Silver Spring, MD 20993–0002, 301–796–7900.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device Xience Prime Ll Everolimus Eluting Coronary Stent System. Xience Prime Ll Everolimus Eluting Coronary Stent System is indicated for improving coronary luminal diameter in patients with symptomatic heart disease due to de novo native coronary artery lesions (length ≤ 32 millimeters (mm)) with reference vessel diameters of ≥2.25 mm to ≤ 4.25 mm. Subsequent to this approval, the USPTO received a patent term restoration application for Xience Prime Ll Everolimus Eluting Coronary Stent System (U.S. Patent No. 5,514,154) from Abbott Cardiovascular Systems Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 4, 2013, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of Xience Prime Ll Everolimus Eluting Coronary Stent System represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that the FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Xience Prime Ll Everolimus Eluting Coronary Stent System is 890 days. Of this time, 694 days occurred during the testing phase of the regulatory review period, while 196 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective:* May 27, 2009. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the FD&C Act for human tests to begin became effective May 27, 2009.

2. *The date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e):* April 20, 2011. The applicant claims October 28, 2010, as the date the premarket approval application (PMA) for Xience Prime Ll Everolimus Eluting Coronary Stent System (PMA P110019) was initially submitted. However, FDA records indicate that PMA P110019 was submitted in full on April 20, 2011.

3. *The date the application was approved:* November 1, 2011. FDA has verified the applicant's claim that PMA P110019 was approved on November 1, 2011.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 630 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by August 11, 2014. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 8, 2014. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. 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. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov,* Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 4, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–13445 Filed 6–9–14; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2001–D–0067 (Formerly Docket No. 2001D–0185)]**

### Draft Guidance for Industry on Providing Submissions in Electronic Format—Postmarketing Safety Reports; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Providing Submissions in Electronic Format—Postmarketing Safety Reports.'' This draft guidance provides general information pertaining to electronic submission of postmarketing safety reports (individual case safety reports (ICSRs), attachments to ICSRs (ICSR attachments), and other postmarketing safety reports) for certain human drug and biological products. We are issuing the draft guidance to help persons required to submit postmarketing safety reports comply with the final rule.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 11, 2014.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the

Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

*For information concerning human drug products:* Jean Chung, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4466, Silver Spring, MD, 20993–0002, 301–796–1874.

*For information concerning human biological products:* Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7268, Silver Spring, MD, 20993–0002, 240–402–7911.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Providing Submissions in Electronic Format—Postmarketing Safety Reports.'' This draft guidance provides general information pertaining to electronic submission of postmarketing safety reports (ICSRs, ICSR attachments, and other postmarketing safety reports) for the following products:

- Drug products marketed for human use with approved new drug applications (NDAs) and abbreviated new drug applications (ANDAs);
- Prescription drug products marketed for human use without an approved NDA or ANDA;
- Biological products, other than vaccines, marketed for human use with approved biologic license applications (or BLAs);
- Nonprescription (over-the-counter or OTC) human drug products marketed without an approved application.

This draft guidance does not apply to vaccines, human cells, tissues, and cellular and tissue-based products regulated under section 361 of the Public Health Service Act, whole blood, components of whole blood, or lot distribution reports.

This draft guidance revises and replaces the draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Postmarketing Individual Case Safety Reports,'' issued on June 12, 2008 (73 FR 33436). Elsewhere in this issue of the **Federal Register,** we are publishing a final rule to require that mandatory postmarketing safety reports for human drug and biological products be submitted to FDA in an electronic format that the Agency can process, review, and archive. The revised draft guidance is intended to help persons subject to mandatory postmarketing safety reporting requirements comply with the final rule. Along with other information, the revised draft guidance provides updated information about the following: (1) Options for submitting postmarketing safety reports to FDA in electronic format, (2) the notification that submitters will receive when FDA has received the electronic postmarketing safety report, and (3) procedures for requesting temporary waivers from the electronic submission requirement.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on submission of postmarketing safety reports in electronic format. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. Comments

Interested persons may submit 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.

## III. Paperwork Reduction Act of 1995

The information collection resulting from this draft guidance is covered by the information collection provisions of the final rule entitled ''Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements,'' which is published elsewhere in this issue of the **Federal Register**. The information collection provisions of the final rule have been submitted to the Office of Management and Budget (OMB) for review, as required under section 3507(d) of the Paperwork Reduction Act. Prior to the effective date of the final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in the final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

## IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov*.

Dated: June 4, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–13479 Filed 6–9–14; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2014–N–0012]**

### Kidney Health Initiative (R18)

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of the Center for Drug Evaluation and Research/Office of Medical Policy's Kidney Health Initiative Program. FDA, Center for Drug Evaluation and Research (CDER), Office of Medical Policy (OMP) is announcing its intent to accept and consider a single source application for the award of a grant to the American Society of Nephrology (ASN) to support the Kidney Health Initiative (KHI).

**DATES:** The application due date is June 30, 2014, by 11:59 p.m., EST.

**ADDRESSES:** Submit electronic applications to: *http://www.grants.gov*.