which it would not have a right of reference or use. Accordingly, an applicant that cross-references relevant studies in its own previous

505(b)(2) application (*i.e.,* studies that were conducted by or for the applicant or to which the applicant has obtained a right of reference or use) would not be a 505(b)(2) applicant as to those portions of its previous 505(b)(2) application. However, an applicant may be relying, in part, for approval of its current NDA upon the Agency's finding of safety and/or effectiveness for a listed drug identified in its previous 505(b)(2) application, to which it does not have a right of reference or use. In this scenario, if an applicant continues to rely upon the original listed drug for approval of its current NDA, then it is a 505(b)(2) application and the applicant must identify the original listed drug in accordance with § 314.54 and comply with other applicable regulatory requirements.

An applicant also may not amend a literature-based 505(b)(2) application to seek approval of a drug that has been modified to have a different active ingredient, different route of administration, different dosage form, or difference in excipients that requires either a separate clinical study to establish safety or effectiveness or, for topical products, that requires a separate in vivo demonstration of bioequivalence.

II.G.3.b. *Proposed amendments subject to section 505(b)(4)(A) of the FD&C Act.* Proposed § 314.60(e) provides that the statutory restriction on amending a 505(b)(2) application to seek approval of a drug that is a different drug from the drug in the original submission of the 505(b)(2) application applies to any proposed amendment, even if the amendment is submitted prior to the Agency's decision regarding whether the 505(b)(2) application can be filed in accordance with § 314.101(a). This standard is consistent with the MMA's amendments to section 505(c)(3)(C) of the FD&C Act to limit the availability of a 30-month stay of approval to patents for which the NDA holder submitted information to FDA ''before the date on which the application (excluding an amendment or supplement to the application) was submitted.''

Under proposed § 314.60, an applicant cannot amend a 505(b)(2) application to seek approval for a drug that has been modified to have a different active ingredient. This includes, but is not limited to, a different salt, ester, or complex of the same active moiety (compare section II.F.1.d). A change in the route of administration or dosage form also cannot be made in an amendment to a 505(b)(2) application unless the product is qualitatively (Q1) the same and quantitatively (Q2) essentially the same as the proposed drug product in the original 505(b)(2) application for all routes of administration or dosage forms, as applicable.

An applicant also cannot amend a 505(b)(2) application to seek approval for a drug that has been modified to have a difference in excipients that requires either a separate clinical study to establish safety or effectiveness or, for topical products, that requires a separate in vivo demonstration of bioequivalence (see § 320.24(b)(4)). These proposed modifications would result in a different drug for which approval must be requested in a new 505(b)(2) application.

However, notwithstanding these restrictions on amendments to a 505(b)(2) application, an applicant is permitted to amend a 505(b)(2) application to identify a new or additional listed drug upon which the application relies for approval.

In addition, proposed § 314.60(e) clarifies that an applicant is permitted to amend a 505(b)(2) application to seek approval for a different strength of the drug product (see section 505(b)(4)(B) of the FD&C Act; see also sections II.A.2.bb and II.G.1.b of this document).

II.G.4. Supplements to a 505(b)(2) Application (Proposed § 314.70(h))

We are proposing to revise § 314.70 regarding supplements to an approved 505(b)(2) application by adding proposed paragraph (h) to implement section 505(b)(4)(A) and (b)(4)(B) of the FD&C Act. Proposed § 314.70(h) states that an applicant may not supplement a 505(b)(2) application to seek approval of a drug that is a different drug from the drug in the original submission of the 505(b)(2) application. For purposes of this section, a drug is a different drug if it has been modified to have a different active ingredient, different route of administration, different dosage form, or difference in excipients that requires either a separate clinical study to establish safety or effectiveness or, for topical products, that requires a separate in vivo demonstration of bioequivalence (see discussion in section II.G.3.b). These proposed modifications would result in a different drug for which approval must be requested in a new 505(b)(2) application.

In addition, proposed § 314.70(h) clarifies that, notwithstanding these restrictions on supplements to a 505(b)(2) application, an applicant is permitted to supplement a 505(b)(2) application to seek approval for a different strength of the drug product (see section 505(b)(4)(B) of the FD&C Act; see also sections II.A.2.bb and II.G.1.b of this document).

We interpret section 505(b)(4)(A) of the FD&C Act to apply to the submission of a 505(b)(2) supplement to an NDA approved through the 505(b)(2) pathway, irrespective of whether the original 505(b)(2) application relied upon published literature or the Agency's finding of safety and/or effectiveness for one or more listed drugs. However, because the statutory text expressly applies to a supplement to a 505(b)(2) application, we do not interpret the restriction in section 505(b)(4)(A) to apply to a 505(b)(2) supplement to an NDA that received approval as a stand-alone 505(b)(1) application unless an intervening 505(b)(2) supplement has been approved for that NDA (see § 314.3(b) (defining the term ''application'' to include all supplements to the application)).

II.H. Procedure for Submission of an Application Requiring Investigations for Approval of a New Indication for, or Other Change From, a Listed Drug (Proposed § 314.54)

We are proposing to revise §§ 314.50(i), 314.54(a), and 314.125(b) to establish the requirement that an applicant identify a pharmaceutically equivalent product, if already approved, as a listed drug relied upon to support approval of a 505(b)(2) application.

FDA's longstanding policy has been that a 505(b)(2) applicant may rely on FDA's finding of safety and/or effectiveness for a listed drug only to the extent that the proposed product in the 505(b)(2) application shares characteristics (*e.g.,* active ingredient, dosage form, route of administration, strength, indication, conditions of use) in common with the listed drug. To the extent that the listed drug and the drug proposed in the 505(b)(2) application differ, the 505(b)(2) application must include sufficient data to demonstrate that the proposed drug meets the statutory approval standard for safety and effectiveness. The 505(b)(2) approval pathway is not intended for a ''duplicate'' of a listed drug that is eligible for approval in an ANDA, and FDA would refuse to file such a 505(b)(2) application (see § 314.101(d)(9)). The Hatch-Waxman Amendments established a specific abbreviated approval pathway for duplicates of a listed drug in section 505(j) of the FD&C Act.

However, there are circumstances in which a proposed drug product that is pharmaceutically equivalent to a listed drug (*i.e.,* drug products in the same dosage form and route(s) of

administration that contain the same amount of the same active drug ingredient and that meet other applicable standards) is not eligible for approval as an ANDA and must be submitted as an NDA. For example, a proposed extended-release drug product may intentionally differ in its pharmacokinetic profile from a listed drug that is also an extended-release drug product such that the proposed product cannot meet the bioequivalence requirement for ANDAs (see section 505(j)(2)(A)(iv) of the FD&C Act; compare § 314.54(b)). Certain drug products intended for parenteral, ophthalmic, otic, or topical use may contain differences in excipients that render the drug product ineligible for submission in an ANDA (see § 314.94(a)(9)(iii) to (a)(9)(v)). For certain complex drug products, an applicant may be unable to demonstrate ''sameness'' of the active ingredient as required for submission of an ANDA (see section 505(j)(2)(A)(ii) of the FD&C Act). A request for approval of a new indication for a pharmaceutically equivalent drug product also is ineligible for submission as an ANDA. These changes to a listed drug must be submitted in an NDA.

We have explained that a 505(b)(2) applicant may rely on FDA's finding of safety and effectiveness for a listed drug ''only to the extent that such reliance would be allowed under section 505(j) of the act'' (1989 proposed rule, 54 FR 28872 at 28892). If a pharmaceutically equivalent drug product has been approved before a 505(b)(2) application is submitted, then we consider the 505(b)(2) applicant to be implicitly relying on the approval of such drug product. We are proposing to revise § 314.54(a)(1)(iii) to require that the listed drug or drugs identified as relied upon by a 505(b)(2) applicant must include any approved drug product that: (1) Is pharmaceutically equivalent to the drug product for which the 505(b)(2) application is submitted and (2) was approved before the 505(b)(2) application was submitted. This requirement is intended to help ensure that the 505(b)(2) pathway is not used to circumvent the statutory obligation that would have applied if the proposed product was submitted as an ANDA—namely, submission of a patent certification for a listed patent that corresponds to the protected aspects of the pharmaceutically equivalent listed drug (see draft guidance for industry entitled ''Applications Covered by Section 505(b)(2)'' (October 1999), available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm079345.pdf*) (''If there is a listed drug that is the pharmaceutical equivalent of the drug proposed in the 505(b)(2) application, the 505(b)(2) applicant should provide patent certifications for the patents listed for the pharmaceutically equivalent drug''). Clarifying revisions in proposed § 314.54(a)(1)(iii) and (a)(1)(vi) replace the reference to ''other drugs'' with ''listed drug'' to conform with our longstanding policy that an applicant may rely upon more than one listed drug to support approval of a 505(b)(2) application. In addition, we are proposing to replace the term ''reference listed drug'' in § 314.54(b) with ''listed drug'' because the descriptor ''reference listed drug'' is a term of art that applies to an ANDA. A 505(b)(2) application may rely on FDA's finding of safety and/or effectiveness for one or more listed drugs.

We also are proposing to add § 314.50(i)(1)(i)(C) to require that if, before the date of submission of the 505(b)(2) application, there is an approved drug product that is pharmaceutically equivalent to the drug product for which the 505(b)(2) application is submitted, the applicant must submit an appropriate patent certification under § 314.50(i) with respect to each patent listed for the pharmaceutically equivalent product that claims the drug substance or drug product or that claims an approved use for such drug.

We are proposing a conforming revision to § 314.125(b) to state that we may refuse to approve a 505(b)(2) application based on the applicant's failure to submit an appropriate patent certification or statement with respect to each listed patent for a drug product that: (1) Is pharmaceutically equivalent to the drug product for which the 505(b)(2) application is submitted and (2) was approved before the 505(b)(2) application was submitted. If FDA approves a pharmaceutically equivalent product within the 60-day filing review period after a 505(b)(2) application is submitted, the 505(b)(2) applicant is not required to identify the product as a listed drug relied upon or submit a patent certification under § 314.50(i) and FDA would not refuse to file the application under § 314.101(d)(9) based on the new approval.

It also should be noted that the requirement to identify a pharmaceutically equivalent product as a listed drug relied upon (and to submit an appropriate patent certification or statement with respect to each listed patent) does not apply if a pharmaceutically equivalent product is approved while the 505(b)(2) application is pending.

We intend to promptly publish on FDA's Web site information regarding the approval of new drug products to facilitate, among other things, a 505(b)(2) applicant's compliance with proposed § 314.54(a)(1)(iii) and (a)(1)(vi) and § 314.50(i)(1)(i)(C).

II.I. Petition To Request a Change From a Listed Drug (Proposed § 314.93)

We are proposing to amend § 314.93 regarding petitioned ANDAs to codify FDA's policy that the listed drug identified in an approved suitability petition can no longer be the basis for submission for an unapproved ANDA after a drug product is approved in an NDA for the change described in the petition (see generally Venlafaxine ER Citizen Petition Response). This proposed revision is intended to facilitate implementation of section 505(j)(2)(D)(i) and (ii) of the FD&C Act and complement proposed revisions to § 314.96(c) regarding amendments to an unapproved ANDA (see section II.F.1.a).

We are proposing to revise § 314.93(f) regarding withdrawal of approval of a suitability petition by redesignating the current text as paragraph (f)(1) and by adding paragraph (f)(2). Proposed § 314.93(f)(2) clarifies that if, after approval of a petition and before approval of an ANDA submitted pursuant to the approved petition, a drug product is approved in an NDA for the change described in the petition, the petition and the listed drug identified in the petition can no longer be the basis for ANDA submission, irrespective of whether FDA has withdrawn approval of the petition. Because an ANDA applicant may not amend its ANDA to change the basis for submission to the new RLD (see section 505(j)(2)(D)(i) of the FD&C Act), a person seeking approval for such drug product would be required to submit a new ANDA that identifies the pharmaceutically equivalent RLD as the basis for ANDA submission and comply with applicable statutory and regulatory requirements.

We also are proposing to add § 314.93(e)(1)(vi) to codify our longstanding policy that FDA will not approve a suitability petition if a drug product is approved in an NDA for the change described in the petition. The suitability petition process is intended for a proposed ''drug product which is not identical to a listed drug in route of administration, dosage form, and strength, or in which one active ingredient is substituted for one of the active ingredients in a listed combination drug'' (§ 314.93(b)). If a pharmaceutically equivalent drug

product has been approved in an NDA, the ANDA applicant should refer to the approved pharmaceutical equivalent designated by the Agency as the RLD as its basis for ANDA submission. Throughout the pendency of review of the ANDA, applicants should confirm that an NDA has not been approved for the drug product described in the suitability petition.

Although FDA currently has the authority to withdraw approval of a suitability petition after a drug product is approved in an NDA for the change described in the petition, we note that it has been the Agency's practice not to rescind approval of the petition under these circumstances due to the administrative burden. We previously have explained: ''we need not withdraw approval of the suitability petition to implement our long-standing practice that the intervening approval of an NDA for the product described by the suitability petition precludes an ANDA applicant from referring to the suitability petition and listed drug described therein as its basis for ANDA submission. Any pending ANDA that referred to the suitability petition and the listed drug described therein would not be eligible for approval, and any newly submitted ANDA that sought to reference the suitability petition instead of the RLD identified in the Orange Book would not be received by the Agency'' (Venlafaxine ER Citizen Petition Response at 25). To ensure that our regulations consistently reflect this policy, we are proposing to add § 314.127(a)(14) to state that FDA will refuse to approve a petitioned ANDA if an NDA subsequently has been approved for the change described in the suitability petition.

II.J. Filing an NDA and Receiving an ANDA (Proposed § 314.101)

II.J.1. Notification of Filing of a 505(b)(2) Application or Receipt of an ANDA

We are proposing to amend § 314.101, with respect to 505(b)(2) applications and ANDAs that contain a paragraph IV certification, to facilitate implementation of the MMA's timing requirements for sending notice of a paragraph IV certification and for efficient enforcement of the FD&C Act.

Section 505(b)(3)(B)(i) and (j)(2)(B)(ii)(I) of the FD&C Act require a 505(b)(2) or ANDA applicant, respectively, to send notice of a paragraph IV certification within 20 days after the date of the postmark on the notice with which FDA informs the applicant that the 505(b)(2) application has been filed or the ANDA has been received (see section II.D.1). Our proposed revisions to § 314.101(a)(2) and (b)(2) clarify that FDA will notify the applicant that the 505(b)(2) application is regarded as filed or the ANDA is regarded as received, respectively, by means of an acknowledgment letter or a paragraph IV acknowledgment letter (see also section II.A.2.c and II.A.2.u).

We are proposing to revise § 314.101(b)(1) and (b)(2) regarding ANDAs to incorporate the statutory definition of a ''substantially complete application,'' which was added by the MMA for purposes of section 505(j)(5) of the FD&C Act (see section 505(j)(5)(B)(iv)(II)(cc) of the FD&C Act and section II.A.2.cc of this document). Proposed § 314.101(b)(1) states that receipt of an ANDA means that FDA has made a threshold determination that the ANDA is substantially complete. We also are proposing to revise proposed § 314.101(b)(2) to clarify that if an ANDA is determined to have been substantially complete as of the date on which it was submitted, the date of submission is considered to be the date of receipt. As noted in section II.A.2.cc, our proposed replacement of the current standard ''sufficiently complete to permit a substantive review'' with the phrase ''substantially complete application'' is not intended to alter the meaning. Rather, we are seeking to consistently use defined terms throughout our regulations.

We are proposing to amend § 314.101(b)(3) to remove the method of notification by which FDA will advise an ANDA applicant that FDA has refused to receive the ANDA under § 314.101(d) or (e). The regulations currently state that FDA will ordinarily notify an ANDA applicant by telephone; however, this does not accurately describe FDA's current practice to inform the ANDA applicant in writing by issuing a ''refuse to receive'' letter.

In proposed § 314.101(b)(4), we establish an administrative consequence for an ANDA applicant that fails to timely provide notice of a paragraph IV certification as required by section 505(j)(2)(B)(ii) of the FD&C Act and § 314.95(b) and (d). If FDA determines that an ANDA applicant did not send notice of a paragraph IV certification within the timeframe described in § 314.95(b) or (d), as applicable, FDA will deem the date that the ANDA was submitted to be delayed by the number of days by which the timeframe for sending notice of a paragraph IV certification was exceeded. As discussed in section II.D.5, an ANDA applicant that fails to provide timely notice of a paragraph IV certification may, based upon the revised date on which the ANDA was determined to have been received, lose its first applicant status and thus its eligibility for 180-day exclusivity. In addition, such an ANDA may be repositioned in the review queue consistent with the revised date of ANDA submission.

II.J.2. Other Proposed Revisions

We are proposing several clarifying revisions to § 314.101. First, we are proposing to delete the reference to section 507 of the FD&C Act in § 314.101(d)(3). As discussed in section II.A.2.b, FDAMA repealed section 507 of the FD&C Act under which marketing applications, including abbreviated applications, for antibiotics had been approved (see section 125 of FDAMA). Section 125(d) of FDAMA provided that abbreviated applications for antibiotics previously approved under section 507 of the FD&C Act would be deemed approved under section 505(j) of the FD&C Act.

Second, we are proposing to replace the term ''application'' in § 314.101(d)(6) and (d)(7) with ''NDA and ANDA'' to clarify that these provisions apply to ANDAs as well as NDAs. As discussed in section II.A.2.b and II.A.2.i, we have proposed to incorporate the commonly used acronyms NDA and ANDA in place of the terms application and abbreviated application, as appropriate, throughout the sections of part 314 and part 320 in this rulemaking. Proposed § 314.101(d)(6) states that FDA may refuse to file an NDA or may not consider an ANDA to be received if the NDA or ANDA does not contain a statement for each nonclinical laboratory study regarding compliance with the requirements of part 58 of this chapter. This criterion is applicable to ANDAs as well as NDAs. Nonclinical studies submitted in an ANDA may include, but are not limited to, dissolution studies and ''dose-dumping'' studies. Proposed § 314.101(d)(7) provides that FDA may refuse to file an NDA or may not consider an ANDA to be received if the NDA or ANDA does not contain a statement for each clinical study regarding whether it was conducted in compliance with the regulations in part 50 and part 56 of this chapter. Clinical studies submitted in an ANDA which may be subject to the regulations in part 50 and part 56 of this chapter include, for example, comparative clinical trials conducted for the purpose of demonstrating bioequivalence (see § 320.24(b)(4); see also § 314.94(a)(7)(iii)).

Third, we are proposing to replace the current text of § 314.101(e)(2) with a

statement that FDA will refuse to file a 505(b)(2) application or will consider an ANDA not to have been received if submission of a 505(b)(2) application or an ANDA for the active moiety is not permitted under § 314.108(b)(2). This is not a substantive revision, as § 314.108(b)(2) describes the conditions set forth in current § 314.101(e)(2)(i) and (e)(2)(ii).

We also propose to add headings to certain paragraphs for administrative convenience.

II.K. Approval of an NDA and ANDA (Proposed § 314.105)

We are proposing to revise § 314.105(a) and (d) regarding approval of an NDA (including a 505(b)(2) application) and an ANDA to remove the references to a ''delayed effective date'' and clarify that an application is approved on the date of issuance of an approval letter. These proposed revisions reflect current FDA practice and policy with respect to approval letters. The Agency does not issue approval letters with delayed effective dates. Rather, the Agency will issue a tentative approval letter when an NDA or ANDA that is otherwise eligible for approval cannot be approved due to unexpired patents, certain circumstances related to patent litigation (see § 314.107(b)(3) and (e)(1)(vi)), or various types of exclusivity (see proposed § 314.107(b)(1)(iii), (c) and (d)). ''Tentative approval'' is defined in proposed § 314.3. We also have made conforming revisions throughout this proposed rulemaking to replace references to the ''effective date'' of an application with language reflecting our current practice.

A drug product granted tentative approval is not an approved drug. Prior to obtaining approval of a 505(b)(2) application or ANDA, the applicant may be requested to submit updated labeling; chemistry, manufacturing, and controls (CMC) data; a safety update; and any other information necessary to ensure that the 505(b)(2) application or ANDA meets the statutory and regulatory requirements for approval. For a 505(b)(2) application or ANDA to be approved, the applicant must receive an approval letter from FDA (see proposed § 314.107(b)(4)).

We note that an applicant with a tentatively approved 505(b)(2) application or ANDA has a continuing obligation to amend its patent certification or statement if, at any time before approval of the 505(b)(2) application or ANDA, the submitted certification is no longer accurate (see proposed §§ 314.50(i)(6) and 314.94(a)(12)(viii)). In the context of a tentatively approved application, this obligation may apply, for example, if the NDA holder for the listed drug relied upon or RLD timely submits new patent information for a patent that claims the drug substance, drug product, or a method of use after the 505(b)(2) application or ANDA has been tentatively approved. In this scenario, the 505(b)(2) or ANDA applicant would be required to submit an amendment to its tentatively approved application with an appropriate patent certification or statement regarding the newly listed patent.

The applicant with a tentatively approved application also may need to update the draft product labeling to incorporate relevant revisions to the labeling of the listed drug relied upon or RLD made after the tentative approval of the 505(b)(2) application or ANDA, respectively. This caveat is particularly relevant for an ANDA, which is required by statute to have, among other things, the same labeling and conditions of use as the RLD (see section 505(j)(2)(A)(i) and (j)(2)(A)(v) of the FD&C Act; compare section 505(j)(10) of the FD&C Act), unless the ANDA applicant is not seeking approval for an indication or other aspect of labeling protected by patent or accorded exclusivity under section 505(j)(4)(D) of the FD&C Act (see § 314.94(a)(8)(iv); see also section 505(j)(2)(A)(viii) of the FD&C Act). In addition, a tentatively approved ANDA for a drug product intended for parenteral, ophthalmic, otic, or topical use that is required to contain the same inactive ingredients in the same concentration as the RLD, subject to exceptions specified in § 314.94(a)(9)(iii) through (a)(9)(v), may be required to modify its drug product and amend its ANDA to address certain changes in the formulation of the RLD subsequent to tentative approval unless FDA has made a determination that the RLD was not withdrawn from sale for reasons of safety or effectiveness (see §§ 314.122 and 314.161; see also discussion in section II.L).

In addition, we are proposing to revise § 314.105(a) and (d) to expressly state that FDA's tentative approval of a drug product is based on information available to FDA at the time of the tentative approval letter (*i.e.,* information in the 505(b)(2) application or ANDA and the status of current good manufacturing practices of the facilities used in the manufacturing and testing of the drug product) and is therefore subject to change on the basis of new information that may come to FDA's attention.

Finally, it should be noted that a tentatively approved application is subject to any applicable period of marketing exclusivity granted to the listed drug relied upon (for a 505(b)(2) application) or RLD (for an ANDA) after tentative approval. For example, approval of a tentatively approved application may be delayed by the intervening grant, pursuant to section 505A of the FD&C Act, of a period of pediatric exclusivity to the NDA holder for the listed drug relied upon or RLD after tentative approval of the 505(b)(2) application or ANDA, respectively (see, *e.g., Barr Labs., Inc.* v. *Thompson,* 238 F. Supp. 2d 236 (D.D.C. 2002) (upholding FDA's determination that a 6-month period of pediatric exclusivity that had attached to a listed patent for which a paragraph III certification had been submitted applied to a tentatively approved application)).

II.L. Refusal to Approve an NDA or ANDA (Proposed §§ 314.125 and 314.127 and Related Provisions in Proposed §§ 314.90 and 314.99)

We are proposing to revise §§ 314.90 and 314.99 to clarify the effect of FDA's grant of an applicant's request for waiver of a requirement under §§ 314.50 through 314.81 or §§ 314.92 through 314.99, respectively. If FDA grants such a request, the applicant's failure to comply with the requirement that is the subject of the waiver request will not constitute a basis for refusal to approve the NDA under § 314.125 or the ANDA under § 314.127, as applicable. We also are proposing corresponding revisions to §§ 314.125(b) and 314.127(a), which address permissive refusal to approve an NDA and mandatory refusal to approve an ANDA, respectively. Proposed § 314.125(b) states that FDA may refuse to approve an NDA for any of the following reasons listed, unless the requirement has been waived pursuant to § 314.90. Proposed § 314.127(a) states that FDA will refuse to approve an ANDA for a new drug under section 505(j) of the FD&C Act for any of the following reasons listed, unless the requirement has been waived pursuant to § 314.99.

Sections 314.90 and 314.99 currently provide that an NDA or ANDA applicant may ask FDA to waive any requirement that applies to the applicant under §§ 314.50 through 314.81 or §§ 314.92 through 314.99, respectively. FDA has interpreted its waiver of a submission requirement under these provisions to carry with it the implicit waiver of any corresponding approval requirement under §§ 314.125 or 314.127. Otherwise, the waiver of a submission requirement for an NDA or ANDA would be meaningless if there was a parallel

requirement under §§ 314.125 or 314.127, respectively, for approval of the application.

The proposed revisions to §§ 314.90 and 314.99, and corresponding proposed revisions to proposed §§ 314.125 and 314.127, codify FDA's approach to this issue. For example, FDA has relied on § 314.99(b) to grant a waiver of the requirement that the formulation of a drug product intended for parenteral use contain the same inactive ingredients in the same concentration as the RLD, with limited exceptions for preservatives, buffers, and antioxidants, where the formulation proposed by the ANDA applicant had previously been approved by FDA as safe and effective. We note that FDA may not waive a statutory requirement (see 1989 Proposed Rule, 54 FR 28872 at 28889).

II.M. Date of Approval of a 505(b)(2) Application or ANDA (Proposed § 314.107)

Section 314.107 establishes the earliest date on which a 505(b)(2) application or ANDA may be approved in light of the statutory provisions that can delay the approval of an application that is otherwise eligible for approval. Approval of a 505(b)(2) application or ANDA can be delayed by the marketing exclusivity granted to another drug product under section 505(c)(3)(E) and (j)(5)(F) of the FD&C Act (and, with respect to ANDAs, section 505(j)(5)(B)(iv) of the FD&C Act for 180-day exclusivity) or pediatric exclusivity under section 505A of the FD&C Act that may attach to a patent listed for a drug product. Approval of a 505(b)(2) application or ANDA also can be delayed by a 30-month stay of approval should the NDA holder or patent owner initiate patent infringement litigation within the statutory timeframe in response to notice of a paragraph IV certification (see section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act). The MMA amended the FD&C Act to alter the circumstances under which a 30-month stay of approval can arise. The MMA also amended the FD&C Act to specify the types of court actions that will terminate a 30-month stay of approval. In addition, approval of a 505(b)(2) application or ANDA can be delayed by a court order pursuant to 35 U.S.C. 271(e)(4)(A) ordering that the application may be approved no earlier than the date specified (irrespective of whether the injunction relates to a patent described in § 314.107(b)(3) (see proposed § 314.107(b)(4) and (e)(1)(vi)).

Table 12 summarizes the proposed changes related to the effect of patent(s) on the listed drug with respect to the date of approval of a 505(b)(2) application or ANDA.

