FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 18, 2009, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of XIENCE V EECSS represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for XIENCE V EECSS is 1,157 days. Of this time, 759 days occurred during the testing phase of the regulatory review period, while 398 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 act) (21 U.S.C. 360j(g)) involving this device became effective*: May 4, 2005. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the act for human tests to begin became effective on May 4, 2005.

2. *The date an application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: June 1, 2007. The applicant claims the premarket approval application (PMA) XIENCE V EECSS (PMA 70015) was submitted in three modules and that Module 1 was initially submitted on July 14, 2006. The applicant claims July 14, 2006, as the date PMA 70015 was initially submitted. It is FDA's position that the approval phase begins when the marketing application is complete. A review of FDA records indicates that PMA 70015 was submitted as a complete application on June 1, 2007, which is considered to be the initially submitted date for PMA 70015.

3. *The date the application was approved*: July 2, 2008. FDA has verified the applicant's claim that PMA 70015 was approved on July 2, 2008.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 937 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**) written or electronic comments and ask for a redetermination by October 5, 2009. 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 February 1, 2010. 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.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 8, 2009.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E9–18530 Filed 8–3–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–E–0020]

Determination of Regulatory Review Period for Purposes of Patent Extension; EOVIST

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for EOVIST 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 Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

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

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 Patents and Trademarks 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 recently approved for marketing the human drug product EOVIST (gadoxetate disodium). EOVIST is indicated for intravenous use in T1–weighted magnetic resonance imaging of the liver to detect and characterize lesions in adults with known or suspected focal liver disease. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for EOVIST (U.S. Patent No. 6,039,931) from Bayer Schering Pharma Aktiengesellschaft, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 26, 2009, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of EOVIST represented the first permitted commercial marketing or

use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for EOVIST is 3,818 days. Of this time, 3,450 days occurred during the testing phase of the regulatory review period, while 368 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: January 21, 1998. The applicant claims January 19, 1998, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 21, 1998, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: July 2, 2007. The applicant claims June 29, 2007, as the date the new drug application (NDA) for EOVIST (NDA 22–090) was initially submitted. However, FDA records indicate that NDA 22–090 was submitted on July 2, 2007.

3. *The date the application was approved:* July 3, 2008. FDA has verified the applicant's claim that NDA 22–090 was approved on July 3, 2008. This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,699 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**) written or electronic comments and ask for a redetermination by October 5, 2009. 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 February 1, 2010. 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.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 8, 2009.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E9–18527 Filed 8–3–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2001–D–0129 (formerly Docket No. 2001D–0064)]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy.'' This guidance document describes a means by which manufacturers of dental amalgam, mercury, and amalgam alloy may comply with special controls that apply to these class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify dental amalgam into class II (special controls), reclassify dental mercury from class I (general controls) to class II (special controls), and designate a special controls guidance document to support the class II classification of these two devices, as well as the current class II classification of amalgam alloy.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Michael Adjodha, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2606, Silver Spring, MD 20993–0002, 301–796–6276.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 20, 2002 (67 FR 7620), FDA issued a proposed rule to issue a separate regulation classifying encapsulated dental amalgam into class II (special controls); amending the class II classification of amalgam alloy by designating special controls; and reclassifying dental mercury from class I (general controls) to class II (special controls). Also, in the **Federal Register** of February 20, 2002 (67 FR 7703), FDA announced the availability of the draft guidance entitled ''Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling,'' which would serve as a special control for all three devices. The comment period on the proposed rule closed on May 21, 2002. FDA reopened the comment period in July 2002 (67 FR 46991) and again in April 2008 (73 FR 22877) to provide the public with additional opportunities to comment and to submit data and information that may have become available since publication of the proposed rule. The comment period closed on July 28, 2008.

FDA received more than 1,400 comments on the proposed rule and the draft special controls guidance document. Because of the intertwined nature of the proposed rule and the draft guidance, and because of the significant overlap in comments, FDA considered all comments in preparing both the final rule and the special controls guidance document. The analysis of comments is contained in the preamble to the final rule.