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.

II. Significance of Special Controls Guidance Document

The final rule designates the guidance document entitled ''Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy'' as the special control for mercury, amalgam alloy, and dental amalgam. FDA believes that adherence to the recommendations described in this guidance document, in addition to the general controls under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*), will provide reasonable assurance of the safety and effectiveness of dental amalgam, mercury, and amalgam alloy. Following the effective date of the final rule, any firm submitting a 510(k) premarket notification for dental amalgam, mercury, or amalgam alloy, as well as any firm currently marketing the devices, must address the issues covered in the special controls guidance. The firm must show that its device addresses the issues of safety and effectiveness identified in the special controls guidance, either by following the recommendations in the guidance or by some other means that provides equivalent assurances of safety and effectiveness.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive ''Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number (1192) to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available at *http://www.regulations.gov*.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Dated: July 28, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–18445 Filed 7–29–09; 4:15 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Heritable Disorders in Newborns and Children; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), notice is hereby given of the following meeting:

Name: Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC).

Dates and Times: September 24, 2009, 8:30 a.m. to 5 p.m. September 25, 2009, 8:30 a.m. to 3 p.m.

Place: Bethesda Marriott–Pooks Hill, 5151 Pooks Hill Road, Bethesda, MD 20814.

Status: The meeting will be open to the public with attendance limited to space availability. Participants are asked to register for the meeting by going to the registration web site at *http://events.SignUp4.com/ACHDNC0909.* The registration deadline is Wednesday, September 23, 2009. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should indicate their needs on the registration web site. The deadline for special accommodation requests is Friday, September 18, 2009. If there are technical problems gaining access to the web site, please contact Tamar R. Shealy, Meetings Manager, Conference and Meetings Management, Altarum Institute, by telephone (202) 828–5100 or via e-mail *conferences@altarum.org.*

Purpose: The Secretary's ACHDNC was established to advise and guide the Secretary regarding the most appropriate application of universal newborn screening tests, technologies, policies, guidelines and programs for effectively reducing morbidity and mortality in newborns and children having or at risk for heritable disorders. The ACHDNC also provides advice and recommendations concerning the grants and projects authorized under the Public Health Service Act, 42 U.S.C. 300b-10, (Heritable Disorders Program) as amended in the Newborn Screening Saves Lives Act of 2008.

Agenda: The meeting will include presentations and continued discussions on the nomination/evaluation process for newborn screening candidate conditions. The agenda will include presentations on the Newborn Screening Use Case, the National Health Information Network, and Newborn Screening Quality Measures, as well as presentations on the continued work and reports of the ACHDNC's subcommittees on laboratory standards and procedures, follow-up and treatment, and education and training.

Proposed agenda items are subject to change as priorities dictate. You can locate the Agenda, Committee Roster and Charter, presentations, and meeting materials at the home page of the Web site at *http://events.SignUp4.com/ACHDNC0909.*

Webcast: The meeting will be Webcast. Information on how to access the Webcast will be available on the day of the meeting by clicking on the meeting date link at *http://events.SignUp4.com/ACHDNC0909.*

Public Comments: Members of the public can present oral comments during the public comment periods of the meeting, which are scheduled for both days of the meeting. Those individuals who want to make a comment are requested to register online by Wednesday, September 23, 2009, at *http://events.SignUp4.com/ACHDNC0909.* Requests will contain the name, address, telephone number, and any professional or business affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The list of public comment participants will be posted on the web site. Written comments should be emailed no later than Wednesday, September 23, 2009, for consideration. Comments should be submitted to Tamar R. Shealy, Meetings Manager, Conference and Meetings Management, Altarum Institute, 1200 18th Street, NW., Suite 700, Washington, DC 20036, *telephone:* 202 828–5100; *fax:* 202 785–3083, or *e-mail: conferences@altarum.org.*

Contact Person: Anyone interested in obtaining other relevant information should write or contact Alaina M. Harris, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A–19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–0721, *aharris@hrsa.gov.* More information on the Advisory Committee is available at *http://mchb.hrsa.gov/heritabledisorderscommittee.*

Dated: July 28, 2009.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E9–18526 Filed 8–3–09; 8:45 am]

BILLING CODE 4165–15–P