TABLE 12—HIGHLIGHTS OF PROPOSED CHANGES REGARDING THE EFFECT OF PATENT(S) ON THE LISTED DRUG [1]

Current regulations	Proposed revisions to regulations
Effect of patent on the listed drug (§ 314.107(b)) • Introduction to criteria for determining date on which approval of a 505(b)(2) application or ANDA will become effective.	*Effect of patent(s) on the listed drug (§ 314.107(b))* • Introduction to criteria that must be used to determine, for each relevant patent, the date that patent will no longer prevent approval. • The first possible date of approval will be calculated for each patent, and the 505(b)(2) application or ANDA may be approved on the last applicable date.
Multiple certifications (§ 314.107(b)(4)) • If the applicant has submitted certifications for more than one patent, the date of approval will be calculated for each certification, and the approval will become effective on the last applicable date.	
Date of approval letter (§ 314.107(b)(1)) • Except as provided in § 314.107(b)(3), (b)(4), and (c), approval will become effective on the date FDA issues an approval letter if the applicant certifies that: (i) there are no relevant patents; or (ii) the patent information has not been submitted to FDA; or (iii) the relevant patent has expired; or (iv) the relevant patent is invalid, unenforceable, or will not be infringed.	*Timing of approval based on patent certification or statement (§ 314.107(b)(1))* • If none of the reasons in § 314.125 or § 314.127 for refusing to approve the application apply, and none of the reasons in § 314.107(d) for delaying approval apply, the 505(b)(2) application or ANDA may be approved— (i) *Immediately,* if the applicant certifies that: (A) the patent information has not been submitted to FDA; or (B) the relevant patent has expired; or (C) the relevant patent is invalid, unenforceable, or will not be infringed, except as provided in § 314.107(b)(3) and (c), and the 45-day period provided for in section 505(c)(3)(C) and 505(j)(5)(B)(iii) of the FD&C Act has expired; or (D) there are no relevant patents. (ii) *Immediately,* if the applicant submits an appropriate statement explaining that a method-of-use patent does not claim an indication or other condition of use for which it is seeking approval.
Patent expiration (§ 314.107(b)(2)) • If the applicant certifies that the relevant patent will expire on a specified date (paragraph III certification), approval will become effective *on* the specified date.	*Timing of approval based on patent certification or statement (§ 314.107(b)(1)(iii))* • If the applicant certifies that the relevant patent will expire on a specified date (paragraph III certification), a 505(b)(2) application or ANDA otherwise eligible for approval may be approved *on* the specified date.
[No corresponding regulation]	*Patent information filed after submission of 505(b)(2) application or ANDA (§ 314.107(b)(2))* • If an NDA holder submits patent information for a listed drug after the date on which a 505(b)(2) application or ANDA relying on such drug was submitted to FDA, the 505(b)(2) or ANDA applicant must submit an amended patent certification or statement in accordance with §§ 314.50(i)(4) and (i)(6) and 314.94(a)(12)(vi) and (a)(12)(viii).

TABLE 12—HIGHLIGHTS OF PROPOSED CHANGES REGARDING THE EFFECT OF PATENT(S) ON THE LISTED DRUG [1]—Continued

Current regulations	Proposed revisions to regulations
	• If the applicant submits a paragraph IV certification to the newly-listed patent information and complies with the notice requirements of § 314.52 or § 314.95, the 505(b)(2) application or ANDA may be approved immediately upon submission of documentation of receipt of notice of paragraph IV certification. • The 45-day period provided for in section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act does not apply.
Disposition of patent litigation (§ 314.107(b)(3)(i)) • (A) Except as provided in § 314.107(b)(3)(ii) through (b)(3)(iv), if —applicant submits a paragraph IV certification; and —patent owner or its representative or the exclusive patent licensee brings suit for patent infringement within 45 days of receipt by the patent owner of the notice of paragraph IV certification, Approval may be made effective 30 months after the date of the receipt of the notice of paragraph IV certification by the patent owner or by the exclusive licensee (or their representatives) unless the court has extended or reduced the period; or • (B) If the patented drug product qualifies for 5-year exclusivity, and	*Disposition of patent litigation (§ 314.107(b)(3)(i))* • (A) Except as provided in § 314.107(b)(3)(ii) through (b)(3)(viii), if, with respect to patents for which required information was submitted before the date on which the 505(b)(2) application or ANDA was submitted to FDA (excluding an amendment or supplement), —applicant submits a paragraph IV certification; and —patent owner or the exclusive patent licensee brings suit for patent infringement within 45 days of receipt of the notice of paragraph IV certification, 505(b)(2) application, or ANDA may be approved 30 months after the later of the date of the receipt of the notice of certification by any owner of the listed patent or by the NDA holder who is an exclusive patent licensee (or their representatives) unless the court has extended or reduced the period; or • (B) If the patented drug product qualifies for 5-year exclusivity, and—patent owner or its representative or the exclusive patent licensee brings suit for patent infringement during the 1-year period beginning 4 years after the date the patented drug was approved and within 45 days of receipt by the patent owner of the notice of paragraph IV certification, Approval may be made effective at the expiration of 7½ years from the date of NDA approval for the patented drug product. —patent owner or its representative or the exclusive patent licensee brings suit for patent infringement during the 1-year period beginning 4 years after the date the patented drug was approved and within 45 days of receipt of the notice of paragraph IV certification, the 505(b)(2) application or ANDA may be approved at the expiration of 7½ years from the date of NDA approval for the patented drug product.
Disposition of patent litigation (§ 314.107(b)(3)(ii)–(b)(3)(iv)) If before the expiration of the 30-month period, or 7½ years where applicable: • (ii) the court issues a final order that the patent is invalid, unenforceable, or not infringed, approval may be made effective on: —the date the court enters judgment; • (iii) the court issues a final order or judgment that the patent has been infringed, approval may be made effective on: —the date the court determines that the patent will expire or otherwise orders • (iv) the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug product until the court decides the issues of patent validity and infringement, and if the court later decides that the patent is invalid, unenforceable, or not infringed, approval may be made effective on: —the date the court enters a final order or judgment that the patent is invalid, unenforceable, or not infringed.	*Disposition of patent litigation (§ 314.107(b)(3)(ii)–(b)(3)(viii)* If before the expiration of the 30-month period, or 7½ years where applicable: • (ii) the district court decides that the patent is invalid, unenforceable, or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the 505(b)(2) application or ANDA may be approved on: —(A) the date on which the court enters judgment reflecting the decision; or —(B) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed. • (iii) the district court decides that the patent has been infringed and the judgment is appealed, the 505(b)(2) application or ANDA may be approved on: —(A) the date on which the mandate is issued by the court of appeals entering judgment that the patent is invalid or not infringed; or —(B) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent is invalid or not infringed. • (iv) the district court decides that the patent has been infringed and the judgment is not appealed or is affirmed, the 505(b)(2) application or ANDA may be approved no earlier than the date specified by the district court in an order under 35 U.S.C. 271(e)(4)(A). • (v) the district court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug product until the court decides the issues of patent validity and infringement: — if the court later decides the patent is invalid, unenforceable, or not infringed, the 505(b)(2) application or ANDA may be approved per § 314.107(b)(3)(ii).

TABLE 12—HIGHLIGHTS OF PROPOSED CHANGES REGARDING THE EFFECT OF PATENT(S) ON THE LISTED DRUG [1]—Continued

Current regulations	Proposed revisions to regulations
	—if the court decides that the patent has been infringed, the 505(b)(2) application or ANDA may be approved per § 314.107(b)(3)(iii) or (b)(3)(iv), as applicable. • (vi) the patent owner or the exclusive patent licensee (or their representatives) agrees in writing that the 505(b)(2) application or ANDA may be approved any time on or after the date of the consent, approval may be granted on or after that date. • (vii) the court enters an order requiring the 30-month or 7½-year period to be terminated, the 505(b)(2) application or ANDA may be approved in accordance with the court's order. • (viii) the court enters an order of dismissal, with or without prejudice, without a finding of infringement, the 505(b)(2) application or ANDA may be approved on or after the date of the order.

[1] These highlights describe important proposed revisions to our regulations, but should not be relied upon in place of the proposed regulation.

II.M.1. General (Proposed § 314.107(a))

We are not proposing any substantive revisions to § 314.107(a). As noted in section II.A.2.dd and II.I, we are proposing to amend references to the ''effective date of approval'' and the date the approval of a 505(b)(2) application or ANDA ''becomes effective'' to simply refer to the date the 505(b)(2) application or ANDA ''is approved.'' The current text incorrectly suggests that FDA might issue an approval letter that would become effective at some date in the future. The proposed revision clarifies that a 505(b)(2) application or ANDA is not approved until the date the Agency issues its approval letter.

II.M.2. Effect of Patent(s) on the Listed Drug (Proposed § 314.107(b))

We are proposing to revise the introduction to proposed § 314.107(b) to clarify that an analysis is required for each relevant patent to determine the effect of one or more patents listed for the listed drug(s) relied upon or the RLD on the date of approval of a 505(b)(2) application or ANDA, respectively. For each relevant patent, the patent certification or statement submitted by the 505(b)(2) or ANDA applicant is reviewed to determine the first possible date of approval based upon each patent. The 505(b)(2) application or ANDA may be approved on the last applicable date for all relevant patents. This approach to the evaluation of multiple patent certifications is described in current § 314.107(b)(4), which is proposed for deletion because the substance of that paragraph is in proposed § 314.107(b).

II.M.2.a. *Timing of approval based on patent certification or statement* (proposed § 314.107(b)(1)). We are proposing to amend § 314.107(b)(1) to describe, in a more comprehensive manner, the timing of approval of a 505(b)(2) application or ANDA based on the patent certification(s) or statement(s) submitted by the 505(b)(2) or ANDA applicant. As explained in proposed § 314.107(b)(1), the timing of approval based on an analysis of an applicant's patent certification(s) or statement(s) is directed to a 505(b)(2) application or ANDA that is otherwise eligible for approval. A 505(b)(2) application or ANDA is otherwise eligible for approval if none of the reasons in § 314.125 or § 314.127 for refusing to approve the 505(b)(2) application or ANDA applies, and if no delay is required by the exclusivity provisions of § 314.108, § 316.31, or section 505A of the FD&C Act (see section II.I).

In proposed § 314.107(b)(1)(i) and (b)(1)(ii), we describe the types of patent certifications or statements that would result in an immediate first possible date of approval of a 505(b)(2) application or ANDA that is otherwise eligible for approval. Proposed § 314.107(b)(1)(i) reflects a reorganization of the current regulation and not a substantive revision. Current § 314.107(b)(i) through (b)(iv) are redesignated as proposed § 314.107(b)(1)(i)(A) through (b)(1)(i)(D). We have proposed to move the phrase ''except as provided in paragraphs (b)(3) and (c)'' from the introduction to current § 314.107(b)(1) to § 314.107(b)(1)(i)(C) to more closely associate this very important and common exception to an immediate date of approval with the paragraph that describes a paragraph IV certification. In addition, we are proposing to clarify that a 505(b)(2) application or ANDA containing a paragraph IV certification may be approved immediately only if the 45-day period provided for in section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act has expired.

We are proposing to revise § 314.107(b)(1)(ii) (the current text of which is proposed for incorporation into § 314.107(b)(1)(i)) to clarify that an appropriate statement under § 314.50(i)(1)(iii) or § 314.94(a)(12)(iii) also could result in an ''immediate'' first possible date of approval. This proposed revision addresses an omission in the current regulations. A 505(b)(2) or ANDA applicant may submit a statement under § 314.50(i)(1)(iii) or § 314.94(a)(12)(iii), respectively, explaining that a method-of-use patent does not claim an indication or other condition of use for which the applicant is seeking approval (see section 505(b)(2)(B) and (j)(2)(A)(viii) of the FD&C Act). If the patent only claims the method of use for which the 505(b)(2) or ANDA applicant submitted a statement under § 314.50(i)(1)(iii) or § 314.94(a)(12)(iii), respectively, then a 505(b)(2) application or ANDA otherwise eligible for approval may be approved immediately.

As described in section II.B.1.a, a listed patent may claim the drug substance and/or drug product in addition to one or more methods of use, and a 505(b)(2) or ANDA applicant could submit a statement under § 314.50(i)(1)(iii) or § 314.94(a)(12)(iii) with respect to one or more methods of use and a paragraph IV certification with respect to the remaining drug substance and/or drug product claims and/or any additional methods of use. In this scenario, the applicant's paragraph IV certification and statement under § 314.50(i)(1)(iii) or § 314.94(a)(12)(iii) to the patent would be analyzed in accordance with proposed § 314.107(b)(1)(i)(C) and (b)(1)(ii) to determine whether the first possible date of approval for the 505(b)(2) application or ANDA based on this patent is ''immediately'' or whether

the exceptions described in § 314.107(b)(3) and (c) apply with respect to the paragraph IV certification. Approval of a 505(b)(2) application or ANDA that contains a statement under § 314.50(i)(1)(iii) or § 314.94(a)(12)(iii) with respect to one or more methods of use and a paragraph IV certification with respect to the remaining patent claims may be subject to a 30-month stay (or 7½ years where applicable) if patent infringement litigation is initiated within the statutory timeframe with respect to the patent claims that were the subject of the paragraph IV certification (see § 314.107(b)(3)). It should be noted that if the paragraph IV certification that gave rise to the 30-month stay (or 7½ years where applicable) is subsequently amended to a statement under § 314.50(i)(1)(iii) or § 314.94(a)(12)(iii) with respect to one or more methods of use, the 30-month stay (or 7½ years where applicable) will not be terminated in the absence of a qualifying event under § 314.107(b)(3).

We are proposing to move § 314.107(b)(2) regarding paragraph III certifications, which delay approval until the date on which the patent will expire, to proposed § 314.107(b)(1)(iii) for organizational convenience. An analysis of the effect of patents on the timing of approval of a 505(b)(2) application or ANDA is made when the 505(b)(2) application or ANDA is otherwise eligible for approval.

II.M.2.b. *Patent information filed after submission of 505(b)(2) application or ANDA* (proposed § 314.107(b)(2)). We are proposing to revise § 314.107(b)(2) (redesignated as proposed § 314.107(b)(1)(iii)) to clarify the effect of patent information filed after submission of a 505(b)(2) application or ANDA on the date of approval of a 505(b)(2) application or ANDA. If an NDA holder submits patent information for a listed drug after the date on which a 505(b)(2) application or ANDA relying upon such drug was submitted to FDA, the 505(b)(2) or ANDA applicant must comply with the requirements of §§ 314.50(i)(4) and (i)(6) and 314.94(a)(12)(vi) and (a)(12)(viii) regarding amendment of its patent certification or statement (see section II.E.4). Thus, if the patent information was timely filed by the NDA holder under § 314.53(d)(3), the 505(b)(2) or ANDA applicant would be required to amend its patent certification or statement for the listed drug relied upon or RLD, respectively, to address the newly listed patent. (A 505(b)(2) or ANDA applicant whose pending application did not contain an appropriate patent certification at the time of submission would be required to submit a patent certification or statement to the newly listed patent even if such patent information was filed by the NDA holder more than 30 days after patent issuance (*i.e.,* untimely filed).)

If the 505(b)(2) or ANDA applicant submits an amendment containing a paragraph IV certification to the newly listed patent, proposed § 314.107(b)(2) clarifies that the 505(b)(2) application or ANDA may be approved immediately upon the submission of an amendment containing documentation that the NDA holder and each patent owner have received notice of paragraph IV certification under § 314.52(e) or § 314.95(e). There is no need to delay approval until the expiration of the 45-day period provided for in section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act. Even if the NDA holder or patent owner initiated patent infringement litigation within the 45-day period after receipt of notice of paragraph IV certification, a 30-month stay of approval would not be available in connection with a paragraph IV certification to a patent submitted after a 505(b)(2) application or ANDA had been submitted to FDA (see section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act).

Although a 30-month stay of approval is not available in these circumstances, a 505(b)(2) or ANDA applicant still must comply with the requirements for provision of notice of paragraph IV certification described in section 505(b)(3) and (j)(2)(B) of the FD&C Act and §§ 314.52 and 314.95. An NDA holder or patent owner may assert a claim of patent infringement against the 505(b)(2) or ANDA applicant in response to the notice of paragraph IV certification and may seek injunctive relief during the pendency of the litigation despite the absence of a 30-month stay. Notice of paragraph IV certification in accordance with applicable regulations also is necessary for an ANDA applicant to be eligible for 180-day exclusivity based upon a paragraph IV certification to a newly listed patent (see section II.D.1).

II.M.2.c. *Disposition of patent litigation* (proposed § 314.107(b)(3)).

II.M.2.c.i. *Approval upon expiration of 30-month stay or 7½ years from date of reference product approval* (proposed § 314.107(b)(3)(i)). We are proposing to revise § 314.107(b)(3)(i)(A) to reflect one of the central elements of the MMA's amendments to the FD&C Act: The limitation on multiple 30-month stays of approval of a 505(b)(2) application or an ANDA containing a paragraph IV certification to certain patents submitted to FDA on or after August 18, 2003. Proposed § 314.107(b)(3)(i)(A) states that a 30-month stay of approval is available only when the patent owner or exclusive patent licensee initiates a patent infringement action within the statutory timeframe in response to a paragraph IV certification to a patent submitted to FDA before the date on which the original 505(b)(2) application or ANDA was submitted. As discussed in section II.E, the MMA expressly provides that, for purposes of determining the availability of a 30-month stay, the date of submission of a 505(b)(2) application or ANDA does not include the date of submission of an amendment or supplement to the 505(b)(2) application or ANDA (see section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act). In other words, there will be no possibility of a 30-month stay with respect to an action for infringement of a patent listed after the reference product is approved if the patent was submitted to FDA on or after the date the 505(b)(2) application or ANDA was first submitted. Due to this limitation, most 505(b)(2) applications and ANDAs will be subject to no more than one 30-month stay of approval.

Multiple 30-month stays, however, still may be possible in certain cases. For example, an original 505(b)(2) application or ANDA may contain a paragraph IV certification to a patent that results in a 30-month stay of approval. If the same application also contains a paragraph III certification to a different patent that was submitted to FDA on or after August 18, 2003, and before the 505(b)(2) application or ANDA was submitted, and the applicant subsequently amends the paragraph III certification to a paragraph IV certification, a second 30-month stay would be possible. Two 30-month stays are possible in this example because the challenged patents that gave rise to sequential actions for patent infringement were both submitted to FDA before submission of the original 505(b)(2) application or ANDA. It should be noted that the relevant benchmark for determining whether a patent was submitted by the NDA holder prior to submission of an original 505(b)(2) application or prior to submission of an ANDA later determined to be substantially complete is the date of submission of the patent to FDA and not the date on which the patent information is published in the Orange Book (see § 314.53(d)(5)). We note, however, that if the original submission of an ANDA is not determined to be substantially complete (*i.e.,* FDA refuses to receive the ANDA under § 314.101), then the relevant

benchmark is the date of the ANDA amendment that results in a subsequent determination that the ANDA is substantially complete.

We also are proposing to revise § 314.107(b)(3)(i) to clarify that a 30-month stay of approval begins on the later of the date of receipt of the notice of paragraph IV certification by any owner of the listed patent or by the NDA holder who is an exclusive patent licensee (or their representatives). This proposed revision codifies our current practice and provides an administratively efficient means of ensuring that each patent owner or NDA holder that is entitled to receive notice of paragraph IV certification receives the full statutory 30-month stay of approval should one of these parties initiate patent infringement litigation within 45 days of its receipt of notice. Even if a patent infringement action was initiated within 45 days of receipt of notice of paragraph IV certification by the first of two intended recipients, the 30-month stay of approval would begin on the later of the dates of receipt of notice of paragraph IV certification by any owner of the listed patent or by the NDA holder.

Finally, we are proposing to revise § 314.107(b)(3) to supplement the list that describes different scenarios related to the timing of approval of a 505(b)(2) application or ANDA containing a paragraph IV certification that was the subject of patent litigation. Many of our proposed additions to the § 314.107(b) list reflect corresponding MMA amendments to section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act (see sections II.M.3.e to II.M.3.h). It should be noted that we are not proposing revisions to § 314.107(b)(3) to describe the date on which a 505(b)(2) application or ANDA may be approved when a 30-month stay relates to a patent to which pediatric exclusivity has attached (see section 505A of the FD&C Act). However, a period of pediatric exclusivity under section 505A of the FD&C Act may affect the approval date of a 505(b)(2) application or ANDA in the circumstances described in § 314.107(b)(3).

II.M.2.c.ii. *Federal district court decision of invalidity, unenforceability, or non infringement* (proposed § 314.107(b)(3)(ii)). The MMA amended section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act for 505(b)(2) applications and ANDAs, respectively, to clarify the type of court decision in patent litigation that will terminate a 30-month stay (or 7½ years where applicable) and lead to approval of a 505(b)(2) application or ANDA that is otherwise eligible for approval. Prior to the MMA, FDA interpreted the reference to a court decision in section 505(c)(3)(C)(i) and (j)(5)(B)(iii)(I) of the FD&C Act to mean ''the court that enters final judgment from which no appeal can be or has been taken'' (see guidance for industry entitled ''Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act'' (March 2000), available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072868.pdf*) (superseded Guidance on Court Decisions). The MMA amended the FD&C Act to codify the types of Federal district court decisions and, as discussed in section II.M.2.c.iii to II.M.2.c.iv, the types of Federal appellate court decisions that will terminate a 30-month stay (or 7½ years where applicable). Accordingly, FDA is not required to delay approval of an otherwise approvable ANDA until there has been a court decision from which no appeal can be or has been taken.

The MMA amended section 505(c)(3)(C)(i) and (j)(5)(B)(iii)(I) of the FD&C Act to describe the Federal district court decisions in patent litigation that will terminate a 30-month stay (or 7½ years where applicable) and lead to approval of a 505(b)(2) application or ANDA that is otherwise eligible for approval (see *Sanofi-Aventis* v. *FDA,* 643 F.Supp.2d 82, 86 (D.D.C.), *inj. denied,* 2009 U.S. Dist. LEXIS 74578 (D.D.C. 2009) (''The plain language of the entry of judgment provision of the Hatch-Waxman Act is clear that the FDA's approval of a generic application 'shall be made effective on the . . . date on which the court *enters* judgment' '' irrespective of whether the enforceability of that judgment is stayed) (emphasis in original)). We are proposing to revise § 314.107(b)(3)(ii) to reflect these statutory revisions that change the decisive event from court issuance of a final order that the patent is invalid, unenforceable, or not infringed to a district court's entry of judgment pursuant to Federal Rule of Civil Procedure (Fed. R. Civ. P.) Rule 58 that the patent is invalid, unenforceable, or not infringed. As with current § 314.107(b)(3)(ii), we are proposing to implement section 505(c)(3)(C)(i) and (j)(5)(B)(iii)(I) of the FD&C Act to include a court decision that the applicable patent is unenforceable. Thus, a Federal district court's entry of judgment that a patent has been infringed by the 505(b)(2) or ANDA applicant but is unenforceable (for example, due to inequitable conduct in patent prosecution) would terminate a 30-month stay (or 7½ years where applicable). Consistent with section 505(c)(3)(C)(i) and (j)(5)(B)(iii)(I) of the FD&C Act, proposed § 314.107(b)(3)(ii) also includes cases in which a Federal district court has made a substantive determination that there is no cause of action for patent infringement or invalidity.

We are proposing to further revise § 314.107(b)(3)(ii) to incorporate the text of section 505(c)(3)(C)(i) and (j)(5)(B)(iii)(I) of the FD&C Act, as amended by the MMA, regarding the timing of approval of a 505(b)(2) application or ANDA in relation to the district court decision. Proposed § 314.107(b)(3)(ii) provides that in cases in which a district court decides that the patent is invalid, unenforceable, or not infringed, the 505(b)(2) application or ANDA may be approved on the date on which the court enters judgment reflecting the decision (paragraph (A)); or the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed (paragraph (B)).

II.M.2.c.iii. *Appeal of Federal district court judgment of infringement* (proposed § 314.107(b)(3)(iii)). The MMA amended section 505(c)(3)(C)(ii) and (j)(5)(B)(iii)(II) of the FD&C Act for 505(b)(2) applications and ANDAs, respectively, to describe the earliest date on which a 30-month stay (or 7½ years where applicable) can be terminated after a Federal district court has decided that the patent has been infringed based on whether the judgment is appealed. We are proposing to revise § 314.107(b)(3)(iii) and, as discussed in section II.M.2.c.iv, § 314.107(b)(3)(iv) to reflect these statutory revisions.

Proposed § 314.107(b)(3)(iii) states that if the Federal district court decides that the patent has been infringed and the district court judgment is appealed, the 505(b)(2) application or ANDA may be approved on the date on which the mandate is issued by the court of appeals entering judgment that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity) (paragraph (A)); or the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed (paragraph (B)). Proposed § 314.107(b)(3)(iii) restates the text of section 505(c)(3)(C)(ii) and (j)(5)(B)(iii)(II) of the FD&C Act except that we are proposing to further specify that the date of the court of appeals decision is the date on which the

mandate is issued by the court of appeals (see Federal Rule of Appellate Procedure Rule 41). This proposal reflects the Agency's current practice in implementing section 505(c)(3)(C)(ii) and (j)(5)(B)(iii)(II) of the FD&C Act, which recognizes that a party may request rehearing by the appellate panel or rehearing en banc. In such circumstances, it would be premature to terminate the 30-month stay and possibly approve the 505(b)(2) application or ANDA while a decision regarding patent noninfringement, invalidity, or unenforceability was being reheard by the court of appeals. By interpreting the ''date on which the court of appeals decides that the patent is invalid or not infringed'' (see section 505(c)(3)(C)(ii) and (j)(5)(B)(iii)(II) of the FD&C Act) to mean the date on which the mandate issues, we are ensuring that the Agency's action reflects the judgment of the court of appeals. We seek comment on this interpretation.

II.M.2.c.iv. *Affirmation or non-appeal of Federal district court judgment of infringement* (proposed § 314.107(b)(3)(iv)). The MMA amended section 505(c)(3)(C)(ii)(II) and (j)(5)(B)(iii)(II)(bb) of the FD&C Act to describe the timing of approval of a 505(b)(2) application or ANDA, respectively, that a Federal district court has decided infringes a patent that was the subject of a paragraph IV certification if the district court decision was not appealed or was affirmed on appeal. In such a case, section 505(c)(3)(C)(ii)(II) and (j)(5)(B)(iii)(II)(bb) of the FD&C Act provide that the 505(b)(2) application or ANDA will be approved on the date specified by the district court in an order under 35 U.S.C. 271(e)(4)(A). We are proposing to revise § 314.107(b)(3)(iv) to reflect these statutory revisions with certain clarifications.

Proposed § 314.107(b)(3)(iv) provides that if the district court decides that the patent at issue is infringed and this judgment is not appealed or is affirmed on appeal, the 505(b)(2) application or ANDA may be approved *no earlier than* the date specified by the district court in an order under 35 U.S.C. 271(e)(4)(A). Although the date specified by the district court order would not be earlier than the date of expiration of the infringed patent (see 35 U.S.C. 271(e)(4)(A)), the date specified by the order may not take into account any other unexpired patents or unexpired exclusivity (or deficiencies in the application) that would delay approval of the 505(b)(2) application or ANDA beyond the date of expiration of the infringed patent. Therefore, proposed § 314.107(b)(3)(iv) states that the 505(b)(2) application or ANDA may be approved no earlier than the date specified in a district court's order under 35 U.S.C. 271(e)(4)(A), rather than using the statutory phrasing that the ''approval shall be made effective on the date'' specified by such order (see section 505(c)(3)(C)(ii)(II) and (j)(5)(B)(iii)(II)(bb) of the FD&C Act and section II.I regarding removal of references to the effective date of approval).

II.M.2.c.v. *Grant of preliminary injunction by Federal district court* (proposed § 314.107(b)(3)(v)). The MMA amended section 505(c)(3)(C)(iii), (c)(3)(C)(iv), (j)(5)(B)(iii)(III), and (j)(5)(B)(iii)(IV) of the FD&C Act to clarify that the timing of approval of a 505(b)(2) application or ANDA, respectively, is subject to provisions of section 505(c)(3)(C)(i), (c)(3)(C)(ii), (j)(5)(B)(iii)(I), and (j)(5)(B)(iii)(II) even if preceded by a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement. We are proposing to revise current § 314.107(b)(3)(iv) (redesignated as proposed § 314.107(b)(3)(v)) to reflect these statutory revisions. Proposed § 314.107(b)(3)(v) cross-references the applicable paragraph of § 314.107(b)(3) that would address the timing of approval of the 505(b)(2) application or ANDA based on the court's decision with respect to patent validity and infringement. If a preliminary injunction is entered before the expiration of the 30-month stay, FDA interprets section 505(j)(5)(B)(iii) of the FD&C Act to require that the stay of approval is extended until the court decides the issues of patent infringement and validity. Once such a decision is made, the references to section 505(j)(5)(B)(iii)(I) and (j)(5)(B)(iii)(II) of the FD&C Act provide for the timing of approval (see section 505(j)(5)(B)(iii)(III) and (j)(5)(B)(iii)(IV) of the FD&C Act). We seek comment on this approach.

In addition, proposed § 314.107(b)(3)(v) makes clear that the court that grants a preliminary injunction pending a decision on the issues of patent validity and infringement refers to the Federal district court hearing the patent infringement action.

II.M.2.c.vi. *Written consent to approval by patent owner or exclusive patent licensee* (proposed § 314.107(b)(3)(vi)). We are proposing to add § 314.107(b)(3)(vi) to clarify that if the patent owner or exclusive patent licensee (or their representatives) agrees in writing that the 505(b)(2) application or ANDA application may be approved, the 30-month stay (or 7½ years where applicable) will be terminated and the approval may be granted on or after the date of the consent. Thus, proposed § 314.107(b)(3)(vi) would permit termination of the 30-month stay (or 7½ years where applicable) without a court order. This scenario may arise, for example, if settlement of the patent litigation results in a license to the 505(b)(2) or ANDA applicant.

