

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, 10903 New Hampshire Ave., Bldg. 51, Rm. 6257, 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 human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, 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 human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product STENDRA (avanafil). STENDRA is indicated for the treatment of erectile dysfunction. Subsequent to this approval, USPTO received a patent term restoration application for STENDRA (U.S. Patent No. 6,656,935) from Mitsubishi Tanabe Pharma Corp., and USPTO requested FDA's assistance in determining this patent's eligibility for patent term

restoration. In a letter dated February 13, 2013, FDA advised USPTO that this human drug product had undergone a regulatory review period and that the approval of STENDRA represented the first permitted commercial marketing or use of the product. Thereafter, USPTO requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for STENDRA is 3,770 days. Of this time, 3,466 days occurred during the testing phase of the regulatory review period, while 304 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* January 2, 2002. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 2, 2002.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* June 29, 2011. FDA has verified the applicant's claim that the new drug application (NDA) for STENDRA (NDA 202276) was submitted on June 29, 2011.

3. *The date the application was approved:* April 27, 2012. FDA has verified the applicant's claim that NDA 202276 was approved on April 27, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,686 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. 2014-13444 Filed 6-9-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-E-1241]

Determination of Regulatory Review Period for Purposes of Patent Extension; Xience Prime LI 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 Prime LI 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, 10903 New Hampshire Ave., Bldg. 51, Rm. 6257,

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 L1 Everolimus Eluting Coronary Stent System. Xience Prime L1 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 $\leq$ 32 millimeters (mm)) with reference vessel diameters of $\geq$ 2.25 mm to $\leq$ 4.25 mm. Subsequent to this approval, the USPTO received a patent term restoration application for Xience Prime L1 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 L1 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 L1 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 L1 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.

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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