2. ''Guidance for Industry and FDA Staff: Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval,'' April 2015, available at *http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm393994.pdf.*

3. ''Guidance for Industry and FDA Staff: Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions,'' April 2015, available at *http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm393978.pdf.*

Dated: April 22, 2015.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2015–09884 Filed 4–28–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–E–0102]

Determination of Regulatory Review Period for Purposes of Patent Extension; Xience Xpedition Everolimus Eluting Coronary Stent System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Xience Xpedition Everolimus Eluting Coronary Stent System and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Campus, Rm. 3180, 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 Patents and Trademarks 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 Xpedition Everolimus Eluting Coronary Stent System. Xience Xpedition Everolimus Eluting Coronary Stent System is indicated for improving coronary luminal diameter in subjects with symptomatic heart disease due to de novo native coronary artery lesions (length ≤32 millimeters (mm)) with reference vessel diameter of ≥2.25 mm and ≤4.25 mm. Subsequent to this approval, the USPTO received a patent term restoration application for Xience Xpedition Everolimus Eluting Coronary Stent System (U.S. Patent No. 7,828,766) 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 May 22, 2014, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of Xience Xpedition Everolimus Eluting Coronary Stent System represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Xience Xpedition Everolimus Eluting Coronary Stent System is 178 days. Of this time, zero (0) days occurred during the testing phase of the regulatory review period, while 178 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:* Not Applicable. Applicant did not perform clinical investigations utilizing the patented device, but, rather, sought and was granted marketing approval based on a supplemental filing to a previously approved premarket approval application (PMA).

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* June 27, 2012. FDA has verified the applicant's claim that the PMA for Xience Xpedition Everolimus Eluting Coronary Stent System (PMA P110019S025) was initially submitted June 27, 2012.

3. *The date the application was approved:* December 21, 2012. FDA has verified the applicant's claim that PMA P110019S025 was approved on December 21, 2012.

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 178 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 June 29, 2015. 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 October 26, 2015. 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: April 23, 2015.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2015–09902 Filed 4–28–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–1213]

Environmental Assessment: Questions and Answers Regarding Drugs With Estrogenic, Androgenic, or Thyroid Activity; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Environmental Assessment: Questions and Answers Regarding Drugs With Estrogenic, Androgenic, or Thyroid Activity.'' This guidance is intended to supplement CDER's guidance for industry on ''Environmental Assessment of Human Drug and Biologics Applications,'' issued July 1998, by addressing specific considerations for drugs that have potential estrogenic, androgenic, or thyroid pathway activity (E, A, or T activity) in environmental organisms. It is intended to help sponsors of such drugs determine whether they should submit environmental assessments (EA) for new drug applications (NDAs) and certain NDA supplements, and to clarify what information such sponsors should include if they submit a claim of categorical exclusion instead of an EA.

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 June 29, 2015.

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, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. 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: Raanan A. Bloom, Environmental Assessment Team, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–2185, *CDER.EA.Team@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Environmental Assessment: Questions and Answers Regarding Drugs With Estrogenic, Androgenic, or Thyroid Activity.'' The National Environmental Policy Act of 1969 (Pub. L. 91–190) requires all Federal agencies to assess the environmental impact of their actions and to ensure that the interested and affected public is informed of the environmental analyses. FDA regulations at 21 CFR part 25 specify that EAs must be submitted as part of certain NDAs, abbreviated new drug applications (ANDAs), biologic license applications (BLAs), supplements to such applications, and investigational new drug applications (INDs), and for various other actions, unless the action qualifies for a categorical exclusion. Failure to submit either an EA or a claim of categorical exclusion is sufficient grounds for FDA to refuse to file or approve an application (§ 25.15(a), 21 CFR 314.101(d)(4), and 601.2(a) and (c)).

Categorical exclusions for actions related to human drugs and biologics are listed at § 25.31. This draft guidance focuses on the categorical exclusion for actions on NDAs and NDA supplements that would increase the use of an active moiety, but the estimated concentration of the substance at the point of entry into the aquatic environment would be below 1 part per billion (1 ppb) (§ 25.31(b)). Although an action that qualifies for this exclusion ordinarily does not require an EA, FDA will require ''at least an EA'' if ''extraordinary circumstances'' indicate that the specific proposed action (*e.g.,* the approval of the NDA) may significantly affect the quality of the human environment (§ 25.21). Research indicates that drugs with endocrine-related activity and, more specifically, drugs with E, A, or T activity have the potential to cause developmental or reproductive effects when present in the aquatic environment at concentrations below 1 ppb.[1]

FDA has, on a case-by-case basis, requested additional information from sponsors of NDAs and NDA supplements for drugs with E, A, or T activity to help it determine whether extraordinary circumstances exist. However, late cycle requests for additional environmental information have the potential to delay approval of applications. Accordingly, this guidance is intended to clarify that sponsors of drugs with potential E, A, or T activity should consult with the Agency early in product development concerning the information FDA may need to determine whether an EA will be required or whether a claim of categorical exclusion will be acceptable, and what information should be included in the EA or claim of categorical exclusion.

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

[1] For example, see Section II.C (pp. 7–13) of USFDA, 2013, ''Response to Citizen Petition to the FDA Commissioner under the National Environmental Policy Act and Administrative Procedure Act Requesting an Amendment to an FDA Rule Regarding Human Drugs and Biologics,'' Docket No. FDA–2010–P–0377; U.S. Environmental Protection Agency (USEPA), Endocrine Disruptor Screening Program (EDSP), last accessed February 17, 2015, at *http://www.epa.gov/endo;* and Organisation for Economic Co-operation and Development (OECD), OECD Work Related to Endocrine Disrupters, last accessed February 17, 2015, at *http://www.oecd.org/env/ehs/testing/oecdworkrelatedtoendocrinedisrupters.htm.*