II.M.2.c.vii. *Court order terminating 30-month or 7½-year period* (proposed § 314.107(b)(3)(vii)). We are proposing to add § 314.107(b)(3)(vii) to clarify that if a court enters an order requiring the termination of the 30-month stay (or 7½ years where applicable), the 505(b)(2) application or ANDA, if otherwise ready for approval, may be approved in accordance with the court order.

II.M.2.c.viii. *Court order of dismissal without a finding of infringement* (proposed § 314.107(b)(3)(viii)). The MMA's amendments to section 505(c)(3)(C)(i), (c)(3)(C)(ii), (j)(5)(B)(iii)(I), and (j)(5)(B)(iii)(II) of the FD&C Act clarify the timing of approval of a 505(b)(2) application or ANDA, respectively, in relation to a settlement order or consent decree stating that the patent that is the subject of the paragraph IV certification is invalid or not infringed. However, the statute does not address whether a 30-month stay may be terminated and a 505(b)(2) application or ANDA approved if the court enters an order of dismissal without a finding of patent infringement—a scenario that FDA encounters frequently. We are proposing to add § 314.107(b)(3)(viii) to codify FDA's policy that court entry of an order of dismissal, with or without prejudice, of patent infringement litigation that was timely initiated in response to notice of a paragraph IV certification will terminate the 30-month period (or 7½ years where applicable) if such order does not state a finding of patent infringement. It is appropriate that a 30-month stay terminates under these circumstances because the statutory purpose of the stay is to allow time for claims of patent infringement to be litigated prior to approval of the potentially infringing drug product. If the patent owner or exclusive patent licensee dismisses the patent infringement action on terms that the court considers proper (see Fed. R. Civ. P. Rule 41(a)(2)), then there should be no further delay of approval of a 505(b)(2) application or ANDA otherwise eligible for approval.

II.M.2.d. *Tentative approval* (proposed § 314.107(b)(4)). We are

proposing to redesignate current § 314.107(b)(3)(v) as proposed § 314.107(b)(4) for organizational convenience. Proposed § 314.107(b)(4) describes tentative approval of a 505(b)(2) application or ANDA as appropriate in accordance with § 314.107(b)(3). In addition, we are proposing to revise § 314.107(b)(4) to state that FDA will issue a tentative approval letter when tentative approval is appropriate in accordance with a court order pursuant to 35 U.S.C. 271(e)(4)(A) that a 505(b)(2) application or ANDA may be approved no earlier than the date specified, irrespective of whether the injunction relates to a patent described in § 314.107(b)(3) (see proposed § 314.107(e)(1)(vi)). This proposed revision is intended to complement proposed § 314.107(g), which clarifies that if a court enters an order requiring that the date of approval be delayed for an already approved 505(b)(2) application or ANDA, FDA will convert the approval to a tentative approval, if appropriate. This scenario may occur, for example, if a patent infringement action is initiated after the 45-day period described in section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act and results in a judgment of patent infringement. Proposed § 314.107(b)(4) would expressly describe FDA's practice of giving effect to the court order under 35 U.S.C. 271(e)(4)(A), irrespective of whether the order relates to a patent associated with a 30-month stay of approval (see, *e.g., Mylan Labs., Inc.* v. *Thompson,* 389 F.3d 1272 (D.C. Cir. 2004)).

We also are proposing to amend references to ''receiv[ing] final approval'' and making an approval ''effective'' to refer instead to receipt of an approval letter (see sections II.A.2.dd and II.I).

II.M.3. Subsequent ANDA Submission (Proposed § 314.107(c))

Section 1102 of the MMA amended section 505(j)(5) of the FD&C Act to modify the conditions under which a 180-day period of exclusivity is granted and to establish conditions under which a first applicant would forfeit the 180-day exclusivity period. As noted in section I.D, we are currently implementing the 180-day exclusivity provisions of the MMA directly from the statute and will determine if additional rulemaking is necessary in the future. At this time, we are proposing to revise § 314.107(c) to remove provisions that have been superseded by the statute, as revised by the MMA, and to generally conform with the statute.

Table 13 summarizes the proposed changes related to submission of an ANDA containing a paragraph IV certification by a subsequent ANDA applicant.

TABLE 13—HIGHLIGHTS OF PROPOSED CHANGES REGARDING SUBSEQUENT ANDA SUBMISSION [1]

Current regulations	Proposed revisions to regulations
Subsequent ANDA submission (§ 314.107(c)(1),(3)) • If an ANDA contains a paragraph IV certification and the ANDA is for a generic copy of the same listed drug for which one or more substantially complete ANDAs were previously submitted containing a paragraph IV certification to the same patent, approval of the subsequent ANDA will be made effective no sooner than 180 days from whichever of the following dates is earlier: —(i) The date the applicant submitting the first application first commences commercial marketing of its drug product; or —(ii) The date of a decision of the court holding the relevant patent invalid, unenforceable, or not infringed. • For purposes of § 314.107(c)(1), if FDA concludes that the applicant submitting the first ANDA is not actively pursuing approval, FDA will make the approval of subsequent ANDAs immediately effective if they are otherwise eligible for an immediately effective approval.	*Subsequent ANDA submission (§ 314.107(c)(1))* • If an ANDA contains a paragraph IV certification for a relevant patent and the ANDA is not that of a first applicant, the ANDA is regarded as that of a subsequent applicant. • The ANDA of a subsequent applicant will not be approved during the period when any first applicant for the drug product is eligible for 180-day exclusivity or during the 180-day exclusivity period of a first applicant. • Any applicable 180-day exclusivity period can not extend beyond the expiration of the patent upon which the 180-day exclusivity period was based.
Subsequent ANDA submission (§ 314.107(c)(2)) • For purposes of § 314.107(c)(1), the 'applicant submitting the first application' is the applicant that submits an ANDA that is both substantially complete and contains a certification that the patent was invalid, unenforceable, or not infringed prior to the submission of any other application for the same listed drug that is both substantially complete and contains the same certification. • A 'substantially complete' application must contain the results of any required bioequivalence studies, or, if applicable, a request for a waiver of such studies.	*Definitions (§ 314.3(b))* • *First applicant* is an applicant that, on the first day on which a substantially complete ANDA containing a paragraph IV certification is submitted for approval of a drug, submits a substantially complete ANDA that contains, and for which the applicant lawfully maintains, a paragraph IV certification for the drug. • *Substantially complete application* is an ANDA that on its face is sufficiently complete to permit a substantive review and contains all the information required under section 505(j)(2)(A) of the FD&C Act and § 314.94.
Subsequent ANDA submission (§ 314.107(c)(4)) • For purposes of § 314.107(c)(1)(i), the applicant submitting the first ANDA shall notify FDA of the date that it commences commercial marketing of its drug product. • If an applicant does not promptly notify FDA of such date, the effective date of approval shall be deemed to be the date of the commencement of first commercial marketing. • Commercial marketing commences with the first date of introduction or delivery for introduction into interstate commerce outside the control of the manufacturer of a drug product, except for investigational use under part 312 of this chapter, but does not include transfer of the drug product for reasons other than sale within the control of the manufacturer or application holder.	*Subsequent ANDA submission (§ 314.107(c)(2))* • For purposes of § 314.107(c)(1), a first applicant must submit a supplement to its ANDA notifying FDA within 30 days of the date of first commercial marketing of its drug product. • If an applicant does not notify FDA, as required above, of this date, the date of first commercial marketing will be deemed to be the date of the drug product's approval. *Definitions (§ 314.3(b))* • *Commercial marketing* is the introduction or delivery for introduction into interstate commerce of a drug product described in an approved ANDA, outside the control of the ANDA holder, except for investigational use under part 312 of this chapter, but does not include transfer of the drug product for reasons other than sale to parties identified in the approved ANDA.

[1] These highlights describe important proposed revisions to our regulations, but should not be relied upon in place of the proposed regulation.

We are proposing to revise § 314.107(c)(1) to incorporate the term ''first applicant,'' as defined by section 505(j)(5)(B)(iv)(II)(bb) of the FD&C Act and in proposed § 314.3(b) (see section II.A.2.q), and to distinguish a ''first applicant'' from a ''subsequent applicant.'' An ANDA has been submitted by a subsequent applicant if the ANDA has not been submitted by a first applicant and contains a paragraph IV certification to a relevant patent that has been listed for the drug product for which a first applicant has submitted an ANDA. A subsequent applicant's ANDA will not be approved during the period when any first applicant for the drug product is eligible for 180-day exclusivity or during the 180-day exclusivity period of a first applicant (see section 505(j)(5)(B)(iv)(I) of the FD&C Act). By including the period during which any first applicant is eligible for 180-day exclusivity, proposed § 314.107(c)(1) clarifies that a subsequent ANDA for the drug product may not be approved while a first applicant is eligible for 180-day exclusivity as long as a forfeiture event has not occurred with respect to that first applicant (see section 505(j)(2)(D)(ii) of the FD&C Act). These proposed revisions replace the current text of § 314.107(c)(1), superseded by statute, which describe a patent-by-patent analysis to determine eligibility for 180-day exclusivity and events that would trigger the start of the 180-day period under the pre-MMA statutory scheme.

We are proposing to delete the definition of the ''applicant submitting the first application'' in current § 314.107(c)(2) because it has been superseded by the statutory definition added by the MMA. We are proposing to incorporate the MMA's definition of the term ''first applicant,'' with minor editorial changes and additional clarifying text, into § 314.3(b) (see section 505(j)(5)(B)(iv)(II)(bb) of the FD&C Act and section II.A.2.q). We also are proposing to delete § 314.107(c)(3), which described the potential consequences of a first applicant's failure to actively pursue approval of its ANDA because this regulation has been superseded by the statutory provisions that specify events that will result in forfeiture of the 180-day exclusivity period by a first applicant (see section 505(j)(5)(D) of the FD&C Act).

The MMA amended the FD&C Act to modify the types of events that can trigger the start of the 180-day exclusivity period for a first applicant (see section 505(j)(5)(B)(iv)(I) of the FD&C Act; see also section 1102(b)(3) of the MMA). Section 505(j)(5)(B)(iv)(I) of the FD&C Act provides that the period of 180-day exclusivity will begin on the ''date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.'' This commercial marketing trigger differs from the version of section 505(j)(5)(B)(iv)(I) in effect prior to enactment of the MMA, which provided that the 180-day exclusivity period will begin on the earlier of two events, one of which was the date the Secretary receives notice from the applicant of the first commercial marketing of the drug eligible for 180-day exclusivity. We are proposing to revise § 314.107(c)(4) to conform with these changes to the FD&C Act and redesignate this provision as § 314.107(c)(2) (''redesignated § 314.107(c)(2)'').

In light of the change in the commercial marketing trigger from the date on which FDA receives notice from the applicant of the first commercial marketing to the date of the first commercial marketing of the drug, we are proposing to revise redesignated § 314.107(c)(2) to require a first applicant to submit correspondence to its ANDA notifying FDA within 30 days of the date of first commercial marketing of the drug product (see current § 314.107(c)(4)). This proposal to require notification within 30 days of the date of first commercial marketing is intended to facilitate the efficient enforcement of the FD&C Act and provide adequate notice to subsequent applicants that have received tentative approval and are awaiting expiration of the period of 180-day exclusivity. If the first applicant does not notify FDA within this timeframe, we are proposing to deem the date of first commercial marketing to be the date of the drug product's approval. This may have the effect of shortening the 180-day period of exclusivity in a manner similar to current § 314.107(c)(4).

We also are proposing to revise redesignated § 314.107(c)(2) to remove the description of ''commercial marketing.'' As explained in section II.A.2.*l,* we are proposing to define ''commercial marketing'' in § 314.3(b) with certain modifications, as compared to current § 314.107(c)(4), to the scope of the exclusion for transfer of the drug product for reasons other than sale.

II.M.4. Delay of Approval Due to Exclusivity (Proposed § 314.107(d))

We are proposing to revise § 314.107(d) to clarify that approval of a 505(b)(2) application or ANDA may be delayed by orphan drug exclusivity and pediatric exclusivity in addition to the exclusivities described in § 314.108. Proposed § 314.107(d) explains that when approval of a 505(b)(2) application or ANDA is delayed under § 314.107 and § 314.108, 21 CFR 316.31 (orphan drug exclusivity), or section 505A of the FD&C Act (pediatric exclusivity), the 505(b)(2) application or ANDA will be approved on the latest of the dates specified under these provisions. We also have made conforming revisions to proposed § 314.107(d) that are described elsewhere in section II.M.

II.M.5. Notification of Court Actions or Documented Agreement (Proposed § 314.107(e))

We are proposing to revise § 314.107(e) to expand the scope of documentation that an applicant must submit to FDA regarding court actions and settlements related to patents. These changes are intended to ensure that FDA is promptly advised of court actions and documented agreements that may affect the timing of approval of a 505(b)(2) application or ANDA for the efficient administration of the FD&C Act. FDA does not have the resources to monitor the numerous court actions that are pending at any given time which may affect the date of approval of a 505(b)(2) application or ANDA that is otherwise eligible for approval.

Table 14 summarizes the proposed changes related to notification of court actions or documented agreements.

TABLE 14—HIGHLIGHTS OF PROPOSED CHANGES REGARDING NOTIFICATION OF COURT ACTIONS OR DOCUMENTED AGREEMENTS[1]

Current regulations	Proposed revisions to regulations
Notification of court actions (§ 314.107(e))	*Notification of court actions or documented agreements (§ 314.107(e)(1) and (e)(2))*

TABLE 14—HIGHLIGHTS OF PROPOSED CHANGES REGARDING NOTIFICATION OF COURT ACTIONS OR DOCUMENTED AGREEMENTS[1]—Continued

Current regulations	Proposed revisions to regulations
• Applicant must submit a copy of the entry of the order or judgment to the Office of Generic Drugs or to the appropriate division in the Office of New Drugs, as applicable, within 10 working days of a final judgment.	• Applicant must submit the following information to FDA, as applicable: —a copy of any judgment by the court (district court or mandate of the court of appeals) or settlement order or consent decree signed and entered by the court (district court or court of appeals) finding a patent described in § 314.107(b)(3) invalid, unenforceable, or not infringed, or finding the patent valid and infringed, and written notification of whether any such court action has been appealed; —A copy of any order entered by the court terminating the 30-month or 7½-year period described in § 314.107(b)(3)(i) and (b)(3)(ii); —A copy of any documented agreement described in § 314.107(b)(3)(vi); —A copy of any preliminary injunction described in § 314.107(b)(3)(v), and a copy of any subsequent court order lifting the injunction; and —A copy of any court order pursuant to 35 U.S.C. 271(e)(4)(A) ordering that a 505(b)(2) application or ANDA may be approved no earlier than the date specified (irrespective of whether the injunction relates to a patent described in § 314.107(b)(3)). • All required information must be sent to the Office of Generic Drugs or to the appropriate division in the Office of New Drugs, as applicable, within 14 days of: —the date of entry by the court, —the date of appeal or expiration of the time for appeal, or —the date of documented agreement, as applicable.

[1] These highlights describe important proposed revisions to our regulations, but should not be relied upon in place of the proposed regulation.

Proposed § 314.107(e)(1)(i) would require a 505(b)(2) or ANDA applicant to submit a copy of any judgment by the court (district court or mandate of the court of appeals) finding a patent described in § 314.107(b)(3) invalid, unenforceable, or not infringed, or finding the patent valid and infringed. This proposed requirement imposes a duty on 505(b)(2) and ANDA applicants to notify FDA regarding any court judgment regardless of whether or not the action for patent infringement has resulted in a substantive determination by the court regarding validity, enforceability, and/or infringement of the patent.

In addition, we are proposing to require 505(b)(2) and ANDA applicants to submit to FDA a copy of certain documented agreements and court actions other than judgments to facilitate FDA's administration of the FD&C Act. Proposed § 314.107(e)(1)(i) would require a 505(b)(2) or ANDA applicant to submit a copy of a settlement order or consent decree signed and entered by the court (district court or court of appeals) finding a patent described in proposed § 314.107(b)(3) invalid, unenforceable, or not infringed, or finding the patent valid and infringed. It should be noted that this proposal would require submission of written documentation that the parties have entered into a settlement that has terminated the patent infringement litigation, but does not require applicants to send copies of the actual settlement agreement to FDA (compare section 1112 of the MMA (requiring that generic drug applicants file certain agreements with the FTC)). Proposed § 314.107(e)(1)(ii) would require a 505(b)(2) or ANDA applicant to submit written notification of whether or not any action by the court described in § 314.107(e)(1)(i) has been appealed within the time permitted for an appeal. Proposed § 314.107(e)(1)(iii) and (e)(1)(iv) would require a 505(b)(2) or ANDA applicant to submit a copy of any order entered by the court terminating the 30-month or 7½-year period described in proposed § 314.107(b)(3)(i) and (b)(3)(ii), and any documented agreement described in proposed § 314.107(b)(3)(vi). Proposed § 314.107(e)(1)(v) would require a 505(b)(2) or ANDA applicant to submit a copy of any preliminary injunction described in § 314.107(b)(3)(v), and a copy of any subsequent court order lifting the injunction. Proposed § 314.107(e)(1)(vi) would require a 505(b)(2) or ANDA applicant to submit a copy of any court order pursuant to 35 U.S.C. 271(e)(4)(A) ordering that a 505(b)(2) application or ANDA may be approved no earlier than the date specified (irrespective of whether the injunction relates to a patent described in § 314.107(b)(3)). This revision is intended to conform with proposed § 314.107(b)(4) (see section II.M.2.d). These court actions and documented agreements also may affect the timing of approval of a 505(b)(2) application or ANDA and frequently are unpublished. If an applicant is unsure whether a particular court action or documented agreement requires notification to FDA under proposed § 314.107(e), we recommend submission.

We also are proposing to modify the timeframe for a 505(b)(2) or ANDA applicant to submit the required information to the appropriate division in OND or to OGD, as applicable, to ensure timely notification to FDA. Proposed § 314.107(e)(2) would require submission of all required information within 14 calendar days of entry by the court, the date of appeal or expiration of the time for appeal, or the date of written agreement, as applicable. We are proposing to change the timeframe for submission of required information from 10 working days to 14 calendar days for clarity and consistency with other counting conventions used in part 314.

II.M.6. Computation of the 45-Day Time Clock (Proposed § 314.107(f))

We are proposing to revise § 314.107(f) to clarify the computation of the 45-day period after receipt of notice of paragraph IV certification and to enhance the requirements for notifying FDA of any legal action filed

within this timeframe. Table 15 summarizes the proposed changes related to the 45-day period after receipt of notice of paragraph IV certification. We seek comment on the proposed notification requirement and alternative ways for FDA to monitor compliance with the FD&C Act.

TABLE 15—HIGHLIGHTS OF PROPOSED CHANGES REGARDING THE 45-DAY PERIOD AFTER RECEIPT OF NOTICE OF PARAGRAPH IV CERTIFICATION [1]

Current regulations	Proposed revisions to regulations
Computation of 45-day time clock (§ 314.107(f)(1)) • The 45-day clock described in § 314.107(b)(3) begins on the day after the date of receipt of the applicant's notice of certification by the patent owner or its representative, and by the approved application holder.	*Computation of 45-day time clock (§ 314.107(f)(1))* • The 45-day clock described in § 314.107(b)(3) as to each recipient required to receive notice of paragraph IV certification under §§ 314.52 or 314.95 begins on the day after the date of receipt of the applicant's notice of certification by each recipient.
Computation of 45-day time clock (§ 314.107(f)(2)) • The 505(b)(2) or ANDA applicant must notify FDA immediately of the filing of any legal action filed within 45 days of receipt of the notice of certification. • The notification to FDA of the legal action must include, among other things: (iv) A certification that an action for patent infringement identified by number, has been filed in an appropriate court on a specified date. • A patent owner or its representative may also notify FDA of the filing of any legal action for patent infringement.	*Notification of filing of legal action (§ 314.107(f)(2)(i) to (f)(2)(ii))* • The 505(b)(2) or ANDA applicant must notify FDA in writing within 14 days of the filing of any legal action filed within 45 days of receipt of the notice of certification by any recipient. • The notification to FDA of the legal action must include, among other things: (iv) A statement that an action for patent infringement, identified by the court, case number and the patent number(s) of the patent(s) at issue in the action, has been filed in an appropriate court on a specified date. • A patent owner or NDA holder (or their representatives) may also notify FDA of the filing of any legal action for patent infringement.
Computation of 45-day time clock (§ 314.107(f)(2)) • If the 505(b)(2) or ANDA applicant or the patent owner or its representative does not notify FDA in writing before the expiration of the 45-day time period or the completion of the Agency's review of the application, whichever occurs later, that a legal action for patent infringement was filed within 45 days of receipt of the notice of certification, approval of the 505(b)(2) application or ANDA will be made effective immediately upon expiration of the 45 days or upon completion of FDA's review and approval of the application, whichever is later.	*Notification of filing of legal action (§ 314.107(f)(2)(iii))* • If the 505(b)(2) or ANDA applicant, the patent owner(s), the NDA holder, or their representatives do not notify FDA in writing before the expiration of the 45-day time period or the completion of the Agency's review of the 505(b)(2) application or ANDA, whichever occurs later, that a legal action for patent infringement was filed within 45 days of receipt of the notice of paragraph IV certification, the 505(b)(2) application or ANDA may be approved upon expiration of the 45-day period (if the 505(b)(2) or ANDA applicant confirms that a legal action for patent infringement has not been filed) or upon completion of FDA's review of the 505(b)(2) application or ANDA, whichever is later.
Computation of 45-day time clock (§ 314.107(f)(3)) • If the patent owner or approved application holder who is an exclusive patent licensee waives its opportunity to file a legal action for patent infringement within 45 days of a receipt of the notice of certification and the patent owner or approved application holder who is an exclusive patent licensee submits to FDA a valid waiver before the 45 days elapse, approval of the ANDA or the 505(b)(2) application will be made effective upon completion of FDA's review and approval of the application. FDA will only accept a waiver in the form specified in § 314.107(f)(3)).	*Waiver (§ 314.107(f)(3))* • If the patent owner or NDA holder who is an exclusive patent licensee (or their representatives) waives its opportunity to file a legal action for patent infringement within 45 days of a receipt of the notice of certification and the patent owner or NDA holder who is an exclusive patent licensee (or their representatives) submits to FDA a valid waiver before the 45 days elapse, the 505(b)(2) application or ANDA may be approved upon completion of the Agency's review of the application. FDA will only accept a waiver in the form specified in § 314.107(f)(3), as proposed for revision.

[1] These highlights describe important proposed revisions to our regulations, but should not be relied upon in place of the proposed regulation.

We are proposing to revise § 314.107(f)(1) to clarify that the 45-day period after receipt of notice of paragraph IV certification is calculated for each recipient required to be notified under §§ 314.52(a) and 314.95(a). This proposed revision would codify FDA's longstanding interpretation of section 505(b)(3) and (j)(2)(B) of the FD&C Act, as amended by the MMA. This interpretation ensures that each person required to receive notice under § 314.52 or § 314.95, as applicable, also receives the full 45-day period in order to evaluate whether to initiate an action for patent infringement and obtain a 30-month (or 7½-year) stay of approval while litigation is pending. Accordingly, a 505(b)(2) or ANDA applicant's notice of paragraph IV certification may result in more than one ''45-day clock'' if the NDA holder and patent owners(s) are different entities and receive notice of paragraph IV certification on different days.

Proposed § 314.107(f)(2) would require that a 505(b)(2) or ANDA applicant notify FDA in writing within 14 calendar days of the filing of any legal action filed within 45 days of receipt of the notice of certification. We are proposing to replace the current requirement for ''immediate'' notification to establish a date certain by which the applicant must send written notification to FDA. This revision is intended to enhance compliance and conform with proposed § 314.107(e), which would require a 505(b)(2) or ANDA applicant to submit notification of court actions and documented agreements (and a copy of certain court actions) to FDA within 14 calendar days of entry by the court, the date of appeal or expiration of the time for appeal, or the date of documented agreement, as applicable (see section II.M.5).

We also are proposing to revise § 314.107(f)(2)(iv) (redesignated as § 314.107(f)(2)(i)(D)) to eliminate the requirement that the notification to the Agency include a ''certification'' that an action has been filed. This requirement has resulted in confusion, and the Agency has concluded that a written ''statement'' containing the necessary information is adequate. We are proposing to require that this statement contain the patent number(s) of the listed patent(s) at issue in the patent infringement action, in addition to the court and case number. The patent number(s) of the listed patent(s) at issue in the litigation will assist FDA in its administration of the approval

requirements for 505(b)(2) applications and ANDAs.

We are proposing to expressly state that an NDA holder or its representative also may notify FDA of the filing of any legal action for patent infringement, irrespective of whether the NDA holder is an exclusive patent licensee and initiated the patent infringement action. The notification must be sent to the appropriate office or division and contain the information described in proposed § 314.107(f)(2)(i).

Proposed § 314.107(f)(2)(iii) clarifies that a 505(b)(2) application or ANDA may be approved upon expiration of the 45-day period (if the 505(b)(2) or ANDA applicant confirms that a legal action for patent infringement has not been filed within the 45-day period) or upon completion of FDA's review of the 505(b)(2) application or ANDA, whichever is later. This provision would apply, for example, if an applicant changed a paragraph III certification or a statement pursuant to section 505(b)(2)(B) or 505(j)(2)(A)(viii), as applicable, to a paragraph IV certification during review of the 505(b)(2) application or ANDA and the 45-day period had not elapsed by the time the office or division was ready to take an action on the application. It is unlikely that this provision would be implicated in most cases, however, because a 505(b)(2) or ANDA applicant is required by statute to provide notice of paragraph IV certification not later than 20 days after the date of the postmark on the acknowledgment letter or paragraph IV acknowledgment letter, and review of an application would not be expected to be completed before the 45-day period for each recipient had ended. The proposed revisions to § 314.107(f)(2)(iii) and (f)(3) would replace the current references to the approval of a 505(b)(2) application or ANDA being made effective because this text incorrectly suggests that FDA might issue an approval letter that would become effective at some date in the future (see section II.A.2.dd and II.I). In addition, proposed § 314.107(f)(2)(iii) clarifies that FDA would not approve a 505(b)(2) application or ANDA upon expiration of the 45-day period unless the 505(b)(2) or ANDA applicant had confirmed that a legal action for patent infringement had not been filed.

Proposed § 314.107(f)(3) would permit a representative of the patent owner or NDA holder who is an exclusive patent licensee to waive the opportunity to file a patent infringement action within the 45-day period. This revision is intended to conform with other sections of part 314, including §§ 314.52 and 314.95 which permit notice of paragraph IV certification to be sent to a representative designated by the patent owner to receive notice and the NDA holder's attorney, agent, or other authorized official.

Finally, we are proposing to revise the title to § 314.107(f) and add titles to paragraphs (f)(1), (f)(2), and (f)(3) of that section for administrative convenience.

II.M.7. Conversion of Approval to Tentative Approval (Proposed § 314.107(g))

We are proposing to add § 314.107(g) to clarify that if FDA issues an approval letter in error or a court enters an order requiring that the date of approval be delayed for an already approved 505(b)(2) application or ANDA, FDA will convert the approval to a tentative approval if appropriate.

An approved application may be converted to tentatively approved status if a court determines that a listed patent has been infringed by a 505(b)(2) or ANDA applicant and issues an order pursuant to 35 U.S.C. 271(e)(4) requiring that the effective date of approval shall not be earlier than the date on which the infringed patent will expire, including any pediatric exclusivity that may attach to that patent (see, *e.g., Mylan Labs., Inc.* v. *Thompson,* 389 F.3d 1272 (D.C. Cir. 2004)). In addition, FDA will convert an approval to tentatively approved status if the approval letter was issued in error (for example, if an ANDA applicant failed to notify FDA of an adverse decision in patent infringement litigation).

II.N. Assessing Bioavailability and Bioequivalence for Drugs Not Intended To Be Absorbed Into the Bloodstream (Proposed § 320.23)

The MMA amends section 505(j)(8) of the FD&C Act to explicitly authorize FDA to establish methods for assessing bioavailability and bioequivalence for drugs that are not absorbed into the bloodstream (see section 505(j)(8)(A)(ii) and (j)(8)(C) of the FD&C Act). These amendments essentially codify our existing practice of establishing such methods, as reflected in current §§ 320.23(a)(1) and 320.24 and in our implementation of these regulations.

Our proposal would revise the text of § 320.23 to more precisely reflect the text of section 505(j)(8) of the FD&C Act. However, these proposed revisions are not intended to change our current interpretation of § 320.23, as the amendments to section 505(j)(8) of the FD&C Act are intended to codify our existing interpretation (see section 1103(b) of the MMA, which specifically states that the amendments made to section 505(j)(8) of the FD&C Act ''do[] not alter the standards for approval of [ANDAs].'').

II.O. Miscellaneous

II.O.1. Clarifying Revisions and Editorial Changes

We are proposing several clarifying revisions and editorial changes throughout the sections of parts 314 and 320 that are the subject of this rulemaking. These changes are intended to promote consistency throughout our regulations, incorporate ''plain language,'' employ grammatically correct phrasing, and otherwise clarify the text of these regulations. Examples of proposed revisions that are not otherwise described in this document are provided below.

- Change ''means'' to ''is'' after each term described in the definitions section (see proposed § 314.3(b));
- change ''shall'' to ''must'' as appropriate (see generally part 314);
- change ''are required'' to ''must'' because an applicant is always required to comply with applicable regulations (see proposed § 314.50(d)(5));
- change ''prior to the submission of'' to ''before submitting'' for clarity (see proposed § 314.50(d)(5));
- change ''claims no uses'' to ''does not claim a use'' to correct grammar (see proposed §§ 314.52(a) and 314.95(a)); and
- change ''each amendment to § 314.50(d)(1)'' to ''each amendment to a section of the NDA described in § 314.50(d)(1)'' for clarity (see proposed § 314.60(d)).

In the codified section of this proposed rule, we have indicated proposed editorial changes as amendatory instructions to remove and add text. In some instances, however, it was necessary to print an entire paragraph to indicate proposed changes that are only editorial changes and would not affect substantive portions of the proposed rule.

We also are proposing to correct statutory citations in part 314 that have changed due to a series of amendments to the FD&C Act (see, *e.g.,* proposed §§ 314.52(c), 314.60(c), and 314.95(c) and (f)).

II.O.2. Effect of Other Rulemaking

In anticipation of the Agency's business process efforts to move all submissions to FDA to electronic submission, we are proposing certain revisions to provisions that clearly contemplate submission of paper to facilitate the transition to electronic submissions and reduce the volume of conforming revisions that may be needed in the future. Examples of these proposed revisions are provided below:

• Change ''in a form other than hard copy, for example, on microfiche or computer tapes'' to ''in an alternate form'' to reflect advances in technology and facilitate the transition to electronic submissions (see proposed § 314.50(f)(4));

• delete references to ''mailing cover'' (see proposed §§ 314.53(d)(6) and 314.70(b)(4)); and

• change ''cover letter'' to ''submission'' (see proposed § 314.70(a)(6)).

FDA is committed to adapting its business practices to evolving technology, including using the significant advancements in Web-based, electronic systems. We anticipate that Web-based filing of most submissions eventually will be required. We anticipate that when such a change to an electronic submission system is implemented, future guidance will address any technical questions related to such submissions. Until such time, the sponsor or applicant must submit them in the manner described in the regulations and to the appropriate FDA location identified in the regulations.

III. Legal Authority

The MMA and sections 505, 505A, 527, and 701 (21 U.S.C. 360cc and 371) of the FD&C Act provide the principal legal authority for this proposed rule. Section 505(b) of the FD&C Act describes the contents of an NDA and 505(b)(2) application, including patent listing and patent certification requirements. Section 505(j) of the FD&C Act describes the contents of an ANDA, including bioequivalence information, patent certification requirements, and criteria for a petitioned ANDA. Section 505(b) and (j) of the FD&C Act restrict certain amendments and supplements to a 505(b)(2) application or an ANDA. Section 505(b), (c), and (j) of the FD&C Act describe the timing of approval for 505(b)(2) applications and ANDAs that are subject to the patent and marketing exclusivity protections accorded the listed drug(s) relied upon and the RLD, respectively. Section 505(j) also describes the availability of 180-day exclusivity for a first ANDA applicant.

Section 505A of the FD&C Act describes the availability of pediatric exclusivity and describes the effect of such exclusivity on approval of 505(b)(2) applications and ANDAs. Section 527 of the FD&C Act describes the effect of orphan exclusivity on approval of 505(b)(2) applications and ANDAs.

Thus, sections 505, 505A, and 527 of the FD&C Act, in conjunction with our general rulemaking authority in section 701(a) of the FD&C Act, serve as our principal legal authority for this proposal.

IV. Analysis of Impacts

FDA has examined the impacts of the proposed 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 (Pub. L. 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 Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. We do not believe this proposed rule would result in a significant impact on a substantial number of small entities, but the impacts are uncertain. Because we are uncertain whether the proposed rule would have a significant economic impact on a substantial number of small entities, this and other sections of the preamble and the full preliminary regulatory impact analysis constitute the Agency's regulatory flexibility analysis.

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 (20132) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

This proposed rule would implement portions of the MMA in a manner that preserves the balance struck in the 1984 Hatch-Waxman Amendments between encouraging the availability of less expensive generic drugs and bringing innovative new drugs to market. This rule would also revise and clarify procedures related to the approval of 505(b)(2) applications and ANDAs to reduce uncertainty among drug firms, reduce costs to industry, and reduce demands on FDA resources responding to industry inquiries.

FDA has been implementing the MMA directly from the statute for several years and based on this experience has identified opportunities to clarify MMA provisions through the adoption of codified language. To the extent that clarified regulatory language improves certainty among regulated entities, this proposal, if promulgated, would reduce industry compliance costs and Agency enforcement costs. The full discussion of economic impacts is available in docket FDA–2011–N–0830 and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm* (Ref. 1).

IV.A. Summary of the Benefits and Costs of the Proposed Rule

Although many provisions of this proposed rule would codify current practice, elements of this proposal would lead to changes that generate additional benefits and costs. This proposed rule would affect applicants and application holders for NDAs (including 505(b)(2) applications) and ANDAs. Provisions of this rule would affect the submission of patent information by NDA holders for listing in the Orange Book and the submission by 505(b)(2) and ANDA applicants of a patent certification or statement addressing the listed patent(s) for the listed drug(s) relied upon or RLD, respectively. This proposed rule would also affect, for those certifying that a listed patent is invalid, unenforceable, or not infringed (paragraph IV certification), the requirements for the provision of notice of the paragraph IV certification to each patent owner and the NDA holder for the listed drug. The proposed rule would also affect other requirements associated with 505(b)(2) applications and ANDAs.

This proposed rule would revise certain aspects of the regulations on listing of patent information, patent certification requirements, and a 30-month stay of approval. It would also update regulations pertaining to the type of bioavailability and bioequivalence data that can be used to support 505(b)(2) applications and ANDAs. These proposed revisions to the Agency's regulations in parts 314 and 320 would implement portions of Title XI of the MMA and facilitate compliance with and enforcement of the FD&C Act.

We present a summary of benefits and costs in Table 16. The estimated annual monetized benefits of this proposed rule are $194,314, and estimated annual monetized costs are $91,371. We have also identified, but are unable to

quantify, impacts from proposed changes to submitted patent information and the implementation of an administrative consequence for failing to provide notice within the timeframe specified by the MMA.

TABLE 16—ECONOMIC DATA: COSTS AND BENEFITS STATEMENT

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate	Period covered	
Benefits							
Annualized Monetized $millions/year	$0.19	$0.19	$0.19		7%	Annual	
	$0.19	$0.19	$0.19		3%	Annual	
Annualized Quantified					7%	Annual	
Qualitative					3%	Annual	
Costs							
Annualized Monetized $millions/year	$0.09	$0.09	$0.09	2012	7%	Annual	
	$0.09	$0.09	$0.09	2012	3%	Annual	
Annualized Quantified					7%		
Qualitative					3%		
Transfers							
Federal Annualized Monetized $millions/year					7%		None.
					3%		
From/To	From:	To:					
Other Annualized Monetized $millions/year					7%		None.
From/To	From:	To:			3%		

Effects
State, Local, or Tribal Government: Not applicable
Small Business: For firms with 25 to 49 employees, which is a more likely lower bound for firms submitting 505(b)(2) applications, the unit cost of this provision would be less than 0.05 percent of average shipments.
Wages: No estimated effect
Growth: No estimated effect

IV.B. Summary of Regulatory Flexibility Analysis

FDA conducted a regulatory flexibility analysis of the impact of the proposed rule on small entities. Statistics on the classification of firms by employment size from the U.S. Bureau of the Census show that in 2005, at least 85 percent of pharmaceutical manufacturing entities had fewer than 500 employees and would have been considered small by the U.S. Small Business Administration (Ref. 2).

We have provided monetized estimates for $194,314 in benefits and $91,371 in costs. These costs of this proposed rule are generally small unit costs incurred across many entities. Our estimated unit costs for all but one item are less than $190 per unit. In table 17, we express the unit cost of an amendment to a patent certification in terms of hundredths of a percent of average establishment shipments. Excluding one item (505(b)(2) applicants providing a patent certification to a pharmaceutically equivalent drug product), there are costs of $83,146 attributable to about 1,200 units. Some affected entities would face multiple unit costs of some type in a year, but even this circumstance would not approach a significant impact on a substantial number of small entities. For a unit cost of $190 to amount to 1 percent of average shipments among establishment with fewer than 5 employees, the entity would have to incur that cost more than 40 times.

TABLE 17—SMALL ENTITY CHARACTERISTICS AND THE IMPACT OF UNIT COSTS ATTRIBUTABLE TO THIS PROPOSED RULE

	Pharmaceutical Preparation Manufacturing (NAICS 325412)	
No. of Employees	<5	20–49
Total Value of Shipments ($1,000)	187,933	978,494
No. of Establishments	228	109
Average Value of Shipments ($)	824,268	8,977,009
Unit Costs of Identifying a Pharmaceutically Equivalent Drug Product as a Listed Drug Relied Upon per § 314.50(i)(1)(i)(C) as a Percentage of the Average Value of Shipments	0.50%	0.046%

V. Paperwork Reduction Act of 1995

This proposed rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). We describe these provisions below in this section of the document with an estimate of the annual reporting burden. Our estimate includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

We invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Abbreviated New Drug Applications and 505(b)(2) Applications; Proposed Revisions to Implement Portions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and Other Changes.

Description of Respondents: Respondents to this collection of information are NDA applicants (including 505(b)(2) applicants) and ANDA applicants, patent owners, and their representatives.

Burden Estimate: This proposed rule would implement portions of Title XI of the MMA that pertain to a 505(b)(2) or ANDA applicant's provision of notice of paragraph IV certification to each patent owner and the NDA holder; the availability of 30-month stays of approval on 505(b)(2) applications and ANDAs that are otherwise ready to be approved; submission of amendments and supplements to 505(b)(2) applications and ANDAs; and the types of bioavailability and bioequivalence data that can be used to support these applications. This proposed rule also would amend certain regulations regarding 505(b)(2) applications and ANDAs to facilitate compliance with and efficient enforcement of the FD&C Act.

FDA currently has OMB approval for the collection of information entitled ''Application for Food and Drug Administration Approval to Market a New Drug'' (OMB control number 0910–0001). This collection of information includes, among other things:

- The requirements in §§ 314.50(i) and 314.94(a)(12) for submission of an appropriate patent certification or statement in a 505(b)(2) application or ANDA;
- the requirements in §§ 314.52 and 314.95 for a 505(b)(2) or ANDA applicant to send notice of any paragraph IV certification to each patent owner and the NDA holder and amend its 505(b)(2) application or ANDA to certify that notice has been provided and to document receipt of the notice;
- the content requirements in § 314.54 for a 505(b)(2) application;
- the requirements in §§ 314.60 and 314.96 for applicants that amend an unapproved 505(b)(2) application or ANDA, respectively;
- the requirements in §§ 314.70 and 314.97 for supplements submitted to FDA for certain changes to an approved 505(b)(2) application or ANDA;
- the requirements in §§ 314.90 and 314.99 for applicants that request waivers from FDA for compliance with §§ 314.50 through 314.81 or §§ 314.92 through 314.99, respectively;
- the procedures in § 314.107(c) by which a first applicant notifies FDA of the date of first commercial marketing;
- the requirement in § 314.107(e) for an applicant to submit to FDA a copy of certain court decisions related to a patent that is the subject of a paragraph IV certification;
- the requirement in § 314.107(f) for a 505(b)(2) or ANDA applicant to notify FDA immediately of the filing of any legal action within 45 days of receipt of the notice of paragraph IV certification by each patent owner or the NDA holder; and
- the requirement in § 314.107(f) for a patent owner or NDA holder who is an exclusive patent licensee that waives its opportunity to file a legal action for patent infringement within the 45-day period to submit to FDA a waiver in the specified format.

FDA has OMB approval for the collection of information entitled ''General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions'' (OMB control number 0910–0183). This collection of information includes, among other things, the requirements in § 314.93 for submitting a suitability petition in accordance with 21 CFR 10.20 and 10.30.

FDA also has received OMB approval for the collection of information entitled ''Applications for Food and Drug Administration Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not Be Infringed'' (OMB control number 0910–0513). This collection of information includes the requirements in § 314.50(h) for submission of patent information in an NDA, an amendment, or a supplement, as described in § 314.53. Section 314.53 requires that an applicant submitting an NDA, an amendment, or a supplement, except as provided in § 314.53(d)(2), submit on Forms FDA 3542a and 3542 the required patent information described in this section.

We are not reestimating these approved burdens. Only the reporting burdens associated with the MMA's amendments to the FD&C Act and the proposed changes to parts 314 and 320 are estimated.

Under section 505(b), (c), and (j) of the FD&C Act and this proposed rule, the following information would be submitted to FDA but is not currently approved by OMB under the PRA:

Proposed § 314.50(i)(1)(i)(C) would require a 505(b)(2) applicant to submit an appropriate patent certification or statement for each patent listed in the Orange Book for a drug product(s) that is pharmaceutically equivalent to the proposed drug product for which the 505(b)(2) application is submitted. Proposed § 314.54 would require a 505(b)(2) applicant to identify a pharmaceutically equivalent product as a listed drug relied upon and to comply with applicable regulatory requirements. Generally, 505(b)(2) applications submitted for a proposed drug product for which there is an approved pharmaceutical equivalent already cite the pharmaceutically equivalent product as a listed drug relied upon to support approval. Therefore, we are not estimating a new burden for proposed § 314.54 at this time. Based on our experience reviewing 505(b)(2) applications, we estimate that proposed § 314.50(i)(1)(i)(C) may result in approximately two instances per year in which an applicant is required to identify a pharmaceutically equivalent drug product as a listed drug relied upon and comply with applicable regulatory requirements (including submission of an appropriate patent certification or statement for each patent listed in the Orange Book for the pharmaceutically equivalent listed drug relied upon). Based on an estimated average of 2.6 patents by each NDA holder for listing in the Orange Book, we estimate that there will be 5.2 responses per year, and the burden hours associated with this requirement in proposed § 314.50(i)(1)(i)(C) will be approximately 2 hours per response. If the patent certification submitted pursuant to proposed § 314.50(i)(1)(i)(C) is a paragraph IV certification, the applicant also must comply with the requirements in § 314.52 for notice of paragraph IV certification, which add

approximately 80 hours (15.33 hours per response) to the currently approved burden hours. This estimate reflects other proposals described in this section of the document that would reduce the currently approved burden for § 314.52 from 16 hours per response to 15 hours per response, and the additional content requirement in proposed § 314.52(c) that would increase the estimated burden by 0.33 hours per response. As previously noted, we are not reestimating approved burdens in this document. Accordingly, the estimate provided for § 314.52(a), (b), (c), and (e) reflects the additional burden that may arise from the requirement in proposed § 314.50(i)(1)(i)(C) if the 505(b)(2) applicant submits a paragraph IV certification. We separately describe and estimate the burden of the additional content requirement in proposed § 314.52(c) for the estimated average of seven 505(b)(2) applications filed per year that contain one or more paragraph IV certification.

Proposed §§ 314.50(i)(6) and 314.94(a)(12)(viii) would require a 505(b)(2) or ANDA applicant to amend its patent certification from a paragraph IV certification to a paragraph III certification after the court enters a final decision from which no appeal has been or can be taken, or signs a settlement order or consent decree with a finding of infringement (unless the patent also is found invalid). Proposed §§ 314.50(i)(6) and 314.94(a)(12)(viii) also would require a 505(b)(2) or ANDA applicant to submit an amended patent certification in certain circumstances after the NDA holder has requested to remove a patent or patent information from the list. Based on our experience and review of selected court decisions, we estimate that there are approximately 12 instances per year in which a party has submitted a court decision or order with a finding of infringement. In addition, there are approximately 24 instances per year in which the NDA holder has requested to remove a patent or patent information from the list and the patent or patent information has been removed. Based on our experience, we estimate that this requirement may result in approximately 36 and 108 instances per year in which an applicant amends its 505(b)(2) application or ANDA, respectively, to submit a revised patent certification, and the burden hours associated with this requirement will be approximately 2 hours per response. Proposed §§ 314.50(i)(6)(iii)(A)(*2*) and 314.94(a)(12)(vi)(C)(*1*)(*ii*) would expressly codify the current requirement for a 505(b)(2) or ANDA applicant to submit a patent certification or statement if, after submission of the application, a new patent is issued by the PTO that in the opinion of the applicant and to the best of its knowledge, claims the listed drug or an approved use for such listed drug and for which information is required to be filed by the NDA holder. The burden hours associated with compliance with current provisions of §§ 314.50(i)(1) through (i)(6) and 314.94(a)(12)(i) through (a)(12)(viii) are described in the burden hours estimate currently approved under OMB control number 0910–0001.

Proposed §§ 314.52(a) and 314.95(a) would expand the list of acceptable delivery methods that may be used to send notice of paragraph IV certification to the NDA holder and each patent owner, and thereby reduce the burden on applicants to submit, under current §§ 314.52(a) and (e), a request to FDA to use common alternate delivery methods. We receive approximately 205 written inquiries per year from 505(b)(2) or ANDA applicants requesting permission to send notice of paragraph IV certification by an overnight delivery service. Proposed §§ 314.52(a) and 314.95(a) would eliminate the requirement to submit a request to use a designated delivery service, as defined in proposed §§ 314.52(f) and 314.95(f). We estimate that approximately 95 percent of these written inquiries will no longer be required because the alternate delivery method would fall within the definition of a ''designated delivery service'' in proposed §§ 314.52(g) and 314.95(g).

Proposed §§ 314.52(c) and 314.95(c) would require that notice of paragraph IV certification contain a statement that the applicant has received the acknowledgment letter or the paragraph IV acknowledgment letter, as applicable. In addition, proposed § 314.52(c) would require that the notice of paragraph IV certification contain a statement that a 505(b)(2) application that contains any required bioavailability or bioequivalence data has been submitted by the applicant and filed by FDA, as required by section 505(b)(3)(D)(i) of the FD&C Act. We estimate that these additional content requirements for the notice of paragraph IV certification would increase the burden of providing notice of paragraph IV certification by approximately 20 minutes. Based on an estimated average of 7 505(b)(2) applications filed per year that contain one or more paragraph IV certifications and 209 ANDAs received per year that contain one or more paragraph IV certifications, we estimate that there will be 21 and 627 responses per year, and the burden hours associated with this requirement will be approximately 20 minutes per response.

Proposed §§ 314.52(d)(1) and 314.95(d)(1) would require notice of paragraph IV certification regardless of whether notice has already been provided for another paragraph IV certification contained in the 505(b)(2) application or ANDA or an amendment or supplement to the 505(b)(2) application or ANDA, as required by section 505(b)(3)(B)(ii) and (j)(2)(B)(ii)(II) of the FD&C Act. Since enactment of the MMA, FDA has regulated directly from the statute and required notice of paragraph IV certification in these circumstances. Thus, the burden associated with this statutory requirement is reflected in the burden hours estimate for §§ 314.52 and 314.95 currently approved under OMB control number 0910–0001.

Proposed §§ 314.52(e) and 314.95(e) would permit a 505(b)(2) or ANDA applicant to submit a single amendment containing documentation of timely sending and receipt of notice of paragraph IV certification. Currently, an applicant is required to amend its 505(b)(2) application or ANDA both at the time of sending notice of paragraph IV certification and after the notice was received by each patent owner and the NDA holder (see current §§ 314.52(b) and (e) and 314.95(b) and (e)). Proposed § 314.95(e) also would require an ANDA applicant to include in its amendment a dated printout of the Orange Book entry for the RLD. FDA has OMB approval for the burden hours estimate of 16 hours per response for the estimated 260 responses submitted annually to comply with §§ 314.52 and 314.95 (see OMB control number 0910–0001). We estimate that 2 hours of the 16 hours per response are attributable to compliance with current §§ 314.52(b) and (e) and 314.95(b) and (e). We estimate that the burden hours associated with the requirement in proposed §§ 314.52(e) and 314.95(e) (including submission of the dated printout of the Orange Book entry) would be approximately 1 hour per response for each of the estimated 7 and 209 responses per year by our updated estimate of 7 505(b)(2) applicants and 209 ANDA applicants whose applications were filed or received, as applicable, by FDA and contained one or more paragraph IV certifications. Therefore, the proposal would reduce the currently approved burden for §§ 314.52 and 314.95 by 1 hour.

Proposed § 314.53(c)(2) would decrease the patent information that NDA applicants are currently required to submit for listing in the Orange Book.

Proposed § 314.53(c)(2) would require an NDA applicant to submit information on a previously submitted patent only if a patent is a reissued patent of a patent previously submitted for listing for the NDA or supplement. Proposed § 314.53(c)(2) would require submission of patent information on whether a drug substance patent claims a polymorph only if such patent claims only a polymorph that is the same active ingredient described in the NDA or supplement. Proposed § 314.53(c)(2) also would provide that an applicant that submits information for a patent that claims either the drug substance or drug product and meets the requirements for patent listing on that basis is not required to provide information on whether that patent also claims the drug product or drug substance, respectively. The information collection resulting from current § 314.50(h) (citing § 314.53) and Form FDA 3542a has been approved by OMB under control number 0910–0153 for FDA's estimate of 20 hours per response. We estimate the proposed revisions to our regulations will reduce the time needed to complete Form FDA 3542a by approximately 3 hours per response.

Proposed § 314.53(d)(2) would enable FDA to reduce duplicative submission of patent information and require such information only for a supplement to change the dosage form or route of administration, to change the strength, to change the drug product from prescription to OTC use, or to correct previously submitted patent information that differently or no longer claims the changed product.

Proposed § 314.53(f)(2) would expressly require correction or change of patent information if the NDA holder determines that a patent or patent claim no longer meets the statutory requirements for listing, if the NDA holder is required by court order to amend patent information or withdraw a patent from the list, or if the term of a listed patent is extended under 35 U.S.C. 156(e). We estimate that these corrections and changes of patent information would result in approximately 62 submissions of Form FDA 3542 or other written submission, as provided in proposed § 314.53(f)(2)(iv), by approximately 39 NDA holders. We further estimate that the burden hours associated with the requirement in proposed § 314.53(f)(2) would be approximately 1 hour per response.

Section 505(b)(4)(A) and (j)(2)(D)(i) of the FD&C Act generally prohibit the submission of certain types of changes in an amendment or a supplement to a 505(b)(2) application or an ANDA, respectively. Proposed §§ 314.60(e) and 314.70(h) would prohibit an applicant from amending or supplementing a 505(b)(2) application to seek approval of a drug that has been modified to have a different active ingredient, different route of administration, different dosage form, or certain differences in excipients that the drug proposed in the original submission of the 505(b)(2) application. These changes must be requested in a new 505(b)(2) application. This proposed requirement conforms with FDA's current policy regarding the types of proposed changes to a drug product that should be submitted as a separate application (see Separate Marketing Application Guidance). Accordingly, the burden associated with this statutory requirement is reflected in the burden hours estimate for §§ 314.50 and 314.94 currently approved under OMB control number 0910–0001 for 505(b)(2) applications and ANDAs, respectively.

Proposed §§ 314.60(f), 314.70(i), 314.96(d), and 314.97(c) would require an applicant to submit a patent certification if approval is sought for either of the following types of amendments or supplements to a 505(b)(2) application or ANDA: (1) To add a new indication or other condition of use or (2) to add a new strength. Proposed §§ 314.60(f) and 314.96(d) also would require an applicant to submit a patent certification if approval is sought for either of the following types of amendments to a 505(b)(2) application or ANDA: (1) To make other than minor changes in product formulation or (2) to change the physical form or crystalline structure of the active ingredient. Although currently the submission of a patent certification is required if, at any time before approval, the applicant learns that the previously submitted patent certification is no longer accurate with respect to the pending application or supplement, as amended (thus the burden hours are currently approved under OMB control number 0910–0001), the patent certification requirements would be broadened under this proposed rule. We estimate that this requirement may result in approximately six and four instances per year in which an applicant is required to submit a patent certification with an amendment or supplement, respectively, to its 505(b)(2) application. We further estimate that this requirement may result in approximately 95 and 16 instances per year in which an applicant is required to submit a patent certification with an amendment or supplement, respectively, to its ANDA. The burden hours associated with these requirements are estimated to be approximately 2 hours per response.

Proposed §§ 314.96(c) and 314.97(b) would prohibit an ANDA applicant from amending or supplementing an ANDA to seek approval of a drug referring to a listed drug that is different from the RLD identified in the ANDA. An applicant must submit a change of the RLD in a new ANDA. We estimate that approximately one ANDA applicant per year will be required to submit a new ANDA instead of submitting an amendment for a change of the RLD. We also estimate that approximately one ANDA applicant per year will be required to submit a new ANDA instead of submitting a supplement for a change of the RLD. We further estimate that the burden of submitting an ANDA and complying with applicable regulatory requirements, including any required study to demonstrate bioequivalence to the new RLD, will be approximately 288 hours for each of the estimated two responses per year.

Proposed § 314.107(e) would expand the scope of the court actions and documented agreements related to a patent described in § 314.107(b)(3) that are required to be submitted to FDA. Proposed § 314.107(e) also would require submission of any court order pursuant to 35 U.S.C. 271(e)(4)(A) ordering that a 505(b)(2) application or ANDA may be approved no earlier than the date specified. FDA has OMB approval for the burden hours estimate of 30 minutes per response for the estimated 98 responses submitted annually by 25 505(b)(2) or ANDA applicants to comply with § 314.107(e) (see OMB control number 0910–0001). Based on our experience, we estimate that 140 505(b)(2) and ANDA applicants will be required to submit a copy of a court action, documented agreement, or written notification of appeal in approximately 310 instances per year. We continue to estimate that the burden associated with submitting a copy of these documents to FDA is approximately 30 minutes per response.

The estimated burden of the burden of this collection of information is described in Table 18.

TABLE 18—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
314.50(i)(1)	2	2.6	5.2	2.	10.4
314.50(i)(6)	36	1	36	2.	72
314.52(a), (b), (c), and (e)	2	2.6	5.2	15.33.	79.7
314.52(c)	7	3	21	0.33 (20 minutes)..	7
314.53(f)	39	1.5	62	1.	62
314.60(f)	6	1	6	2.	12
314.70(i)	4	1	4	2.	8
314.94(a)(12)	108	1	108	2.	216
314.95(c)	209	3	627	0.33 (20 minutes)..	209
314.96(c)	1	1	1	288.	288
314.96(d)	95	1	95	2.	190
314.97(b)	1	1	1	288.	288
314.97(c)	16	1	16	2.	32
314.107(e)	140	2.2	310	0.5 (30 minutes)..	155
Total Reporting Burden Hours					1629.1

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We have submitted the information collection requirements of this rule to OMB for review. Interested persons are requested to send comments regarding information collection to the Office of Information and Regulatory Affairs, OMB (see **ADDRESSES**).

VI. Environmental Impact

The Agency has determined under 21 CFR 25.30(h) and 25.31(a) and (g) 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. Effective Date

FDA proposes that any final rule based on this proposal become effective 60 days after publication in the **Federal Register**.

We intend to apply this rule, if finalized, to any new submission received by FDA on or after the effective date. This proposed rule provides sufficient notice to all interested parties, including NDA holders, NDA applicants (including 505(b)(2) applicants), and ANDA applicants to adjust their submissions and actions by the time we issue any final rule. However, we invite comments on how a final rule should be implemented.

VIII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would 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 tentatively concludes that the proposed 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.

IX. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. 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.*

X. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis for Abbreviated New Drug Applications and 505(b)(2) Applications; Proposed Rule, available at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

2. U.S. Department of Commerce, Bureau of the Census, Economic Census, Manufacturing Industry Series, Pharmaceutical Preparation Manufacturing, Table 4, EC02–311–325412 (RV), 2002.

List of Subjects

21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 320

Drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, FDA proposes to amend 21 CFR parts 314 and 320 as follows:

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

■ 1. The authority citation for 21 CFR part 314 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 355a, 356, 356a, 356b, 356c, 360cc, 371, 374, 379e.

■ 2. Section 314.3 is revised to read as follows:

§ 314.3 Definitions.

(a) The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act apply to

those terms when used in this part and part 320 of this chapter.

(b) The following definitions of terms apply to this part and part 320 of this chapter:

180-day exclusivity period is the 180-day period beginning on the date of the first commercial marketing of the drug (including the commercial marketing of the reference listed drug) by any first applicant. The 180-day period ends on the day before the date on which an ANDA submitted by an applicant other than a first applicant could be approved.

Abbreviated application, abbreviated new drug application, or ANDA is the application described under § 314.94, including all amendments and supplements to the application.

Acknowledgment letter is a written, postmarked communication from FDA to an applicant stating that the Agency has determined that a 505(b)(2) application or ANDA is sufficiently complete to permit a substantive review. An acknowledgment letter indicates that the 505(b)(2) application is regarded as filed or the ANDA is regarded as received.

Act is the Federal Food, Drug, and Cosmetic Act (section 201 *et seq.* (21 U.S.C. 301 *et seq.*)).

Active ingredient is any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.

Active moiety is the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.

ANDA holder is the applicant that owns an approved ANDA.

Applicant is any person who submits an NDA (including a 505(b)(2) application) or ANDA or an amendment or supplement to an NDA or ANDA under this part to obtain FDA approval of a new drug and any person who owns an approved NDA (including a 505(b)(2) application) or ANDA.

Application, new drug application, or NDA is the application described under § 314.50, including all amendments and supplements to the application. An NDA refers to ''stand-alone'' applications submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act and to 505(b)(2) applications.

505(b)(2) application is an NDA submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for a drug for which the investigations described in section 505(b)(1)(A) of the Federal Food, Drug, and Cosmetic Act and relied upon by the applicant for approval of the NDA were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

Approval letter is a written communication to an applicant from FDA approving an NDA or an ANDA.

Assess the effects of the change is to evaluate the effects of a manufacturing change on the identity, strength, quality, purity, and potency of a drug product as these factors may relate to the safety or effectiveness of the drug product.

Authorized generic drug is a listed drug, as defined in this section, that has been approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act and is marketed, sold, or distributed directly or indirectly to the retail class of trade with labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trademark that differs from that of the listed drug.

Bioavailability is the rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of drug action. For drug products that are not intended to be absorbed into the bloodstream, bioavailability may be assessed by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or active moiety becomes available at the site of drug action.

Bioequivalence is the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. Where there is an intentional difference in rate (*e.g.,* in certain extended release dosage forms), certain pharmaceutical equivalents or alternatives may be considered bioequivalent if there is no significant difference in the extent to which the active ingredient or moiety from each product becomes available at the site of drug action. This applies only if the difference in the rate at which the active ingredient or moiety becomes available at the site of drug action is intentional and is reflected in the proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug. For drug products that are not intended to be absorbed into the bloodstream, bioequivalence may be assessed by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or active moiety becomes available at the site of drug action.

Bioequivalence requirement is a requirement imposed by FDA for in vitro and/or in vivo testing of specified drug products that must be satisfied as a condition of marketing.

Class 1 resubmission is the resubmission of an NDA or efficacy supplement, following receipt of a complete response letter, that contains one or more of the following: Final printed labeling, draft labeling, certain safety updates, stability updates to support provisional or final dating periods, commitments to perform postmarketing studies (including proposals for such studies), assay validation data, final release testing on the last lots used to support approval, minor reanalyses of previously submitted data, and other comparatively minor information.

Class 2 resubmission is the resubmission of an NDA or efficacy supplement, following receipt of a complete response letter, that includes any item not specified in the definition of ''Class 1 resubmission,'' including any item that would require presentation to an advisory committee.

Commercial marketing is the introduction or delivery for introduction into interstate commerce of a drug product described in an approved ANDA, outside the control of the ANDA holder, except for investigational use under part 312 of this chapter, but does not include transfer of the drug product for reasons other than sale to parties identified in the approved ANDA.

Complete response letter is a written communication to an applicant from FDA usually describing all of the deficiencies that the Agency has identified in an NDA or ANDA that must be satisfactorily addressed before it can be approved.

Component is any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product.

Date of approval is the date on the approval letter from FDA stating that the NDA or ANDA is approved. ''Date of approval'' refers only to a final approval and not to a tentative approval.

Dosage form is the physical manifestation containing the active and inactive ingredients that delivers a dose of the drug product. This includes such factors as:

(1) The physical appearance of the drug product,

(2) The physical form of the drug product prior to dispensing to the patient,

(3) The way the product is administered, and

(4) The design features that affect frequency of dosing.

Drug product is a finished dosage form, *e.g.,* tablet, capsule, or solution that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.

Drug substance is an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body, but does not include intermediates used in the synthesis of such ingredient.

Efficacy supplement is a supplement to an approved NDA proposing to make one or more related changes from among the following changes to product labeling:

(1) Add or modify an indication or claim;

(2) Revise the dose or dose regimen;

(3) Provide for a new route of administration;

(4) Make a comparative efficacy claim naming another drug product;

(5) Significantly alter the intended patient population;

(6) Change the marketing status from prescription to over-the-counter use;

(7) Provide for, or provide evidence of effectiveness necessary for, the traditional approval of a product originally approved under subpart H of part 314; or

(8) Incorporate other information based on at least one adequate and well-controlled clinical study.

FDA is the Food and Drug Administration.

First applicant is an applicant that, on the first day on which a substantially complete ANDA containing a paragraph IV certification is submitted for approval of a drug, submits a substantially complete ANDA that contains, and for which the applicant lawfully maintains, a paragraph IV certification for the drug.

Inactive ingredient is any component other than an active ingredient.

Listed drug is a new drug product that has been approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act for safety and effectiveness or under section 505(j) of the Federal Food, Drug, and Cosmetic Act, which has not been withdrawn or suspended under section 505(e)(1) through (e)(5) or section 505(j)(6) of the Federal Food, Drug, and Cosmetic Act, and which has not been withdrawn from sale for what FDA has determined are reasons of safety or effectiveness. Listed drug status is evidenced by the drug product's identification in the current edition of FDA's ''Approved Drug Products With Therapeutic Equivalence Evaluations'' (the list) as an approved drug. A drug product is deemed to be a listed drug on the date of the approval letter for the NDA or ANDA for that drug product.

NDA holder is the applicant that owns an approved NDA.

Newly acquired information is data, analyses, or other information not previously submitted to the Agency, which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (*e.g.,* meta-analyses) if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.

Original application, original NDA is a pending NDA for which FDA has never issued a complete response letter or approval letter, or an NDA that was submitted again after FDA had refused to file it or after it was withdrawn without being approved.

Paragraph IV acknowledgment letter is a written, postmarked communication from FDA to an applicant stating that the Agency has determined that a 505(b)(2) application or ANDA containing a paragraph IV certification is sufficiently complete to permit a substantive review. A paragraph IV acknowledgment letter indicates that the 505(b)(2) application is regarded as filed or the ANDA is regarded as received.

Paragraph IV certification is a patent certification of invalidity, unenforceability, or noninfringement described in § 314.50(i)(1)(i)(A)(*4*) or § 314.94(a)(12)(i)(A)(*4*).

Patent owner is the owner of the patent for which information is submitted for an NDA.

Pharmaceutical alternatives are drug products that contain the identical therapeutic moiety, or its precursor, but not necessarily in the same amount or dosage form or as the same salt or ester. Each such drug product individually meets either the identical or its own respective compendial or other applicable standard of identity, strength, quality, and purity, including potency and, where applicable, content uniformity, disintegration times, and/or dissolution rates.

Pharmaceutical equivalents are drug products in identical dosage forms and route(s) of administration that contain identical amounts of the identical active drug ingredient, *i.e.,* the same salt or ester of the same therapeutic moiety, or, in the case of modified release dosage forms that require a reservoir or overage or such forms as prefilled syringes where residual volume may vary, that deliver identical amounts of the active drug ingredient over the identical dosing period; do not necessarily contain the same inactive ingredients; and meet the identical compendial or other applicable standard of identity, strength, quality, and purity, including potency and, where applicable, content uniformity, disintegration times, and/or dissolution rates.

Postmark is an independently verifiable evidentiary record of the date on which a document is transmitted, in an unmodifiable format, to another party. For postmarks made by the U.S. Postal Service or a designated delivery service, the date of transmission is the date on which the document is received by the domestic mail service of the U.S. Postal Service or by a designated delivery service. For postmarks documenting an electronic event, the date of transmission is the date (in a particular time zone) that FDA sends the electronic transmission on its host system as evidenced by a verifiable record. If the sender and the intended recipient are located in different time zones, it is the sender's time zone that provides the controlling date of electronic transmission.

Reference listed drug is the listed drug identified by FDA as the drug product upon which an applicant relies in seeking approval of its ANDA.

Reference standard is the drug product selected by FDA that an applicant seeking approval of an ANDA must use in conducting an in vivo bioequivalence study required for approval.

Resubmission is submission by the applicant of all materials needed to fully address all deficiencies identified in the complete response letter. An NDA or ANDA for which FDA issued a complete response letter, but which was withdrawn before approval and later submitted again, is not a resubmission.

Right of reference or use is the authority to rely upon, and otherwise

use, an investigation for the purpose of obtaining approval of an NDA, including the ability to make available the underlying raw data from the investigation for FDA audit, if necessary.

Same drug product formulation is the formulation of the drug product submitted for approval and any formulations that have minor differences in composition or method of manufacture from the formulation submitted for approval, but are similar enough to be relevant to the Agency's determination of bioequivalence.

Specification is the quality standard (*i.e.*, tests, analytical procedures, and acceptance criteria) provided in an approved NDA or ANDA to confirm the quality of drug substances, drug products, intermediates, raw materials, reagents, components, in-process materials, container closure systems, and other materials used in the production of a drug substance or drug product. For the purpose of this definition, acceptance criteria means numerical limits, ranges, or other criteria for the tests described.

Strength is the amount of drug substance contained in, delivered, or deliverable from a drug product, which includes:

(1)(i) The total quantity of drug substance in mass or units of activity in a dosage unit or container closure (*e.g.*, weight/unit dose, weight/volume or weight/weight in a container closure, or units/volume or units/weight in a container closure); and/or, as applicable.

(ii) The concentration of the drug substance in mass or units of activity per unit volume or mass (*e.g.*, weight/weight, weight/volume, or units/volume); or

(2) Such other criteria the Agency establishes for determining the amount of drug substance contained in, delivered, or deliverable from a drug product if the weights and measures described in paragraph (i) of this definition do not apply (*e.g.*, certain drug-device combination products for which the amount of drug substance is emitted per use or unit time).

Substantially complete application is an ANDA that on its face is sufficiently complete to permit a substantive review and contains all the information required under section 505(j)(2)(A) of the Federal Food, Drug, and Cosmetic Act and § 314.94.

Tentative approval is notification that an NDA or ANDA otherwise meets the requirements for approval under the Federal Food, Drug, and Cosmetic Act, but cannot be approved because there is a 7-year period of orphan exclusivity for a listed drug under section 527 of the Federal Food, Drug, and Cosmetic Act and § 316.31 of this chapter, or that a 505(b)(2) application or ANDA otherwise meets the requirements for approval under the Federal Food, Drug, and Cosmetic Act, but cannot be approved until the conditions in § 314.107(b)(1)(iii), (b)(3), or (c) are met; because there is a period of exclusivity for the listed drug under § 314.108; because there is a period of pediatric exclusivity for the listed drug under section 505A of the Federal Food, Drug, and Cosmetic Act, or because a court order pursuant to 35 U.S.C. 271(e)(4)(A) orders that the application may be approved no earlier than the date specified. A drug product that is granted tentative approval is not an approved drug and will not be approved until FDA issues an approval letter after any necessary additional review of the NDA or ANDA.

The list is the list of approved drug products published in FDA's current ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' available electronically on FDA's Web site at *http://www.fda.gov/cder.*

Therapeutic equivalents are approved drug products that are pharmaceutical equivalents and for which bioequivalence has been demonstrated. Therapeutic equivalents can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.

■ 3. Section 314.50 is amended by:

■ a. Removing from paragraph (a) introductory text, paragraphs (a)(5), (d)(1)(v), (d)(5)(v), and (d)(5)(vi)(*a*), paragraph (e)(2) introductory text, and paragraphs (f)(3), (g)(2), and (k) the word ''shall'' each time it appears and adding in its place the word ''must'';

■ b. Removing from paragraphs (a)(5), (b), (c)(1), (c)(2)(i), and (c)(2)(iv) through (c)(2)(viii), paragraph (d) introductory text, paragraphs (d)(1)(i), (d)(1)(ii)(*a*), (d)(1)(iii) through (d)(1)(v), (d)(3)(ii), and (d)(5)(iv), paragraph (e)(1)(i) introductory text, paragraph (e)(2), paragraph (f) introductory text, paragraphs (f)(1) through (f)(3), (g)(2), (j)(4)(i), (j)(4)(ii), and (k), paragraph (l) heading, paragraph (l)(1) introductory text, and paragraphs (l)(2) and (l)(4) the word ''application'' each time it appears and adding in its place ''NDA'';

■ c. Removing from paragraph (j) introductory text the word ''shall'' and adding in its place the word ''must'' and removing the phrase ''new drug application'' and adding in its place ''NDA''; and

■ d. Revising the section heading and section introductory text, paragraphs (a)(1) and (d)(5)(vi)(*b*), paragraph (e)(1) introductory text, paragraphs (f)(4), (g)(3), and (i), paragraph (j)(4) introductory text, the first two sentences of paragraph (j)(4)(iii), and paragraph (l)(3).

The revisions read as follows:

§ 314.50 Content and format of an NDA.

NDAs and supplements to approved NDAs are required to be submitted in the form and contain the information, as appropriate for the particular submission, required under this section. Three copies of the NDA are required: An archival copy, a review copy, and a field copy. An NDA for a new chemical entity will generally contain an application form, an index, a summary, five or six technical sections, case report tabulations of patient data, case report forms, drug samples, and labeling, including, if applicable, any Medication Guide required under part 208 of this chapter. Other NDAs will generally contain only some of those items, and information will be limited to that needed to support the particular submission. These include an NDA of the type described in section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, an amendment, and a supplement. The NDA is required to contain reports of all investigations of the drug product sponsored by the applicant, and all other information about the drug pertinent to an evaluation of the NDA that is received or otherwise obtained by the applicant from any source. FDA will maintain guidance documents on the format and content of NDAs to assist applicants in their preparation.

(a) * * *

(1) The name and address of the applicant; the date of the NDA; the NDA number if previously issued (for example, if the NDA is a resubmission or an amendment or supplement); the name of the drug product, including its established, proprietary, code, and chemical names; the dosage form and strength; the route of administration; the identification numbers of all INDs (as defined in § 312.3(b) of this chapter) that are referenced in the NDA; the identification numbers of all drug master files and other applications under this part that are referenced in the NDA; and the drug product's proposed indications for use.

* * * * *

(d) * * *

(5) * * *

(vi) * * *

(*b*) The applicant must, under section 505(i) of the Federal Food, Drug, and Cosmetic Act, update periodically its pending NDA with new safety information learned about the drug that

may reasonably affect the statement of contraindications, warnings, precautions, and adverse reactions in the draft labeling and, if applicable, any Medication Guide required under part 208 of this chapter. These ''safety update reports'' must include the same kinds of information (from clinical studies, animal studies, and other sources) and must be submitted in the same format as the integrated summary in paragraph (d)(5)(vi)(*a*) of this section. In addition, the reports must include the case report forms for each patient who died during a clinical study or who did not complete the study because of an adverse event (unless this requirement is waived). The applicant must submit these reports:

(*1*) 4 months after the initial submission;

(*2*) In a resubmission following receipt of a complete response letter; and

(*3*) At other times as requested by FDA. Before submitting the first such report, applicants are encouraged to consult with FDA regarding further details on its form and content.

* * * * *

(e) * * * (1) Upon request from FDA, the applicant must submit the samples described below to the places identified in the Agency's request. FDA generally will ask applicants to submit samples directly to two or more Agency laboratories that will perform all necessary tests on the samples and validate the applicant's analytical procedures.

* * * * *

(f) * * *

(4) Applicants are invited to meet with FDA before submitting an NDA to discuss the presentation and format of supporting information. If the applicant and FDA agree, the applicant may submit tabulations of patient data and case report forms in an alternate form.

(g) * * *

(3) If an applicant who submits an NDA under section 505(b) of the Federal Food, Drug, and Cosmetic Act obtains a ''right of reference or use,'' as defined under § 314.3(b), to an investigation described in clause (A) of section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act, the applicant must include in its NDA a written statement signed by the owner of the data from each such investigation that the applicant may rely on in support of the approval of its NDA, and provide FDA access to, the underlying raw data that provide the basis for the report of the investigation submitted in its NDA.

* * * * *

(i) *Patent certification*—(1) *Contents.* A 505(b)(2) application is required to contain the following:

(i) *Patents claiming drug substance, drug product, or method of use.* (A) A certification with respect to each patent issued by the U.S. Patent and Trademark Office that, in the opinion of the applicant and to the best of its knowledge, claims the drug substance or drug product on which investigations that are relied upon by the applicant for approval of its 505(b)(2) application were conducted or that claims an approved use for such drug and for which information is required to be filed under section 505(b) and (c) of the Federal Food, Drug, and Cosmetic Act and § 314.53. For each such patent, the applicant must provide the patent number and certify, in its opinion and to the best of its knowledge, one of the following circumstances:

(*1*) That the patent information has not been submitted to FDA. The applicant must entitle such a certification ''Paragraph I Certification'';

(*2*) That the patent has expired. The applicant must entitle such a certification ''Paragraph II Certification'';

(*3*) The date on which the patent will expire. The applicant must entitle such a certification ''Paragraph III Certification''; or

(*4*) That the patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the drug product for which the 505(b)(2) application is submitted. The applicant must entitle such a certification ''Paragraph IV Certification''. This certification must be submitted in the following form:

> I, (*name of applicant*), certify that Patent No. _____ (*is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of*) (*name of proposed drug product*) for which this 505(b)(2) application is submitted.

The certification must be accompanied by a statement that the applicant will comply with the requirements under § 314.52(a) with respect to providing a notice to each owner of the patent or its representative and to the holder of the approved NDA for the drug product which is claimed by the patent or a use of which is claimed by the patent and with the requirements under § 314.52(b) with respect to sending the notice and under § 314.52(c) with respect to the content of the notice.

(B) If the drug on which investigations that are relied upon by the applicant were conducted is itself a licensed generic drug of a patented drug first approved under section 505(b) of the Federal Food, Drug, and Cosmetic Act, the appropriate patent certification under this section with respect to each patent that claims the first-approved patented drug or that claims an approved use for such a drug.

(C) If, before the date of submission of the 505(b)(2) application, there is an approved drug product that is pharmaceutically equivalent to the drug product for which the 505(b)(2) application is submitted, an appropriate patent certification under this section with respect to each patent that claims the drug substance or drug product or that claims an approved use for such drug.

(ii) *No relevant patents.* If, in the opinion of the applicant and to the best of its knowledge, there are no patents described in paragraph (i)(1)(i) of this section, a certification in the following form:

> In the opinion and to the best knowledge of (*name of applicant*), there are no patents that claim the drug or drugs on which investigations that are relied upon in this 505(b)(2) application were conducted or that claim a use of such drug or drugs.

(iii) *Method-of-use patent.* (A) If information that is submitted under section 505(b) or (c) of the Federal Food, Drug, and Cosmetic Act and § 314.53 is for a method-of-use patent, and the labeling for the drug product for which the applicant is seeking approval does not include any indications or other conditions of use that are covered by the use patent, a statement explaining that the method-of-use patent does not claim any of the proposed indications or other conditions of use.

(B) If the labeling of the drug product for which the applicant is seeking approval includes an indication or other condition of use that, according to the patent information submitted under section 505(b) or (c) of the Federal Food, Drug, and Cosmetic Act and § 314.53 or in the opinion of the applicant, is claimed by a use patent, the applicant must submit an applicable certification under paragraph (i)(1)(i) of this section.

(2) [Reserved]

(3) *Licensing agreements.* If a 505(b)(2) application is for a drug or method of using a drug claimed by a patent and the applicant has a licensing agreement with the patent owner, the applicant must submit a certification under paragraph (i)(1)(i)(A)(*4*) of this section (''Paragraph IV Certification'') as to that patent and a statement that it has been granted a patent license. If the patent owner consents to approval of the 505(b)(2) application (if otherwise justified) as of a specific date, the 505(b)(2) application must contain a written statement from the patent owner that it has a licensing agreement with

the applicant and that it consents to approval of the 505(b)(2) application as of a specific date.

(4) *Untimely filing of patent information.* If a patent described in paragraph (i)(1)(i) of this section is issued and the holder of the approved NDA for the patented drug does not file with FDA the required information on the patent within 30 days of issuance of the patent, an applicant who submitted a 505(b)(2) application that, before the submission of the patent information, contained an appropriate patent certification is not required to submit an amended certification to address the patent that is late-listed with respect to the pending 505(b)(2) application. Except as provided in § 314.53(f)(1), an NDA holder's amendment to the description of the approved method(s) of use claimed by the patent will be considered untimely filing of patent information if:

(i) The amendment is submitted more than 30 days after patent issuance and it is not related to a corresponding change in approved product labeling; or

(ii) The amendment is submitted more than 30 days after a corresponding change in approved product labeling. An applicant whose 505(b)(2) application is filed after the NDA holder's untimely filing of patent information or whose 505(b)(2) application was previously filed but did not contain an appropriate patent certification at the time of the patent submission must submit a certification under paragraph (i)(1)(i) of this section or a statement under paragraph (i)(1)(iii) of this section as to that patent.

(5) *Disputed patent information.* If an applicant disputes the accuracy or relevance of patent information submitted to FDA, the applicant may seek a confirmation of the correctness of the patent information in accordance with the procedures under § 314.53(f). Unless the patent information is withdrawn or changed, the applicant must submit an appropriate certification for each relevant patent.

(6) *Amended certifications.* A certification submitted under paragraphs (i)(1)(i) through (i)(1)(iii) of this section may be amended at any time before the approval of the 505(b)(2) application. An applicant must submit an amended certification as an amendment to a pending 505(b)(2) application. If an applicant with a pending 505(b)(2) application voluntarily makes a patent certification for an untimely filed patent, the applicant may withdraw the patent certification for the untimely filed patent. Once an amendment for the change in certification has been submitted, the 505(b)(2) application will no longer be considered to be one containing the prior certification.

(i) *After finding of infringement.* An applicant who has submitted a paragraph IV certification and is sued for patent infringement must submit an amendment to change its certification if a court enters a final decision from which no appeal has been or can be taken, or signs a settlement order or consent decree in the action that includes a finding that the patent is infringed, unless the final decision, settlement order, or consent decree also finds the patent to be invalid. In its amendment, the applicant must certify under paragraph (i)(1)(i)(A)(*3*) of this section that the patent will expire on a specific date or, with respect to a patent claiming a method of use, the applicant may instead provide a statement under paragraph (i)(1)(iii) of this section if the applicant amends its 505(b)(2) application such that the applicant is no longer seeking approval for a method of use claimed by the patent.

(ii) *After request to remove a patent or patent information from the list.* If the list reflects that an NDA holder has requested that a patent be removed from the list and no ANDA applicant is eligible for 180-day exclusivity based on a paragraph IV certification to that patent, the patent will be removed and any applicant with a pending 505(b)(2) application (including a tentatively approved 505(b)(2) application) who has made a certification with respect to such patent must submit an amendment to withdraw its certification. In the amendment, the applicant must state the reason for withdrawing the certification (that the patent has been removed from the list). If the list reflects that an NDA holder has requested that a patent be removed from the list and one or more first applicants are eligible for 180-day exclusivity based on a paragraph IV certification to that patent, the patent shall remain listed until any 180-day exclusivity is extinguished. A 505(b)(2) applicant is not required to provide or maintain a certification to a patent that remains listed only for purposes of a first applicant's 180-day exclusivity for its ANDA. Once an amendment to withdraw the certification has been submitted, the 505(b)(2) application will no longer be considered to be one containing a paragraph IV certification to the patent. If removal of a patent from the list results in there being no patents listed for the listed drug(s) identified in the 505(b)(2) application, the applicant must submit an amended certification reflecting that there are no listed patents.

(iii) *Other amendments.* (A) Except as provided in paragraphs (i)(4) and (i)(6)(iii)(B) of this section:

(*1*) An applicant must amend a submitted certification if, at any time before the approval of the 505(b)(2) application, the applicant learns that the submitted certification is no longer accurate; and

(*2*) An applicant must submit a certification or statement under paragraph (i)(1) of this section if, after submission of the 505(b)(2) application, a new patent is issued by the U.S. Patent and Trademark Office that, in the opinion of the applicant and to the best of its knowledge, claims a listed drug relied upon or that claims an approved use for such listed drug for which information is required to be filed under section 505(b) and (c) of the Federal Food, Drug, and Cosmetic Act and § 314.53.

(B) An applicant is not required to submit a supplement to change a submitted certification when information on an otherwise applicable patent is submitted after the approval of the 505(b)(2) application, except as provided in § 314.70(i).

(j) * * *

(4) If the applicant claims exclusivity under § 314.108(b)(4) or (b)(5), the following information to show that the NDA contains ''new clinical investigations'' that are ''essential to approval of the application or supplement'' and ''were conducted or sponsored by the applicant'':

* * * * *

(iii) * * * If the applicant was the sponsor named in the Form FDA 1571 for an IND under which the new clinical investigation(s) that is essential to the approval of its NDA was conducted, identification of the IND by number. If the applicant was not the sponsor of the IND under which the clinical investigation(s) was conducted, a certification that the applicant or its predecessor in interest provided substantial support for the clinical investigation(s) that is essential to the approval of its NDA, and information supporting the certification. * * *

* * * * *

(l) * * *

(3) *Field copy.* The applicant must submit a field copy of the NDA that contains the technical section described in paragraph (d)(1) of this section, a copy of the application form required under paragraph (a) of this section, a copy of the summary required under paragraph (c) of this section, and a certification that the field copy is a true copy of the technical section described in paragraph (d)(1) of this section

contained in the archival and review copies of the NDA.

* * * * *

■ 4. Section 314.52 is revised to read as follows:

§ 314.52 Notice of certification of invalidity or noninfringement of a patent.

(a) *Notice of certification.* For each patent that claims the listed drug or drugs relied upon or that claims a use for such listed drug or drugs and for which the applicant submits a paragraph IV certification, the applicant must send notice of such certification by registered or certified mail, return receipt requested, or by a designated delivery service, as defined in paragraph (g) of this section to each of the following persons:

(1) Each owner of the patent that is the subject of the certification or the representative designated by the owner to receive the notice. The name and address of the patent owner or its representative may be obtained from the U.S. Patent and Trademark Office; and

(2) The holder of the approved NDA under section 505(b) of the Federal Food, Drug, and Cosmetic Act for each drug product which is claimed by the patent or a use of which is claimed by the patent and for which the applicant is seeking approval, or, if the NDA holder does not reside or maintain a place of business within the U.S., the NDA holder's attorney, agent, or other authorized official. The name and address of the NDA holder or its attorney, agent, or authorized official may be obtained from the Orange Book Staff, Office of Generic Drugs, 7620 Standish Pl., Rockville, MD 20855.

(3) This paragraph does not apply to a use patent that does not claim a use for which the applicant is seeking approval.

(4) An applicant may send notice by an alternative method only if FDA has agreed in advance that the method will produce an acceptable form of documentation.

(b) *Sending the notice.* (1) Except as provided under paragraph (d) of this section, the applicant must send the notice required by paragraph (a) of this section on or after the date it receives a paragraph IV acknowledgment letter from FDA, but not later than 20 days after the date of the postmark on the paragraph IV acknowledgment letter. The 20-day clock described in this paragraph begins on the day after the date of the postmark on the paragraph IV acknowledgment letter. When the 20th day falls on Saturday, Sunday, or a Federal holiday, the 20th day will be the next day that is not a Saturday, Sunday, or Federal holiday.

(2) Any notice required by paragraph (a) of this section is invalid if it is sent before the applicant's receipt of a paragraph IV acknowledgment letter. The applicant will not have complied with this paragraph until it sends valid notice.

(3) At the same time it sends the notice required by paragraph (a) of this section, the applicant must submit to FDA an amendment to its 505(b)(2) application that includes a statement certifying that the notice has been provided to each person identified under paragraph (a) of this section and that the notice met the content requirement under paragraph (c) of this section. A copy of the notice itself need not be submitted to the Agency.

(c) *Content of a notice.* In the notice, the applicant must cite section 505(b)(3)(D) of the Federal Food, Drug, and Cosmetic Act and must include, but is not limited to, the following information:

(1) A statement that a 505(b)(2) application that contains any required bioavailability or bioequivalence studies has been submitted by the applicant and filed by FDA.

(2) The NDA number.

(3) A statement that the applicant has received the paragraph IV acknowledgment letter for the 505(b)(2) application.

(4) The established name, if any, as defined in section 502(e)(3) of the Federal Food, Drug, and Cosmetic Act, of the proposed drug product.

(5) The active ingredient, strength, and dosage form of the proposed drug product.

(6) The patent number and expiration date of each patent on the list alleged to be invalid, unenforceable, or not infringed.

(7) A detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed. The applicant must include in the detailed statement:

(i) For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed.

(ii) For each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.

(8) If the applicant alleges that the patent will not be infringed and the applicant may later decide to file a civil action for declaratory judgment in accordance with section 505(c)(3)(D) of the Federal Food, Drug, and Cosmetic Act, then the notice must be accompanied by an offer of confidential access to the 505(b)(2) application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the paragraph IV certification.

(9) If the applicant does not reside or have a place of business in the United States, the name and address of an agent in the United States authorized to accept service of process for the applicant.

(d) *Amendment or supplement to a 505(b)(2) application.* (1) If, after receipt of an acknowledgment letter or paragraph IV acknowledgment letter, an applicant submits an amendment or supplement to its 505(b)(2) application that includes a paragraph IV certification, the applicant must send the notice required by paragraph (a) of this section at the same time that the amendment or supplement to the 505(b)(2) application is submitted to FDA, regardless of whether the applicant has already given notice with respect to another such certification contained in the 505(b)(2) application or in an amendment or supplement to the 505(b)(2) application.

(2) If, before receipt of a paragraph IV acknowledgment letter, an applicant submits a paragraph IV certification in an amendment, the applicant must send the notice required by paragraph (a) of this section in accordance with the procedures in paragraph (b) of this section.

(3) An applicant that submits an amendment or supplement to seek approval of a different strength must provide notice of any paragraph IV certification in accordance with paragraphs (d)(1) or (d)(2) of this section, as applicable.

(e) *Documentation of timely sending and receipt of notice.* The applicant must amend its 505(b)(2) application to provide documentation of the date of receipt of the notice required under paragraph (a) of this section by each person provided the notice. The amendment must be submitted to FDA within 30 days after the last date on which notice was received by a person described in paragraph (a) of this section. The applicant's amendment also must include documentation that its notice was sent on a date that complies with the timeframe required by paragraph (b) or paragraph (d) of this section, as applicable. FDA will accept, as adequate documentation of the date the notice was sent, a copy of the registered mail receipt, certified mail receipt, or receipt from a designated delivery service, as defined in paragraph (g) of this section. FDA will accept as adequate documentation of the date of receipt a return receipt, a signature proof of delivery by a designated

delivery service, or a letter acknowledging receipt by the person provided the notice. An applicant may rely on another form of documentation only if FDA has agreed to such documentation in advance. A copy of the notice itself need not be submitted to the Agency.

(f) *Approval.* If the requirements of this section are met, the Agency will presume the notice to be complete and sufficient and will count the day following the date of receipt of the notice by the patent owner or its representative and by the approved NDA holder as the first day of the 45-day period provided for in section 505(c)(3)(C) of the Federal Food, Drug, and Cosmetic Act. FDA may, if the applicant amends its 505(b)(2) application with a written statement that a later date should be used, count from such later date.

(g) *Designated delivery services.* (1) For purposes of this section, the term ''designated delivery service'' is any delivery service provided by a trade or business that the Agency determines:

(i) Is available to the general public throughout the United States;

(ii) Records electronically to its database, kept in the regular course of its business, or marks on the cover in which any item referred to in this section is to be delivered, the date on which such item was given to such trade or business for delivery; and

(iii) Provides overnight or 2-day delivery service throughout the United States.

(2) FDA will periodically issue guidance regarding designated delivery services that meet these criteria.

■ 5. Section 314.53 is revised to read as follows:

§ 314.53 Submission of patent information.

(a) *Who must submit patent information.* This section applies to any applicant who submits to FDA an NDA or an amendment to it under section 505(b) of the Federal Food, Drug, and Cosmetic Act and § 314.50 or a supplement to an approved NDA under § 314.70, except as provided in paragraph (d)(2) of this section.

(b) *Patents for which information must be submitted and patents for which information must not be submitted*—(1) *General requirements.* An applicant described in paragraph (a) of this section must submit the required information, on the required FDA declaration form, set forth in paragraph (c) of this section for each patent that claims the drug or a method of using the drug that is the subject of the NDA or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. For purposes of this part, such patents consist of drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents. For patents that claim the drug substance, the applicant must submit information only on those patents that claim the drug substance that is the subject of the pending or approved NDA or that claim a drug substance that is the same as the active ingredient that is the subject of the approved or pending NDA. For patents that claim only a polymorph that is the same as the active ingredient described in the approved or pending NDA, the applicant must certify in the required FDA declaration form that the applicant has test data, as set forth in paragraph (b)(2) of this section, demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA. For patents that claim a drug product, the applicant must submit information only on those patents that claim a drug product, as is defined in § 314.3, that is described in the pending or approved application. For patents that claim a method of use, the applicant must submit information only on those patents that claim indications or other conditions of use for which approval is sought or has been granted in the NDA. The applicant must separately identify each pending or approved method of use and related patent claim(s). For approved NDAs, the applicant submitting the method-of-use patent must identify with specificity the section of the approved labeling that corresponds to the method of use claimed by the patent submitted. If the scope of the method-of-use claim(s) of the patent does not cover every use of the drug, the applicant must only identify the specific portion(s) of the indication or other condition of use claimed by the patent. Process patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates are not covered by this section, and information on these patents must not be submitted to FDA.

(2) *Test data for submission of patent information for patents that claim only a polymorph.* The test data, referenced in paragraph (b)(1) of this section, must include the following:

(i) A full description of the polymorphic form of the drug substance, including its physical and chemical characteristics and stability; the method of synthesis (or isolation) and purification of the drug substance; the process controls used during manufacture and packaging; and such specifications and analytical methods as are necessary to assure the identity, strength, quality, and purity of the polymorphic form of the drug substance;

(ii) The executed batch record for a drug product containing the polymorphic form of the drug substance and documentation that the batch was manufactured under current good manufacturing practice requirements;

(iii) Demonstration of bioequivalence between the executed batch of the drug product that contains the polymorphic form of the drug substance and the drug product as described in the NDA;

(iv) A list of all components used in the manufacture of the drug product containing the polymorphic form and a statement of the composition of the drug product; a statement of the specifications and analytical methods for each component; a description of the manufacturing and packaging procedures and in-process controls for the drug product; such specifications and analytical methods as are necessary to assure the identity, strength, quality, purity, and bioavailability of the drug product, including release and stability data complying with the approved product specifications to demonstrate pharmaceutical equivalence and comparable product stability; and

(v) Comparative in vitro dissolution testing on 12 dosage units each of the executed test batch and the NDA product.

(c) *Reporting requirements*—(1) *General requirements.* An applicant described in paragraph (a) of this section must submit the required patent information described in paragraph (c)(2) of this section for each patent that meets the requirements described in paragraph (b) of this section. We will not accept the patent information unless it is submitted on the appropriate form, Form FDA 3542 or 3542a, and contains the information required in paragraph (c)(2) of this section. These forms may be obtained on the Internet at *http://www.fda.gov* by searching for ''forms''.

(2) *Drug substance (active ingredient), drug product (formulation or composition), and method-of-use patents*—(i) *Original declaration.* For each patent that claims a drug substance (active ingredient), drug product (formulation and composition), or method of use, the applicant must submit Form FDA 3542a. The following information and verification is required, subject to the exceptions listed in paragraph (c)(2)(i)(S) of this section:

(A) NDA number;

(B) Name of NDA sponsor;

(C) Trade name (or proposed trade name) of new drug;

(D) Active ingredient(s) of new drug;

(E) Strength(s) of new drug;

(F) Dosage form of new drug;

(G) U.S. patent number, issue date, and expiration date of patent submitted;

(H) The patent owner's name, full address, phone number and, if available, fax number and email address;

(I) The name, full address, phone number and, if available, fax number and email address of an agent or representative who resides or maintains a place of business within the United States authorized to receive notice of patent certification under section 505(b)(3) and (j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and §§ 314.52 and 314.95 (if patent owner or NDA applicant or holder does not reside or have a place of business within the United States);

(J) Information on whether the patent is a reissued patent of a patent submitted previously for listing for the NDA or supplement;

(K) Information on whether the expiration date is a new expiration date if the patent had been submitted previously for listing;

(L) Information on whether the patent is a product-by-process patent in which the product claimed is novel;

(M) Information on the drug substance (active ingredient) patent, including the following:

(*1*) Whether the patent claims the drug substance that is the active ingredient in the drug product described in the NDA or supplement;

(*2*) Whether the patent claims only a polymorph that is the same active ingredient that is described in the pending NDA or supplement;

(*3*) Whether the applicant has test data, described in paragraph (b)(2) of this section, demonstrating that a drug product containing only the polymorph will perform the same as the drug product described in the NDA or supplement, and a description of the polymorphic form(s) claimed by the patent for which such test data exist;

(*4*) Whether the patent claims only a metabolite of the active ingredient; and

(*5*) Whether the patent claims only an intermediate;

(N) Information on the drug product (composition/formulation) patent, including the following:

(*1*) Whether the patent claims the drug product for which approval is being sought, as defined in § 314.3; and

(*2*) Whether the patent claims only an intermediate;

(O) Information on each method-of-use patent, including the following:

(*1*) Whether the patent claims one or more methods of using the drug product for which use approval is being sought and a description of each pending method of use or related indication and related patent claim of the patent being submitted;

(*2*) Identification of the specific section(s) of the proposed labeling for the drug product that corresponds to the method of use claimed by the patent submitted (if the scope of the method-of-use claim(s) of the patent does not cover every use of the drug, the applicant must only identify the specific portion(s) of the indication or other condition of use claimed by the patent); and

(*3*) An applicant that submits information for a patent that claims one or more methods of using the drug product must also submit information described in either paragraph (c)(2)(i)(M) or (c)(2)(i)(N) of this section, regarding whether that patent also claims either the drug substance (active ingredient) or the drug product (composition/formulation).

(P) Whether there are no relevant patents that claim the drug substance (active ingredient), drug product (formulation or composition), or method(s) of use, for which the applicant is seeking approval and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product;

(Q) A signed verification that states:

The undersigned declares that this is an accurate and complete submission of patent information for the NDA, amendment, or supplement pending under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct.;

and

(R) Information on whether the applicant, patent owner or attorney, agent, representative, or other authorized official signed the form; the name of the person; and the full address, phone number and, if available, the fax number and email address.

(S) Exceptions to required submission of patent information:

(*1*) If an applicant submits the information described in paragraph (c)(2)(i)(M) of this section for a patent that claims the drug substance (active ingredient) and meets the requirements for listing on that basis, then the applicant is not required to provide the information described in paragraph (c)(2)(i)(N) of this section on whether that patent also claims the drug product (composition/formulation).

(*2*) If an applicant submits the information described in paragraph (c)(2)(i)(N) of this section for a patent that claims the drug product (composition/formulation) and meets the requirements for listing on that basis, then the applicant is not required to provide the information described in paragraph (c)(2)(i)(M) of this section on whether that patent also claims the drug substance (active ingredient).

(ii) *Submission of patent information upon and after approval.* Within 30 days after the date of approval of its NDA or supplement, the applicant must submit Form FDA 3542 for each patent that claims the drug substance (active ingredient), drug product (formulation and composition), or approved method of use. FDA will rely only on the information submitted on this form and will not list or publish patent information if the patent declaration is incomplete or indicates the patent is not eligible for listing. Patent information must also be submitted for patents issued after the date of approval of the NDA as required in paragraph (c)(2)(ii) of this section. As described in paragraph (d)(3) of this section, to be timely filed, patent information for patents issued after the date of approval of the NDA must be submitted to FDA within 30 days of the date of issuance of the patent. If the applicant submits the required patent information within the 30 days, but we notify an applicant that a declaration form is incomplete or shows that the patent is not eligible for listing, the applicant must submit an acceptable declaration form within 15 days of FDA notification to be considered timely filed. The following information and verification statement is required, subject to the exceptions listed in paragraph (c)(2)(ii)(T) of this section:

(A) NDA number;

(B) Name of NDA sponsor;

(C) Trade name of new drug;

(D) Active ingredient(s) of new drug;

(E) Strength(s) of new drug;

(F) Dosage form of new drug;

(G) Approval date of NDA or supplement;

(H) U.S. patent number, issue date, and expiration date of patent submitted;

(I) The patent owner's name, full address, phone number and, if available, fax number and email address;

(J) The name, full address, phone number and, if available, fax number and email address of an agent or representative who resides or maintains

a place of business within the United States authorized to receive notice of patent certification under section 505(b)(3) and (j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and §§ 314.52 and 314.95 (if patent owner or NDA applicant or holder does not reside or have a place of business within the United States);

(K) Information on whether the patent is a reissued patent of a patent submitted previously for listing for the NDA or supplement;

(L) Information on whether the expiration date is a new expiration date if the patent had been submitted previously for listing;

(M) Information on whether the patent is a product-by-process patent in which the product claimed is novel;

(N) Information on the drug substance (active ingredient) patent, including the following:

(*1*) Whether the patent claims the drug substance that is the active ingredient in the drug product described in the approved NDA;

(*2*) Whether the patent claims only a polymorph that is the same as the active ingredient that is described in the approved NDA;

(*3*) Whether the applicant has test data, described in paragraph (b)(2) of this section, demonstrating that a drug product containing only the polymorph will perform the same as the drug product described in the approved NDA and a description of the polymorphic form(s) claimed by the patent for which such test data exist;

(*4*) Whether the patent claims only a metabolite of the active ingredient; and

(*5*) Whether the patent claims only an intermediate;

(O) Information on the drug product (composition/formulation) patent, including the following:

(*1*) Whether the patent claims the approved drug product as defined in § 314.3; and

(*2*) Whether the patent claims only an intermediate;

(P) Information on each method-of-use patent, including the following:

(*1*) Whether the patent claims one or more approved methods of using the approved drug product and a description of each approved method of use or indication and related patent claim of the patent being submitted;

(*2*) Identification of the specific section(s) of the approved labeling for the drug product that corresponds to the method of use claimed by the patent submitted (if the scope of the method-of-use claim(s) of the patent does not cover every use of the drug, the applicant must only identify the specific portion(s) of the indication or other condition of use claimed by the patent);

(*3*) The description of the patented method of use as required for publication (which must contain adequate information to assist 505(b)(2) and ANDA applicants in determining whether a listed method-of-use patent claims a use for which the 505(b)(2) or ANDA applicant is not seeking approval; for example, if the scope of the method-of-use claim(s) of the patent does not cover every approved use of the drug, then the description of the patented method of use must contain only the specific portion(s) of the indication or other method of use claimed by the patent); and

(*4*) An applicant that submits information for a patent that claims one or more methods of using the drug product must also submit information described in either paragraph (c)(2)(ii)(N) or (c)(2)(ii)(O) of this section, regarding whether that patent also claims either the drug substance (active ingredient) or the drug product (composition/formulation).

(Q) Whether there are no relevant patents that claim the approved drug substance (active ingredient), the approved drug product (formulation or composition), or approved method(s) of use and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product;

(R) A signed verification that states:

> The undersigned declares that this is an accurate and complete submission of patent information for the NDA, amendment, or supplement approved under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct.;

and

(S) Information on whether the applicant, patent owner or attorney, agent, representative, or other authorized official signed the form; the name of the person; and the full address, phone number and, if available, the fax number and email address.

(T) Exceptions to required submission of patent information:

(*1*) If an applicant submits the information described in paragraph (c)(2)(ii)(N) of this section for a patent that claims the drug substance (active ingredient) and meets the requirements for listing on that basis, then the applicant is not required to provide the information described in paragraph (c)(2)(ii)(O) of this section on whether that patent also claims the drug product (composition/formulation).

(*2*) If an applicant submits the information described in paragraph (c)(2)(ii)(O) of this section for a patent that claims the drug product (composition/formulation) and meets the requirements for listing on that basis, then the applicant is not required to provide the information described in paragraph (c)(2)(ii)(N) of this section on whether that patent also claims the drug substance (active ingredient).

(3) *No relevant patents.* If the applicant believes that there are no relevant patents that claim the drug substance (active ingredient), drug product (formulation or composition), or the method(s) of use for which the applicant has received approval, and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product, the applicant will verify this information in the appropriate forms, Form FDA 3542 or 3542a.

(4) *Authorized signature.* The declarations required by this section must be signed by the applicant or patent owner, or the applicant's or patent owner's attorney, agent (representative), or other authorized official.

(d) *When and where to submit patent information*—(1) *Original NDA.* An applicant must submit with its original NDA submitted under this part, including a 505(b)(2) application, the information described in paragraph (c) of this section on each drug substance (ingredient), drug product (formulation and composition), and method-of-use patent issued before the NDA is filed with FDA and for which patent information is required to be submitted under this section. If a patent is issued after the NDA is filed with FDA but before the NDA is approved, the applicant shall, within 30 days of the date of issuance of the patent, submit the required patent information in an amendment to the NDA under § 314.60.

(2) *Supplements.* (i) An applicant must submit patent information required under paragraph (c) of this section for a patent that claims the drug substance, drug product, or method of use for which approval is sought in any of the following supplements:

(A) To change the dosage form or route of administration;

(B) To change the strength; or

(C) To change the drug product from prescription use to over-the-counter use.

(ii) If the applicant submits a supplement for a change other than one of the changes listed under paragraph (d)(2)(i) of this section (for example, to change the formulation, to add a new indication or other condition of use, or to make any other patented change regarding the drug substance, drug product, or any method of use), the following patent information submission requirements apply:

(A) If existing patents for which information has already been submitted to FDA for the product approved in the original NDA claim the changed product, the applicant is not required to resubmit this patent information unless the description of the patented method of use would change upon approval of the supplement, and FDA will continue to list this patent information for the product;

(B) If one or more existing patents for which information has already been submitted to FDA no longer claim the changed product, the applicant must submit a request to remove that patent information from the list at the time of approval of the supplement;

(C) If one or more existing drug substance (active ingredient), drug product (formulation and composition), or method-of-use patents claim the changed product for which approval is sought in the supplement and such patent information has not been submitted to FDA, the applicant must submit the patent information required under paragraph (c) of this section.

(3) *Newly issued patents.* If a patent is issued for a drug substance, drug product, or method of use after an NDA is approved, the applicant must submit to FDA, as described in paragraph (d)(4) of this section, the required patent information within 30 days of the date of issuance of the patent. If the required patent information is not submitted within 30 days of the issuance of the patent, FDA will list the patent, but patent certifications will be governed by the provisions regarding untimely filed patents at §§ 314.50(i)(4) and (i)(6) and 314.94(a)(12)(vi) and (a)(12)(viii).

(4) *Submission of Forms FDA 3542a and 3542.*

(i) *Patent information submitted with the filing of an NDA, amendment, or supplement.* The applicant must submit patent information required by paragraphs (c)(1) and (c)(2)(i) of this section and § 314.50(h) or § 314.70(f) on Form FDA 3542a to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901–B Ammendale Rd., Beltsville, MD 20705–1266. Form FDA 3542a should not be submitted to the Orange Book Staff in the Office of Generic Drugs.

(ii) *Patent information submitted upon and after approval of an NDA or supplement.* The applicant must submit patent information required by paragraphs (c)(1) and (c)(2)(ii) of this section on Form FDA 3542 to the Office of Generic Drugs, OGD Document Room, Attention: Orange Book Staff, 7620 Standish Pl., Rockville, MD 20855.

(5) *Submission date.* Patent information will be considered to be submitted to FDA for purposes of paragraph (d)(3) of this section as of the earlier of the date the information submitted on Form FDA 3542 is date-stamped by the Office of Generic Drugs, Document Room, or officially received electronically by FDA through the Electronic Submissions Gateway.

(6) *Identification.* Each submission of patent information, except information submitted with an original NDA, must bear prominent identification as to its contents, *i.e.,* ''Patent Information,'' or, if submitted after approval of an NDA, ''Time-Sensitive Patent Information.''

(e) *Public disclosure of patent information.* FDA will publish in the list the patent number and expiration date of each patent that is required to be, and is, submitted to FDA by an applicant, and for each use patent, the approved indications or other conditions of use covered by a patent. FDA will publish such patent information upon approval of the NDA, or, if the patent information is submitted by the applicant after approval of an NDA as provided under paragraph (d)(2) of this section, as soon as possible after the submission to the Agency of the patent information. A request for copies of the submitted patent information must be sent in writing to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. This information, and requests for delisting patents, will be subject to public disclosure.

(f) *Correction or change of patent information*—(1) *Requests by persons other than the NDA holder.* If any person disputes the accuracy or relevance of patent information submitted to the Agency under this section and published by FDA in the list, or believes that an NDA holder has failed to submit required patent information, that person must first notify the Agency in a written or electronic communication titled ''314.53(f) Patent Listing Dispute'' that states the grounds for disagreement. Such notification should be directed to the Office of Generic Drugs, OGD Document Room, Attention: Orange Book Staff, 7620 Standish Pl., Rockville, MD 20855. The Agency will then request of the applicable NDA holder that the correctness of the patent information or omission of patent information be confirmed within 30 days. For listed patents that claim an approved method of using the drug product, FDA will request that the NDA holder confirm the correctness of its description of the approved indication or method of use that has been included as the ''Use Code'' in the Orange Book, and provide information on the specific approved use claimed by the patent that enables the Agency to make a determination in accordance with section 505(b)(2)(B) or 505(j)(2)(C)(viii) of the Federal Food, Drug, and Cosmetic Act. Unless the NDA holder withdraws or amends its patent information in response to FDA's request, the Agency will not change the patent information in the list. If the NDA holder does not change the patent information submitted to FDA, a 505(b)(2) application or an ANDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act submitted for a drug that is claimed by a patent for which information has been submitted must, despite any disagreement as to the correctness of the patent information, contain an appropriate certification for each listed patent. However, if there is insufficient information to make a determination in accordance with section 505(b)(2)(B) or 505(j)(2)(C)(viii) of the Federal Food, Drug, and Cosmetic Act, and the NDA holder has confirmed the correctness of its description of the specific approved use claimed by the patent, the Agency will review the proposed labeling for the 505(b)(2) application or ANDA with deference to the 505(b)(2) or ANDA applicant's interpretation of the scope of the patent.

(2) *Requests by the NDA holder.*—(i) *Patents or patent claims that no longer meet the statutory requirements for listing.* If the NDA holder determines that a patent or patent claim no longer meets the requirements for listing in section 505(b)(1) or 505(c)(2) of the Federal Food, Drug, and Cosmetic Act (including if there has been a judicial finding of invalidity for a listed patent, from which no appeal has been or can be taken), the NDA holder is required to promptly notify FDA to withdraw the patent or patent information and request that the patent or patent information be removed from the list. If the NDA holder is required by court order to amend patent information or withdraw a patent from the list, it must submit a copy of the order, within 14 days of the date the order was entered, to the Office of

Generic Drugs, OGD Document Room, Attention: Orange Book Staff, 7620 Standish Pl., Rockville, MD 20855. FDA will remove a patent from the list if there is no first applicant eligible for 180-day exclusivity or upon the expiration of the 180-day exclusivity period of a first applicant.

(ii) *Patent term restoration.* If the term of a listed patent is extended under 35 U.S.C. 156(e), the NDA holder must submit on Form FDA 3542 a correction to the expiration date of the patent. This correction must be submitted within 30 days of receipt of a certificate of extension as described in 35 U.S.C. 156(e)(1) or documentation of an extension of the term of the patent as described in 35 U.S.C. 156(e)(2).

(iii) *Submission of corrections or changes to patent information.* Corrections or changes to previously submitted patent information, other than withdrawal of a patent and requests to remove a patent from the list, must be submitted on Form FDA 3542 or 3542a, as appropriate. We will not accept the corrections or changes unless they are submitted on the appropriate forms.

(iv) *Submission of patent withdrawals and requests to remove a patent from the list.* Withdrawal of a patent and requests to remove a patent from the list must be submitted to the same addresses described in paragraph (d)(4) of this section, except that the withdrawal or request to remove a patent from the list is not required to be submitted on Form FDA 3542 and may be submitted by letter. Withdrawal of a patent and a request to delist a patent must contain the following information:

(A) The NDA number to which the request applies;

(B) Each product(s) approved in the NDA to which the request applies; and

(C) The patent number.

6. Section 314.54 is amended by removing the word ''shall'' and adding in its place the word ''must'' in paragraph (a)(1) introductory text and paragraph (a)(1)(i) and by revising the section heading, paragraph (a) introductory text, and paragraphs (a)(1)(iii), (a)(1)(vi), (a)(4), and (b) to read as follows:

§ 314.54 Procedure for submission of a 505(b)(2) application requiring investigations for approval of a new indication for, or other change from, a listed drug.

(a) The Federal Food, Drug, and Cosmetic Act does not permit approval of an ANDA for a new indication, nor does it permit approval of other changes in a listed drug if investigations, other than bioavailability or bioequivalence studies, are essential to the approval of the change. Any person seeking approval of a drug product that represents a modification of a listed drug (*e.g.,* a new indication or new dosage form) and for which investigations, other than bioavailability or bioequivalence studies, are essential to the approval of the changes may, except as provided in paragraph (b) of this section, submit a 505(b)(2) application. This 505(b)(2) application need contain only that information needed to support the modification(s) of the listed drug.

(1) * * *

(iii) Identification of each listed drug for which FDA has made a finding of safety and effectiveness and on which finding the applicant relies in seeking approval of its proposed drug product by established name, if any, proprietary name, dosage form, strength, route of administration, name of listed drug's application holder, and listed drug's approved NDA number. The listed drug or drugs identified as relied upon must include any approved drug product that:

(A) Is pharmaceutically equivalent to the drug product for which the 505(b)(2) application is submitted; and

(B) Was approved before the 505(b)(2) application was submitted.

* * * * *

(vi) Any patent certification or statement required under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act with respect to any relevant patents that claim the listed drug or drugs on which investigations relied on by the applicant for approval of the application were conducted, or that claim a use for the listed drug or drug(s).

* * * * *

(4) The applicant must submit a field copy of the 505(b)(2) application that contains the technical section described in § 314.50(d)(1), a copy of the information required under § 314.50(a) and (c), and certification that the field copy is a true copy of the technical section described in § 314.50(d)(1) contained in the archival and review copies of the 505(b)(2) application.

(b) A 505(b)(2) application may not be submitted under this section for a drug product whose only difference from a listed drug is that:

(1) The extent to which its active ingredient(s) is absorbed or otherwise made available to the site of action is less than that of the listed drug; or

(2) The rate at which its active ingredient(s) is absorbed or otherwise made available to the site of action is unintentionally less than that of the listed drug.

■ 7. Section 314.60 is amended by:

■ a. Removing the word ''application'' each time it appears and adding in its place ''NDA'';

■ b. Removing ''(505)(c)(3)(D)(ii)'' in paragraphs (c)(1)(i) and (c)(2) and adding in its place ''(505)(c)(3)(E)(ii)'';

■ c. Adding paragraph headings in paragraphs (a), (b), and (c);

■ d. Revising the section heading and paragraph (d); and

■ e. Adding new paragraphs (e) and (f).

The revisions read as follows:

§ 314.60 Amendments to an unapproved NDA, supplement, or resubmission.

(a) *Submission of NDA.* * * *

(b) *Submission of major amendment.* * * *

(c) *Limitation on certain amendments.* * * *

(d) *Field copy.* The applicant must submit a field copy of each amendment to a section of the NDA described in § 314.50(d)(1). The applicant must include in its submission of each such amendment to FDA a statement certifying that a field copy of the amendment has been sent to the applicant's home FDA district office.

(e) *Different drug.* An applicant may not amend a 505(b)(2) application to seek approval of a drug that is a different drug from the drug in the original submission of the 505(b)(2) application. For purposes of this section, a drug is a different drug if it has been modified to have a different active ingredient, different route of administration, different dosage form, or difference in excipients that requires either a separate clinical study to establish safety or effectiveness or, for topical products, that requires a separate in vivo demonstration of bioequivalence. However, notwithstanding the limitation described in this paragraph, an applicant may amend the 505(b)(2) application to seek approval of a different strength.

(f) *Patent certification requirements.* An amendment to a 505(b)(2) application is required to contain patent certifications described in § 314.50(i) if approval is sought for any of the following types of amendments:

(1) To add a new indication or other condition of use;

(2) To add a new strength;

(3) To make other than minor changes in product formulation; or

(4) To change the physical form or crystalline structure of the active ingredient.

■ 8. Section 314.70 is amended by:

■ a. Removing the word ''application'' each time it appears and adding in its place ''NDA'';

■ b. Removing the words ''cover letter'' in paragraph (a)(6), and adding in their place the word ''submission'';

■ c. Removing the words ''and its mailing cover'' in paragraph (b)(4);

■ d. Revising the section heading and paragraph (f); and

■ e. Adding paragraphs (h) and (i).

The revisions read as follows:

§ 314.70 Supplements and other changes to an approved NDA.

* * * * *

(f) *Patent information.* The applicant must comply with the patent information requirements under section 505(c)(2) of the Federal Food, Drug, and Cosmetic Act and § 314.53.

* * * * *

(h) *Different drug.* An applicant may not supplement a 505(b)(2) application to seek approval of a drug that is a different drug from the drug in the approved 505(b)(2) application. For purposes of this section, a drug is a different drug if it has been modified to have a different active ingredient, different route of administration, different dosage form, or difference in excipients that requires either a separate clinical study to establish safety or effectiveness or, for topical products, that requires a separate in vivo demonstration of bioequivalence. However, notwithstanding the limitation described in this paragraph, an applicant may supplement the 505(b)(2) application to seek approval of a different strength.

(i) *Patent certification requirements.* (1) Except as provided in paragraph (i)(2) of this section, a supplement to a 505(b)(2) application is required to contain patent certifications described in § 314.50(i) if approval is sought for either of the following types of supplements:

(i) To add a new indication or other condition of use; or

(ii) To add a new strength.

(2) A supplement to a 505(b)(2) application that only seeks approval to add a new indication or other condition of use is required to contain patent certifications described in § 314.50(i) only for patents that are identified as claiming an approved use. If a method-of-use patent is identified as also claiming the drug substance or drug product, the patent certification also must address the drug substance and/or drug product claims.

■ 9. Section 314.90 is amended by removing the word ''application'' each time it appears and adding in its place ''NDA'' and by adding paragraph (c) to read as follows:

§ 314.90 Waivers.

* * * * *

(c) If FDA grants the applicant's waiver request with respect to a requirement under §§ 314.50 through 314.81, the waived requirement will not constitute a basis for refusal to approve an NDA under § 314.125.

■ 10. Section 314.93 is amended by:

■ a. Removing the words ''abbreviated new drug applications'' in paragraph (a) and adding in their place ''ANDAs'';

■ b. Removing the words ''abbreviated new drug application'' in paragraphs (b), (c), and (e)(3) and adding in their place ''ANDA'';

■ c. Removing the word ''or'' from the end of paragraph (e)(1)(iv) ;

■ d. Removing ''reasons.'' in paragraph (e)(1)(v) and adding in its place ''reasons; or'';

■ e. Adding paragraph (e)(1)(vi);

■ f. Redesignating paragraph (f) as paragraph (f)(1); and

■ g. Adding paragraph (f)(2).

The revisions read as follows:

§ 314.93 Petition to request a change from a listed drug.

* * * * *

(e) * * *

(1) * * *

(vi) A drug product is approved in an NDA for the change described in the petition.

* * * * *

(f) * * *

(2) If, after approval of a petition and before approval of an ANDA submitted pursuant to the approved petition, a drug product is approved in an NDA for the change described in the petition, the petition and the listed drug identified in the petition can no longer be the basis for ANDA submission, irrespective of whether FDA has withdrawn approval of the petition. A person seeking approval for such drug product must submit a new ANDA that identifies the pharmaceutically equivalent reference listed drug as the basis for ANDA submission and comply with applicable regulatory requirements.

■ 11. Section 314.94 is amended by:

■ a. Removing the words ''abbreviated application'' in paragraphs (a)(5)(ii)(A), (a)(6)(ii), (d)(1)(i), and (d)(4) each time they appear and adding in their place ''ANDA'';

■ b. Removing the word ''shall'' in paragraphs (a)(9)(i) through (a)(9)(iv), (a)(12)(i)(A)(*1*) through (a)(12)(i)(A)(*3*), and (a)(12)(vii) each time it appears and adding in its place the word ''must'';

■ c. Removing and reserving paragraph (a)(12)(iv); and

■ d. Revising the section heading and the introductory text, paragraph (a) heading and introductory text, paragraphs (a)(1) and (a)(2), paragraph (a)(3) heading and introductory text, paragraphs (a)(3)(i), (a)(3)(iii), the first sentence of paragraph (a)(7)(ii), paragraphs (a)(7)(iii), (a)(8)(i),(a)(9)(v), paragraph (a)(12)(i)(A) introductory text, paragraphs (a)(12)(i)(A)(*4*), (a)(12)(i)(B), (a)(12)(iii)(A), (a)(12)(iii)(B), (a)(12)(v), (a)(12)(vi), (a)(12)(viii), (a)(13), (b), paragraph (d) heading, paragraph (d)(1) introductory text, and paragraphs (d)(2) and (d)(5).

The revisions read as follows:

§ 314.94 Content and format of an ANDA.

ANDAs are required to be submitted in the form and contain the information required under this section. Three copies of the application are required, an archival copy, a review copy, and a field copy. FDA will maintain guidance documents on the format and content of applications to assist applicants in their preparation.

(a) *ANDAs.* Except as provided in paragraph (b) of this section, the applicant must submit a complete archival copy of the ANDA that includes the following:

(1) *Application form.* The applicant must submit a completed and signed application form that contains the information described under § 314.50(a)(1), (a)(3), (a)(4), and (a)(5). The applicant must state whether the submission is an ANDA under this section or a supplement to an ANDA under § 314.97.

(2) *Table of contents.* The archival copy of the ANDA is required to contain a table of contents that shows the volume number and page number of the contents of the submission.

(3) *Basis for ANDA submission.* An ANDA must refer to a listed drug. Ordinarily, that listed drug will be the drug product selected by the Agency as the reference standard for conducting bioequivalence testing. The application must contain:

(i) The name of the reference listed drug, including its dosage form and strength. For an ANDA based on an approved petition under § 10.30 of this chapter or § 314.93, the reference listed drug must be the same as the listed drug approved in the petition.

* * * * *

(iii) For an ANDA based on an approved petition under § 10.30 of this chapter or § 314.93, a reference to the FDA-assigned docket number for the petition and a copy of FDA's correspondence approving the petition.

* * * * *

(7) * * *

(ii) If the ANDA is submitted pursuant to a petition approved under § 314.93,

the results of any bioavailability or bioequivalence testing required by the Agency, or any other information required by the Agency to show that the active ingredients of the proposed drug product are of the same pharmacological or therapeutic class as those in the reference listed drug and that the proposed drug product can be expected to have the same therapeutic effect as the reference listed drug. * * *

* * * * *

(iii) For each in vivo or in vitro bioequivalence study contained in the ANDA:

(A) A description of the analytical and statistical methods used in each study; and

(B) With respect to each study involving human subjects, a statement that it either was conducted in compliance with the institutional review board regulations in part 56 of this chapter, or was not subject to the regulations under § 56.104 or § 56.105 of this chapter, and that it was conducted in compliance with the informed consent regulations in part 50 of this chapter.

(8) *Labeling*—(i) *Listed drug labeling.* A copy of the currently approved labeling (including, if applicable, any Medication Guide required under part 208 of this chapter) for the listed drug referred to in the ANDA, if the ANDA relies on a reference listed drug.

* * * * *

(9) * * *

(v) *Inactive ingredient changes permitted in drug products intended for topical use.* Generally, a drug product intended for topical use, solutions for aerosolization or nebulization, and nasal solutions must contain the same inactive ingredients as the reference listed drug identified by the applicant under paragraph (a)(3) of this section. However, an ANDA may include different inactive ingredients provided that the applicant identifies and characterizes the differences and provides information demonstrating that the differences do not affect the safety or efficacy of the proposed drug product.

* * * * *

(12) *Patent certification*—(i) *Patents claiming drug, drug product, or method of use.* (A) A certification with respect to each patent issued by the U.S. Patent and Trademark Office that, in the opinion of the applicant and to the best of its knowledge, claims the reference listed drug or that claims a use of such listed drug for which the applicant is seeking approval under section 505(j) of the Federal Food, Drug, and Cosmetic Act and for which information is required to be filed under section 505(b) and (c) of the Federal Food, Drug, and Cosmetic Act and § 314.53. For each such patent, the applicant must provide the patent number and certify, in its opinion and to the best of its knowledge, one of the following circumstances:

* * * * *

(*4*) That the patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the drug product for which the ANDA is submitted. The applicant shall entitle such a certification ''Paragraph IV Certification''. This certification must be submitted in the following form:

> I, (*name of applicant),* certify that Patent No. _____(*is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of*) (*name of proposed drug product*) for which this application is submitted.

The certification must be accompanied by a statement that the applicant will comply with the requirements under § 314.95(a) with respect to providing a notice to each owner of the patent or their representatives and to the holder of the approved application for the listed drug, with the requirements under § 314.95(b) with respect to sending the notice, and with the requirements under § 314.95(c) with respect to the content of the notice.

(B) If the ANDA refers to a listed drug that is itself a licensed generic product of a patented drug first approved under section 505(b) of the Federal Food, Drug, and Cosmetic Act, the appropriate patent certification under paragraph (a)(12)(i) of this section with respect to each patent that claims the first-approved patented drug or that claims a use for such drug.

* * * * *

(iii) *Method-of-use patent.* (A) If patent information is submitted under section 505(b) or (c) of the Federal Food, Drug, and Cosmetic Act and § 314.53 for a patent claiming a method of using the listed drug, and the labeling for the drug product for which the applicant is seeking approval does not include any indications or other conditions of use that are covered by the use patent, a statement explaining that the method-of-use patent does not claim any of the proposed indications or other conditions of use.

(B) If the labeling of the drug product for which the applicant is seeking approval includes an indication or other condition of use that, according to the patent information submitted under section 505(b) or (c) of the Federal Food, Drug, and Cosmetic Act and § 314.53 or in the opinion of the applicant, is claimed by a use patent, an applicable certification under paragraph (a)(12)(i) of this section.

(iv) [Reserved]

(v) *Licensing agreements.* If the ANDA is for a drug or method of using a drug claimed by a patent and the applicant has a licensing agreement with the patent owner, a paragraph IV certification as to that patent and a statement that it has been granted a patent license.

(vi) *Untimely filing of patent information.* If a patent on the listed drug is issued and the holder of the approved NDA for the listed drug does not file with FDA the required information on the patent within 30 days of issuance of the patent, an applicant who submitted an ANDA for that drug that contained an appropriate patent certification before the submission of the patent information is not required to submit an amended certification to address the patent that is late-listed with respect to the pending ANDA. Except as provided in § 314.53(f)(1), an NDA holder's amendment to the description of the approved method(s) of use claimed by the patent will be considered untimely filing of patent information if:

(A) The amendment is submitted more than 30 days after patent issuance and it is not related to a corresponding change in approved product labeling; or

(B) The amendment is submitted more than 30 days after a corresponding change in approved product labeling. An applicant whose ANDA is submitted after the NDA holder's untimely filing of patent information, or whose pending ANDA was previously submitted but did not contain an appropriate patent certification at the time of the patent submission, must submit a certification under paragraph (a)(12)(i) of this section or a statement under paragraph (a)(12)(iii) of this section as to that patent.

* * * * *

(viii) *Amended certifications.* A certification submitted under paragraphs (a)(12)(i) through (a)(12)(iii) of this section may be amended at any time before the date of approval of the ANDA. If an applicant with a pending ANDA voluntarily makes a patent certification for an untimely filed patent, the applicant may withdraw the patent certification for the untimely filed patent. An applicant must submit an amended certification as an amendment to a pending ANDA. Once an amendment is submitted to change a certification, the ANDA will no longer be considered to contain the prior certification.

(A) *After finding of infringement.* An applicant who has submitted a paragraph IV certification and is sued for patent infringement must submit an amendment to change its certification if a court enters a final decision from which no appeal has been or can be taken, or signs a settlement order or consent decree in the action that includes a finding that the patent is infringed, unless the final decision, settlement order, or consent decree also finds the patent to be invalid. In its amendment, the applicant must certify under paragraph (a)(12)(i)(A)(*3*) of this section that the patent will expire on a specific date. Once an amendment for the change has been submitted, the ANDA will no longer be considered to be one containing a paragraph IV certification to the patent. If a final judgment finds the patent to be invalid and infringed, an amended certification is not required.

(B) *After request to remove a patent or patent information from the list.* If the list reflects that an NDA holder has requested that a patent be removed from the list and no ANDA applicant is eligible for 180-day exclusivity based on a paragraph IV certification to that patent, the patent will be removed and any applicant with a pending ANDA (including a tentatively approved application) who has made a certification with respect to such patent must submit an amendment to withdraw its certification. In the amendment, the applicant must state the reason for withdrawing the certification (that the patent is or has been removed from the list). If the list reflects that an NDA holder has requested that a patent be removed from the list and one or more first applicants are eligible for 180-day exclusivity based on a paragraph IV certification to that patent, the patent shall remain listed until any 180-day exclusivity is extinguished. If one or more first applicants are eligible for 180-day exclusivity based on a paragraph IV certification to a patent that has been reissued, then the first applicant must submit a paragraph IV certification to the reissued patent within 30 days of listing to have lawfully maintained its paragraph IV certification for purposes of eligibility for 180-day exclusivity. After any applicable 180-day exclusivity has been extinguished, the patent will be removed and any applicant with a pending ANDA (including a tentatively approved application) who has made a certification with respect to such patent must submit an amendment to withdraw its certification. Once an amendment to withdraw the certification has been submitted, the ANDA will no longer be considered to be one containing a paragraph IV certification to the patent. If removal of a patent from the list results in there being no patents listed for the listed drug identified in the ANDA, the applicant must submit an amended certification reflecting that there are no listed patents.

(C) *Other amendments.* (*1*) Except as provided in paragraphs (a)(12)(vi) and (a)(12)(viii)(C)(*2*) of this section:

(*i*) An applicant must amend a submitted certification if, at any time before the date of approval of the ANDA, the applicant learns that the submitted certification is no longer accurate; and

(*ii*) An applicant must submit a certification or statement under paragraph (a)(12)(i) of this section if, after submission of the ANDA, a new patent is issued by the U.S. Patent and Trademark Office that, in the opinion of the applicant and to the best of its knowledge, claims the reference listed drug or that claims an approved use for such reference listed drug and for which information is required to be filed under section 505(b) and (c) of the Federal Food, Drug, and Cosmetic Act and § 314.53. For a paragraph IV certification, the certification must not be submitted earlier than the first working day after the day the patent is published in the list.

(*2*) An applicant is not required to submit a supplement to change a submitted certification when information on a patent on the listed drug is submitted after the approval of the ANDA, except as provided in § 314.97(c).

(13) *Financial certification or disclosure statement.* An ANDA must contain a financial certification or disclosure statement as required by part 54 of this chapter.

(b) *Drug products subject to the Drug Efficacy Study Implementation (DESI) review.* If the ANDA is for a duplicate of a drug product that is subject to FDA's DESI review (a review of drug products approved as safe between 1938 and 1962) or other DESI-like review and the drug product evaluated in the review is a listed drug, the applicant must comply with the provisions of paragraph (a) of this section.

(c) [Reserved]

(d) *Format of an ANDA.* (1) The applicant must submit a complete archival copy of the ANDA as required under paragraphs (a) and (c) of this section. FDA will maintain the archival copy during the review of the ANDA to permit individual reviewers to refer to information that is not contained in their particular technical sections of the ANDA, to give other Agency personnel access to the ANDA for official business, and to maintain in one place a complete copy of the ANDA.

* * * * *

(2) For ANDAs, the applicant must submit a review copy of the ANDA that contains two separate sections. One section must contain the information described under paragraphs (a)(2) through (a)(6), (a)(8), and (a)(9) of this section, and section 505(j)(2)(A)(vii) of the Federal Food, Drug, and Cosmetic Act and a copy of the analytical procedures and descriptive information needed by FDA's laboratories to perform tests on samples of the proposed drug product and to validate the applicant's analytical procedures. The other section must contain the information described under paragraphs (a)(3), (a)(7), and (a)(8) of this section. Each of the sections in the review copy is required to contain a copy of the application form described under § 314.50(a).

* * * * *

(5) The applicant must submit a field copy of the ANDA that contains the technical section described in paragraph (a)(9) of this section, a copy of the application form required under paragraph (a)(1) of this section, and a certification that the field copy is a true copy of the technical section described in paragraph (a)(9) of this section contained in the archival and review copies of the ANDA.

■ 12. Section 314.95 is revised to read as follows:

§ 314.95 Notice of certification of invalidity or noninfringement of a patent.

(a) *Notice of certification.* For each patent that claims the listed drug or that claims a use for such listed drug for which the applicant is seeking approval and for which the applicant submits a paragraph IV certification, the applicant must send notice of such certification by registered or certified mail, return receipt requested, or by a designated delivery service, as defined in paragraph (g) of this section to each of the following persons:

(1) Each owner of the patent which is the subject of the certification or the representative designated by the owner to receive the notice. The name and address of the patent owner or its representative may be obtained from the U.S. Patent and Trademark Office; and

(2) The holder of the approved NDA under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the listed drug that is claimed by the patent and for which the applicant is seeking approval or, if the NDA holder does not reside or maintain a place of business

within the United States, the NDA holder's attorney, agent, or other authorized official. The name and address of the NDA holder or its attorney, agent, or authorized official may be obtained from the Orange Book Staff, Office of Generic Drugs, 7620 Standish Pl., Rockville, MD 20855.

(3) This paragraph does not apply to a use patent that does not claim a use for which the applicant is seeking approval.

(4) An applicant may send notice by an alternative method only if FDA has agreed in advance that the method will produce an acceptable form of documentation.

(b) *Sending the notice.* (1) Except as provided under paragraph (d) of this section, the applicant must send the notice required by paragraph (a) of this section on or after the date it receives an acknowledgment letter or a paragraph IV acknowledgment letter from FDA, but not later than 20 days after the date of the postmark on the acknowledgment letter. The 20-day clock described in this paragraph begins on the day after the date of the postmark on the paragraph IV acknowledgment letter. When the 20th day falls on Saturday, Sunday, or a Federal holiday, the 20th day will be the next day that is not a Saturday, Sunday, or Federal holiday.

(2) Any notice required by paragraph (a) of this section is invalid if it is sent before the applicant's receipt of an acknowledgment letter or a paragraph IV acknowledgment letter, or before the first working day after the day the patent is published in the list. The applicant will not have complied with this paragraph until it sends valid notice.

(3) At the same time it sends the notice required by paragraph (a) of this section, the applicant must submit to FDA an amendment to its ANDA that includes a statement certifying that the notice has been provided to each person identified under paragraph (a) of this section and that the notice met the content requirements under paragraph (c) of this section. A copy of the notice itself need not be submitted to the Agency.

(c) *Contents of a notice.* In the notice, the applicant must cite section 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and must include, but is not limited to, the following information:

(1) A statement that FDA has received an ANDA submitted by the applicant containing any required bioavailability or bioequivalence data or information.

(2) The ANDA number.

(3) A statement that the applicant has received the acknowledgment letter or paragraph IV acknowledgment letter for the ANDA.

(4) The established name, if any, as defined in section 502(e)(3) of the Federal Food, Drug, and Cosmetic Act, of the proposed drug product.

(5) The active ingredient, strength, and dosage form of the proposed drug product.

(6) The patent number and expiration date of each listed patent for the reference listed drug alleged to be invalid, unenforceable, or not infringed.

(7) A detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed. The applicant must include in the detailed statement:

(i) For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed.

(ii) For each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.

(8) If the applicant alleges that the patent will not be infringed and the applicant may later decide to file a civil action for declaratory judgment in accordance with section 505(j)(5)(C) of the Federal Food, Drug, and Cosmetic Act, then the notice must be accompanied by an offer of confidential access to the ANDA for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the paragraph IV certification.

(9) If the applicant does not reside or have a place of business in the United States, the name and address of an agent in the United States authorized to accept service of process for the applicant.

(d) *Amendment or supplement to an ANDA.* (1) If, after receipt of a paragraph IV acknowledgment letter, an applicant submits an amendment or supplement to its ANDA that includes a paragraph IV certification, the applicant must send the notice required by paragraph (a) of this section at the same time that the amendment or supplement to the ANDA is submitted to FDA, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(2) If, before receipt of an acknowledgment letter or a paragraph IV acknowledgment letter, an applicant submits an amendment to its ANDA that includes a paragraph IV certification, the applicant must send the notice required by paragraph (a) of this section in accordance with the procedures in paragraph (b) of this section. If an ANDA applicant's notice of its paragraph IV certification is timely provided in accordance with paragraph (b) of this section, FDA will base its determination of whether the applicant is a first applicant on the date of submission of the amendment containing the paragraph IV certification.

(3) An applicant that submits an amendment or supplement to seek approval of a different strength must provide notice of any paragraph IV certification in accordance with paragraph (d)(1) or (d)(2) of this section, as applicable.

(e) *Documentation of timely sending and receipt of notice.* The applicant must amend its ANDA to provide documentation of the date of receipt of the notice required under paragraph (a) of this section by each person provided the notice. The amendment must be submitted to FDA within 30 days after the last date on which notice was received by a person described in paragraph (a) of this section. The applicant's amendment also must include documentation that its notice was sent on a date that complies with the timeframe required by paragraph (b) or paragraph (d) of this section, as applicable, and a dated printout of the entry for the reference listed drug in FDA's ''Approved Drug Products With Therapeutic Equivalence Evaluations'' (the list) that includes the patent that is the subject of the paragraph IV certification. FDA will accept, as adequate documentation of the date the notice was sent, a copy of the registered mail receipt, certified mail receipt, or receipt from a designated delivery service, as defined in paragraph (g) of this section. FDA will accept as adequate documentation of the date of receipt a return receipt, signature proof of delivery by a designated delivery service, or a letter acknowledging receipt by the person who provided the notice. An applicant may rely on another form of documentation only if FDA has agreed to such documentation in advance. A copy of the notice itself need not be submitted to the Agency.

(f) *Approval.* If the requirements of this section are met, FDA will presume the notice to be complete and sufficient, and it will count the day following the date of receipt of the notice by the patent owner or its representative and by the approved application holder as the first day of the 45-day period provided for in section 505(j)(5)(B)(iii) of the Federal Food, Drug, and Cosmetic Act. FDA may, if the applicant provides a written statement to FDA that a later date should be used, count from such later date.

(g) *Designated delivery services.* (1) For purposes of this section, the term ''designated delivery service'' means any delivery service provided by a trade or business that the Agency determines:

(i) Is available to the general public throughout the United States;

(ii) Records electronically to its database, kept in the regular course of its business, or marks on the cover in which any item referred to in this section is to be delivered, the date on which such item was given to such trade or business for delivery; and

(iii) Provides overnight or 2-day delivery service throughout the United States.

(2) FDA will periodically issue guidance regarding designated delivery services that meet these criteria.

■ 13. Section 314.96 is amended by:

■ a. Revising the section heading;

■ b. Removing from the heading of paragraph (a) and from paragraph (a)(1) the words ''abbreviated new drug application'' and adding in their place ''ANDA'';

■ c. Removing from paragraph (a)(1) ''320.1(g)'' and adding in its place ''314.3'';

■ d. Removing from paragraph (b) the word ''shall'' each time it appears and adding in its place the word ''must'';

■ e. Adding a heading to paragraph (b); and

■ f. Adding paragraphs (c) and (d).

The revisions read as follows:

§ 314.96 Amendments to an unapproved ANDA.

* * * * *

(b) *Field copy.* * * *

(c) *Different listed drug.* An applicant may not amend an ANDA to seek approval of a drug referring to a listed drug that is different from the reference listed drug identified in the ANDA. This paragraph applies if, at any time before the approval of the ANDA, a different listed drug is approved that is the pharmaceutical equivalent to the product in the ANDA and is designated as a reference listed drug. This paragraph also applies if changes are proposed in an amendment to the ANDA such that the proposed product is a pharmaceutical equivalent to a different listed drug than the reference listed drug identified in the ANDA. A change of the reference listed drug must be submitted in a new ANDA. However, notwithstanding the limitation described in this paragraph, an applicant may amend the ANDA to seek approval of a different strength.

(d) *Patent certification requirements.* An amendment to an ANDA is required to contain patent certifications described in § 314.94(a)(12) if approval is sought for any of the following types of amendments:

(1) To add a new indication or other condition of use;

(2) To add a new strength;

(3) To make other than minor changes in product formulation; or

(4) To change the physical form or crystalline structure of the active ingredient.

■ 14. Section 314.97 is revised to read as follows:

§ 314.97 Supplements and other changes to an approved ANDA.

(a) *General requirements.* The applicant must comply with the requirements of §§ 314.70 and 314.71 regarding the submission of supplemental applications and other changes to an approved ANDA.

(b) *Different listed drug.* An applicant may not supplement an ANDA to seek approval of a drug referring to a listed drug that is different from the current reference listed drug identified in the ANDA. This paragraph applies if changes are proposed in a supplement to the ANDA such that the proposed product is a pharmaceutical equivalent to a different listed drug than the reference listed drug identified in the ANDA. A change of reference listed drug must be submitted in a new ANDA. However, notwithstanding the limitation described in this paragraph, an applicant may supplement the ANDA to seek approval of a different strength.

(c) *Patent certification requirements.* A supplement to an ANDA is required to contain patent certifications described in § 314.94(a)(12) if approval is sought for either of the following types of supplements:

(1) To add a new indication or other condition of use; or

(2) To add a new strength.

■ 15. Section 314.99 is revised to read as follows:

§ 314.99 Other responsibilities of an applicant of an ANDA.

(a) An applicant must comply with the requirements of § 314.65 regarding withdrawal by the applicant of an unapproved ANDA and § 314.72 regarding a change in ownership of an ANDA.

(b) An applicant may ask FDA to waive under this section any requirement that applies to the applicant under §§ 314.92 through 314.99. The applicant must comply with the requirements for a waiver under § 314.90. If FDA grants the applicant's waiver request with respect to a requirement under §§ 314.92 through 314.99, the waived requirement will not constitute a basis for refusal to approve an ANDA under § 314.127.

■ 16. Section 314.101 is revised to read as follows:

§ 314.101 Filing an NDA and receiving an ANDA.

(a) *Filing an NDA.* (1) Within 60 days after FDA receives an NDA, the Agency will determine whether the NDA may be filed. The filing of an NDA means that FDA has made a threshold determination that the NDA is sufficiently complete to permit a substantive review.

(2) If FDA finds that none of the reasons in paragraphs (d) and (e) of this section for refusing to file the NDA applies, the Agency will file the NDA and notify the applicant in writing. In the case of a 505(b)(2) application that contains a paragraph IV certification, the applicant will be notified via a paragraph IV acknowledgment letter. The date of filing will be the date 60 days after the date FDA received the NDA. The date of filing begins the 180-day period described in section 505(c) of the Federal Food, Drug, and Cosmetic Act. This 180-day period is called the ''filing clock.''

(3) If FDA refuses to file the NDA, the Agency will notify the applicant in writing and state the reason under paragraph (d) or (e) of this section for the refusal. If FDA refuses to file the NDA under paragraph (d) of this section, the applicant may request in writing within 30 days of the date of the Agency's notification an informal conference with the Agency about whether the Agency should file the NDA. If, following the informal conference, the applicant requests that FDA file the NDA (with or without amendments to correct the deficiencies), the Agency will file the NDA over protest under paragraph (a)(2) of this section, notify the applicant in writing, and review it as filed. If the NDA is filed over protest, the date of filing will be the date 60 days after the date the applicant requested the informal conference. The applicant need not resubmit a copy of an NDA that is filed over protest. If FDA refuses to file the NDA under paragraph (e) of this section, the applicant may amend the NDA and resubmit it, and the Agency will make a determination under this section whether it may be filed.

(b) *Receiving an ANDA.* (1) An ANDA will be reviewed after it is submitted to determine whether the ANDA may be received. Receipt of an ANDA means that FDA has made a threshold determination that the ANDA is substantially complete.

(2) If FDA finds that none of the reasons in paragraphs (d) and (e) of this section for considering the ANDA not to have been received applies, the ANDA is substantially complete and the Agency will receive the ANDA and notify the applicant in writing. If an ANDA is determined to be substantially complete, the date of submission is considered to be the date of receipt. In the case of an ANDA that contains a paragraph IV certification, the applicant will be notified via a paragraph IV acknowledgment letter.

(3) If FDA considers the ANDA not to have been received under paragraph (d) or (e) of this section, FDA will notify the applicant. The applicant may then:

(i) Withdraw the ANDA under § 314.99; or

(ii) Amend the ANDA to correct the deficiencies; or

(iii) Take no action, in which case FDA will refuse to receive the ANDA.

(4) If, after an ANDA has been received under paragraph (b)(2) of this section, FDA determines that the applicant did not send notice of a paragraph IV certification as required under § 314.95 within the timeframe specified in paragraph (b) or (d) of that section, the date that the ANDA was submitted will be deemed to be delayed by the number of days by which the timeframe required by § 314.95(b) or (d) was exceeded. When the date as delayed falls on Saturday, Sunday, or a Federal holiday, the filing date will be the next day that is not a Saturday, Sunday, or a Federal holiday.

(c) [Reserved]

(d) *Application deficiencies.* FDA may refuse to file an NDA or may not consider an ANDA to be received if any of the following applies:

(1) The NDA or ANDA does not contain a completed application form.

(2) The NDA or ANDA is not submitted in the form required under § 314.50 or § 314.94.

(3) The NDA or ANDA is incomplete because it does not on its face contain information required under section 505(b) or section 505(j) of the Federal Food, Drug, and Cosmetic Act and § 314.50 or § 314.94.

(4) The applicant fails to submit a complete environmental assessment that addresses each of the items specified in the applicable format under § 25.40 of this chapter or fails to provide sufficient information to establish that the requested action is subject to categorical exclusion under § 25.30 or § 25.31 of this chapter.

(5) The NDA or ANDA does not contain an accurate and complete English translation of each part of the application that is not in English.

(6) The NDA or ANDA does not contain a statement for each nonclinical laboratory study that it was conducted in compliance with the requirements set forth in part 58 of this chapter or, for each study not conducted in compliance with part 58 of this chapter, a brief statement of the reason for the noncompliance.

(7) The NDA or ANDA does not contain a statement for each clinical study that it was conducted in compliance with the institutional review board regulations in part 56 of this chapter or was not subject to those regulations, and that it was conducted in compliance with the informed consent regulations in part 50 of this chapter or, if the study was subject to but was not conducted in compliance with those regulations, the NDA or ANDA does not contain a brief statement of the reason for the noncompliance.

(8) The drug product that is the subject of the submission is already covered by an approved NDA or ANDA and the applicant of the submission:

(i) Has an approved NDA or ANDA for the same drug product; or

(ii) Is merely a distributor and/or repackager of the already approved drug product.

(9) The NDA is submitted as a 505(b)(2) application for a drug that is a duplicate of a listed drug and is eligible for approval under section 505(j) of the Federal Food, Drug, and Cosmetic Act.

(e) *Regulatory deficiencies.* The Agency will refuse to file an NDA or will consider an ANDA not to have been received if any of the following applies:

(1) The drug product is subject to licensing by FDA under the Public Health Service Act (42 U.S.C. 201 *et seq.*) and subchapter F of this chapter.

(2) Submission of a 505(b)(2) application or an ANDA for the active moiety is not permitted under § 314.108(b)(2).

(f) *Outcome of FDA review.* (1) Within 180 days after the date of filing, plus the period of time the review period was extended (if any), FDA will either:

(i) Approve the NDA; or

(ii) Issue a notice of opportunity for a hearing if the applicant asked FDA to provide it an opportunity for a hearing on an NDA in response to a complete response letter.

(2) Within 180 days after the date of receipt, plus the period of time the review clock was extended (if any), FDA will either approve or disapprove the ANDA. If FDA disapproves the ANDA, FDA will issue a notice of opportunity for hearing if the applicant asked FDA to provide it an opportunity for a hearing on an ANDA in response to a complete response letter.

(3) This paragraph does not apply to NDAs or ANDAs that have been withdrawn from FDA review by the applicant.

■ 17. Section 314.105 is revised to read as follows:

§ 314.105 Approval of an NDA and an ANDA.

(a) FDA will approve an NDA and send the applicant an approval letter if none of the reasons in § 314.125 for refusing to approve the NDA applies. An NDA is approved on the date of the issuance of the approval letter. FDA will issue a tentative approval letter if an NDA otherwise meets the requirements for approval under the Federal Food, Drug, and Cosmetic Act, but cannot be approved because there is a 7-year period of orphan exclusivity for the listed drug under section 527 of the Federal Food, Drug, and Cosmetic Act and § 316.31, or if a 505(b)(2) application otherwise meets the requirements for approval under the Federal Food, Drug, and Cosmetic Act, but cannot be approved until the conditions in § 314.107(b)(3) or (c) are met; because there is a period of exclusivity for the listed drug under § 314.108; or because there is a period of pediatric exclusivity for the listed drug under section 505A of the Federal Food, Drug, and Cosmetic Act. A drug product that is granted tentative approval is not an approved drug and will not be approved until FDA issues an approval after any necessary additional review of the NDA. FDA's tentative approval of a drug product is based on information available to FDA at the time of the tentative approval letter (*i.e.,* information in the 505(b)(2) application and the status of current good manufacturing practices of the facilities used in the manufacturing and testing of the drug product) and is therefore subject to change on the basis of new information that may come to FDA's attention. A new drug product may not be marketed until the date of the approval letter.

(b) FDA will approve an NDA and issue the applicant an approval letter on the basis of draft labeling if the only deficiencies in the NDA concern editorial or similar minor deficiencies in the draft labeling. Such approval will be conditioned upon the applicant incorporating the specified labeling changes exactly as directed, and upon the applicant submitting to FDA a copy of the final printed labeling prior to marketing.

(c) FDA will approve an NDA after it determines that the drug meets the

statutory standards for safety and effectiveness, manufacturing and controls, and labeling, and an ANDA after it determines that the drug meets the statutory standards for manufacturing and controls, labeling, and, where applicable, bioequivalence. While the statutory standards apply to all drugs, the many kinds of drugs that are subject to the statutory standards and the wide range of uses for those drugs demand flexibility in applying the standards. Thus FDA is required to exercise its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet the statutory standards. FDA makes its views on drug products and classes of drugs available through guidance documents, recommendations, and other statements of policy.

(d) FDA will approve an ANDA and send the applicant an approval letter if none of the reasons in § 314.127 for refusing to approve the ANDA applies. The date of approval is the date of the issuance of the Agency's approval letter. FDA will issue a tentative approval letter if an ANDA otherwise meets the requirements for approval under the Federal Food, Drug, and Cosmetic Act, but cannot be approved because there is a 7-year period of orphan exclusivity for the listed drug under section 527 of the Federal Food, Drug, and Cosmetic Act and § 316.31, or cannot be approved until the conditions in § 314.107(b)(3) or (c) are met; because there is a period of exclusivity for the listed drug under § 314.108; or because there is a period of pediatric exclusivity for the listed drug under section 505A of the Federal Food, Drug, and Cosmetic Act. A drug product that is granted tentative approval is not an approved drug and will not be approved until FDA issues an approval after any necessary additional review of the ANDA. FDA's tentative approval of a drug product is based on information available to FDA at the time of the tentative approval letter (*i.e.,* information in the ANDA and the status of current good manufacturing practices of the facilities used in the manufacturing and testing of the drug product) and is therefore subject to change on the basis of new information that may come to FDA's attention. A new drug product may not be marketed until the date of the approval letter.

■ 18. Section 314.107 is revised to read as follows:

§ 314.107 Date of approval of a 505(b)(2) application or ANDA.

(a) *General.* A drug product may be introduced or delivered for introduction into interstate commerce when the 505(b)(2) application or ANDA for the drug product is approved. A 505(b)(2) application or ANDA for a drug product is approved on the date FDA issues an approval letter under § 314.105 for the 505(b)(2) application or ANDA.

(b) *Effect of patent(s) on the listed drug.* As described in paragraphs (b)(1) and (b)(2) of this section, the status of patents listed for the listed drug(s) relied upon or reference listed drug, as applicable, must be considered in determining the first possible date of approval of a 505(b)(2) application or ANDA. The criteria in paragraphs (b)(1) and (b)(2) of this section will be used to determine, for each relevant patent, the date that patent will no longer prevent approval. The first possible date of approval will be calculated for each patent, and the 505(b)(2) application or ANDA may be approved on the last applicable date.

(1) *Timing of approval based on patent certification or statement.* If none of the reasons in § 314.125 or § 314.127 for refusing to approve the application applies, and none of the reasons in paragraph (d) of this section for delaying approval applies, the 505(b)(2) application or ANDA may be approved as follows:

(i) Immediately, if the applicant certifies under § 314.50(i) or § 314.94(a)(12) that:

(A) The applicant is aware of a relevant patent but the patent information required under section 505(b) or (c) of the Federal Food, Drug, and Cosmetic Act has not been submitted to FDA; or

(B) The relevant patent has expired; or

(C) The relevant patent is invalid, unenforceable, or will not be infringed, except as provided in paragraphs (b)(3) and (c) of this section, and the 45-day period provided for in section 505(c)(3)(C) and (j)(5)(B)(iii) of the Federal Food, Drug, and Cosmetic Act has expired; or

(D) There are no relevant patents.

(ii) Immediately, if the applicant submits an appropriate statement under § 314.50(i) or § 314.94(a)(12) explaining that a method-of-use patent does not claim an indication or other condition of use for which the applicant is seeking approval.

(iii) On the date specified, if the applicant certifies under § 314.50(i) or § 314.94(a)(12) that the relevant patent will expire on a specified date.

(2) *Patent information filed after submission of 505(b)(2) application or ANDA.* If the holder of the approved NDA for the listed drug submits patent information required under § 314.53 after the date on which the 505(b)(2) application or ANDA was submitted to FDA, the 505(b)(2) applicant or ANDA applicant must comply with the requirements of § 314.50(i)(4) and (i)(6) and § 314.94(a)(12)(vi) and (a)(12)(viii) regarding amendment of its patent certification or statement. If the applicant submits an amendment certifying under § 314.50(i)(1)(i)(A)(*4*) or § 314.94(a)(12)(i)(A)(*4*) that the relevant patent is invalid, unenforceable, or will not be infringed, and complies with the requirements of § 314.52 or § 314.95, the 505(b)(2) application or ANDA may be approved immediately upon submission of documentation of receipt of notice of paragraph IV certification under § 314.52(e) or § 314.95(e). The 45-day period provided for in section 505(c)(3)(C) and (j)(5)(B)(iii) of the Federal Food, Drug, and Cosmetic Act does not apply in these circumstances.

(3) *Disposition of patent litigation—(i) Approval upon expiration of 30-month period or 7½ years from date of reference product approval.* (A) Except as provided in paragraphs (b)(3)(ii) through (b)(3)(viii) of this section, if, with respect to patents for which required information was submitted under § 314.53 before the date on which the 505(b)(2) application or ANDA was submitted to FDA (excluding an amendment or supplement to the 505(b)(2) application or ANDA), the applicant certifies under § 314.50(i) or § 314.94(a)(12) that the relevant patent is invalid, unenforceable, or will not be infringed, and the patent owner or its representative or the exclusive patent licensee brings suit for patent infringement within 45 days of receipt of the notice of certification from the applicant under § 314.52 or § 314.95, the 505(b)(2) application or ANDA may be approved 30 months after the later of the date of the receipt of the notice of certification by any owner of the listed patent or by the NDA holder who is an exclusive patent licensee (or their representatives) unless the court has extended or reduced the period because of a failure of either the plaintiff or defendant to cooperate reasonably in expediting the action; or

(B) If the patented drug product qualifies for 5 years of exclusive marketing under § 314.108(b)(2) and the patent owner or its representative or the exclusive patent licensee brings suit for patent infringement during the 1-year period beginning 4 years after the date the patented drug was approved and within 45 days of receipt of the notice of certification from the applicant under § 314.52 or § 314.95, the 505(b)(2) application or ANDA may be approved at the expiration of 7½ years from the date of approval of the NDA for the patented drug product.

(ii) *Federal district court decision of invalidity, unenforceability, or non-infringement.* If before the expiration of the 30-month period, or 7½ years where applicable, the district court decides that the patent is invalid, unenforceable, or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the 505(b)(2) application or ANDA may be approved on:

(A) The date on which the court enters judgment reflecting the decision; or

(B) The date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed.

(iii) *Appeal of Federal district court judgment of infringement.* If before the expiration of the 30-month period, or 7½ years where applicable, the district court decides that the patent has been infringed, and if the judgment of the district court is appealed, the 505(b)(2) application or ANDA may be approved on:

(A) The date on which the mandate is issued by the court of appeals entering judgment that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(B) The date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed.

(iv) *Affirmation or non-appeal of Federal district court judgment of infringement.* If before the expiration of the 30-month period, or 7½ years where applicable, the district court decides that the patent has been infringed, and if the judgment of the district court is not appealed or is affirmed, the 505(b)(2) application or ANDA may be approved no earlier than the date specified by the district court in an order under 35 U.S.C. 271(e)(4)(A).

(v) *Grant of preliminary injunction by Federal district court.* If before the expiration of the 30-month period, or 7½ years where applicable, the district court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug product until the court decides the issues of patent validity and infringement, and if the court later decides that the patent is invalid, unenforceable, or not infringed, the 505(b)(2) application or ANDA may be approved as provided in paragraph (b)(3)(ii) of this section. If the court decides that the patent has been infringed, the 505(b)(2) application or ANDA may be approved as provided in paragraph (b)(3)(iii) or (b)(3)(iv) of this section, whichever is applicable.

(vi) *Written consent to approval by patent owner or exclusive patent licensee.* If before the expiration of the 30-month period, or 7½ years where applicable, the patent owner or the exclusive patent licensee (or their representatives) agrees in writing that the 505(b)(2) application or ANDA may be approved any time on or after the date of the consent, approval may be granted on or after that date.

(vii) *Court order terminating 30-month or 7½ year period.* If before the expiration of the 30-month period, or 7½ years where applicable, the court enters an order requiring the 30-month or 7½-year period to be terminated, the 505(b)(2) application or ANDA may be approved in accordance with the court's order.

(viii) *Court order of dismissal without a finding of infringement.* If before the expiration of the 30-month period, or 7½ years where applicable, the court enters an order of dismissal, with or without prejudice, without a finding of infringement, the 505(b)(2) application or ANDA may be approved on or after the date of the order.

(4) *Tentative approval.* FDA will issue a tentative approval letter when tentative approval is appropriate in accordance with paragraphs (b)(3) or (e)(1)(vi) of this section. In order for a 505(b)(2) application or ANDA to be approved under paragraph (b)(3) of this section, the applicant must receive an approval letter from the Agency. Tentative approval of an application does not constitute ''approval'' of an application and cannot, absent an approval letter from the Agency, result in an approval under paragraph (b)(3) of this section.

(c) *Subsequent ANDA submission.* (1) If an ANDA contains a paragraph IV certification for a relevant patent and the ANDA is not that of a first applicant, the ANDA is regarded as the ANDA of a subsequent applicant. The ANDA of a subsequent applicant will not be approved during the period when any first applicant is eligible for 180-day exclusivity or during the 180-day exclusivity period of a first applicant. Any applicable 180-day exclusivity period cannot extend beyond the expiration of the patent upon which the 180-day exclusivity period was based.

(2) For purposes of paragraph (c)(1) of this section, a first applicant must submit correspondence to its ANDA notifying FDA within 30 days of the date of first commercial marketing of its drug product. If an applicant does not notify FDA, as required in this paragraph, of this date, the date of first commercial marketing will be deemed to be the date of the drug product's approval.

(d) *Delay due to exclusivity.* The Agency will also delay the approval of a 505(b)(2) application or an ANDA if delay is required by the exclusivity provisions in § 314.108, § 316.31, or section 505A of the Federal Food, Drug, and Cosmetic Act. When the approval of a 505(b)(2) application or ANDA is delayed under this section and § 314.108, § 316.31, or section 505A of the Federal Food, Drug, and Cosmetic Act, the 505(b)(2) application or ANDA will be approved on the latest of the days specified under this section and § 314.108, § 316.31, or section 505A of the Federal Food, Drug, and Cosmetic Act, as applicable.

(e) *Notification of court actions or documented agreement.* (1) The applicant must submit the following information to FDA, as applicable:

(i) A copy of any judgment by the court (district court or mandate of the court of appeals) or settlement order or consent decree signed and entered by the court (district court or court of appeals) finding a patent described in paragraph (b)(3) of this section invalid, unenforceable, or not infringed, or finding the patent valid and infringed;

(ii) Written notification of whether or not any action by the court described in paragraph (e)(1)(i) of this section has been appealed within the time permitted for an appeal;

(iii) A copy of any order entered by the court terminating the 30-month or 7½-year period described in paragraphs (b)(3)(i) and (b)(3)(ii) of this section;

(iv) A copy of any documented agreement described in paragraph (b)(3)(vi) of this section;

(v) A copy of any preliminary injunction described in paragraph (b)(3)(v) of this section, and a copy of any subsequent court order lifting the injunction; and

(vi) A copy of any court order pursuant to 35 U.S.C. 271(e)(4)(A) ordering that a 505(b)(2) application or ANDA may be approved no earlier than the date specified (irrespective of whether the injunction relates to a patent described in paragraph (b)(3) of this section).

(2) All information required by paragraph (e)(1) of this section must be sent to the Office of Generic Drugs (HFD–600) or to the appropriate division in the Office of New Drugs within 14 days of the date of entry by the court, the date of appeal or expiration of the time for appeal, or the

date of documented agreement, as applicable.

(f) *Forty-five day period after receipt of notice of paragraph IV certification*—(1) *Computation of 45-day time clock.* The 45-day clock described in paragraph (b)(3) of this section as to each recipient required to receive notice of paragraph IV certification under § 314.52 or § 314.95 begins on the day after the date of receipt of the applicant's notice of paragraph IV certification by the recipient. When the 45th day falls on Saturday, Sunday, or a Federal holiday, the 45th day will be the next day that is not a Saturday, Sunday, or a Federal holiday.

(2) *Notification of filing of legal action.* (i) The 505(b)(2) or ANDA applicant must notify FDA in writing within 14 days of the filing of any legal action filed within 45 days of receipt of the notice of paragraph IV certification by any recipient. A 505(b)(2) applicant must send the notification to the appropriate division in the Office of New Drugs reviewing the 505(b)(2) application. An ANDA applicant must send the notification to FDA's Office of Generic Drugs (HFD–600). The notification to FDA of the legal action must include:

(A) The 505(b)(2) application or ANDA number.

(B) The name of the 505(b)(2) or ANDA applicant.

(C) The established name of the drug product or, if no established name exists, the name(s) of the active ingredient(s), the drug product's strength, and dosage form.

(D) A statement that an action for patent infringement, identified by the court, case number, and the patent number(s) of the patent(s) at issue in the action, has been filed in an appropriate court on a specified date.

(ii) A patent owner or NDA holder (or their representatives) may also notify FDA of the filing of any legal action for patent infringement. The notice should contain the information and be sent to the offices or divisions described in paragraph (f)(2)(i) of this section.

(iii) If the 505(b)(2) or ANDA applicant, the patent owner(s), the NDA holder, or their representatives do not notify FDA in writing before the expiration of the 45-day time period or the completion of the Agency's review of the 505(b)(2) application or ANDA, whichever occurs later, that a legal action for patent infringement was filed within 45 days of receipt of the notice of paragraph IV certification, the 505(b)(2) application or ANDA may be approved upon expiration of the 45-day period (if the 505(b)(2) or ANDA applicant confirms that a legal action for patent infringement has not been filed) or upon completion of the Agency's review of the 505(b)(2) application or ANDA, whichever is later.

(3) *Waiver.* If the patent owner or NDA holder who is an exclusive patent licensee (or their representatives) waives its opportunity to file a legal action for patent infringement within 45 days of a receipt of the notice of certification and the patent owner or NDA holder who is an exclusive patent licensee (or their representatives) submits to FDA a valid waiver before the 45 days elapse, the 505(b)(2) application or ANDA may be approved upon completion of the Agency's review of the application. FDA will only accept a waiver in the following form:

(*Name of patent owner or NDA holder who is an exclusive patent licensee or their representatives*) has received notice from (*name of applicant*) under (*section 505(b)(3) or 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act*) and does not intend to file an action for patent infringement against (*name of applicant*) concerning the drug (*name of drug*) before (*date on which 45 days elapses*). (*Name of patent owner or NDA holder who is an exclusive patent licensee*) waives the opportunity provided by (*section 505(c)(3)(C) or 505(j)(5)(B)(iii) of the Federal Food, Drug, and Cosmetic Act*) and does not object to FDA's approval of (*name of applicant)'s (505(b)(2) application or ANDA*) for (*name of drug*) with an approval date on or after the date of this submission.

(g) *Conversion of approval to tentative approval.* If FDA issues an approval letter in error or a court enters an order requiring, in the case of an already approved 505(b)(2) application or ANDA, that the date of approval be delayed, FDA will convert the approval to a tentative approval if appropriate.

■ 19. Section 314.108 is amended by:

■ a. Revising paragraph (a) introductory text and the definitions of ''Approved under section 505(b)'', ''Essential to approval'', and ''New chemical entity'';

■ b. Removing from paragraph (a) the definitions of ''Active moiety'', ''Date of approval'', and ''FDA'';

■ c. Adding alphabetically to paragraph (a) the definition of ''Bioavailability study''; and

■ d. Revising paragraph (b).

The revisions read as follows:

§ 314.108 New drug product exclusivity.

(a) *Definitions.* The definitions at § 314.3 and the following definitions of terms apply to this section:

Approved under section 505(b) means an NDA submitted under section 505(b) and approved on or after October 10, 1962, or an application that was ''deemed approved'' under section 107(c)(2) of Public Law 87–781.

Bioavailability study means a study to determine the bioavailability or the pharmacokinetics of a drug.

* * * * *

Essential to approval means, with regard to an investigation, that there are no other data available that could support approval of the NDA.

New chemical entity means a drug that contains no active moiety that has been approved by FDA in any other NDA submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act.

* * * * *

(b) *Submission of and date of approval of a 505(b)(2) application or ANDA.*

(1) [Reserved]

(2) If a drug product that contains a new chemical entity was approved after September 24, 1984, in an NDA submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act, no person may submit a 505(b)(2) application or ANDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act for a drug product that contains the same active moiety as in the new chemical entity for a period of 5 years from the date of approval of the first approved NDA, except that the 505(b)(2) application or ANDA may be submitted after 4 years if it contains a certification of patent invalidity or noninfringement described in § 314.50(i)(1)(i)(A)(*4*) or § 314.94(a)(12)(i)(A)(*4*).

(3) The approval of a 505(b)(2) application or ANDA described in paragraph (b)(2) of this section will occur as provided in § 314.107(b)(1) or (b)(2), unless the owner of a patent that claims the drug, the patent owner's representative, or exclusive licensee brings suit for patent infringement against the applicant during the 1-year period beginning 48 months after the date of approval of the NDA for the new chemical entity and within 45 days after receipt of the notice described at § 314.52 or § 314.95, in which case, approval of the 505(b)(2) application or ANDA will occur as provided in § 314.107(b)(3).

(4) If an NDA:

(i) Was submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act;

(ii) Was approved after September 24, 1984;

(iii) Was for a drug product that contains an active moiety that has been previously approved in another NDA under section 505(b) of the Federal Food, Drug, and Cosmetic Act; and

(iv) Contained reports of new clinical investigations (other than bioavailability

studies) conducted or sponsored by the applicant that were essential to approval of the application, for a period of 3 years after the date of approval of the application, the Agency will not approve a 505(b)(2) application or an ANDA for the conditions of approval of the original NDA, or an ANDA submitted pursuant to an approved petition under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act that relies on the information supporting the conditions of approval of an original NDA.

(5) If a supplemental NDA:

(i) Was approved after September 24, 1984; and

(ii) Contained reports of new clinical investigations (other than bioavailability studies) that were conducted or sponsored by the applicant that were essential to approval of the supplemental NDA, for a period of 3 years after the date of approval of the supplemental application, the Agency will not approve a 505(b)(2) application or an ANDA for a change, or an ANDA submitted pursuant to an approved petition under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act that relies on the information supporting a change approved in the supplemental NDA.

■ 20. Section 314.125 is amended by:

■ a. Removing the word ''application'' wherever it appears in the section heading, paragraph (a) introductory text, and paragraphs (a)(2), (b)(7), (b)(9), (b)(10), (b)(12), and (b)(14) through (b)(18) and adding in its place ''NDA'';

■ b. Revising paragraph (b) introductory text; and

■ c. Adding paragraph (b)(19).

The revisions read as follows:

§ 314.125 Refusal to approve an NDA.

* * * * *

(b) FDA may refuse to approve an NDA for any of the following reasons, unless the requirement has been waived under § 314.90:

* * * * *

(19) The 505(b)(2) application failed to contain a patent certification or statement with respect to each listed patent for an approved drug product that:

(i) Is pharmaceutically equivalent to the drug product for which the 505(b)(2) application is submitted; and

(ii) Was approved before the 505(b)(2) application was submitted.

* * * * *

■ 21. Section 314.127 is amended by:

■ a. Removing the words ''abbreviated application'' and ''abbreviated new drug application'' wherever they appear in paragraphs (a) and (b) and adding in their place ''ANDA'';

■ b. Revising the section heading and paragraph (a) introductory text; and

■ c. Adding paragraph (a)(14).

The revisions read as follows:

§ 314.127 Refusal to approve an ANDA.

(a) FDA will refuse to approve an ANDA for a new drug under section 505(j) of the Federal Food, Drug, and Cosmetic Act for any of the following reasons, unless the requirement has been waived under § 314.99:

* * * * *

(14) For an ANDA submitted pursuant to an approved suitability petition, an NDA subsequently has been approved for the change described in the suitability petition.

* * * * *

PART 320—BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS

■ 22. The authority citation for part 320 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 355, 371.

■ 23. Section 320.1 is revised to read as follows:

§ 320.1 Definitions.

The definitions contained in § 314.3 of this chapter apply to those terms when used in this part.

■ 24. Section 320.23 is amended by:

■ a. Revising the last sentence in paragraph (a)(1);

■ b. Removing the word ''shall'' in paragraph (a)(2) and adding in its place the word ''must'';

■ c. Redesignating paragraph (b) as paragraph (b)(1); and

■ d. Adding new paragraph (b)(2).

The revisions read as follows:

§ 320.23 Basis for measuring in vivo bioavailability or demonstrating bioequivalence.

(a)(1) * * * For drug products that are not intended to be absorbed into the bloodstream, bioavailability may be assessed by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or active moiety becomes available at the site of action.

* * * * *

(b) * * *

(2) For drug products that are not intended to be absorbed into the bloodstream, bioequivalence may be demonstrated by scientifically valid methods that are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.

Dated: January 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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