regulatory review period, while 678 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*: July 30, 1999. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the act for human tests to begin became effective on June 30, 1999. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on July 30, 1999, which represents the IDE effective date.

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)*: December 22, 2004. The applicant claims December 21, 2004, as the date the premarket approval application (PMA) for MACROPLASTIQUE IMPLANTS (PMA P040050) was initially submitted. However, FDA records indicate that PMA P040050 was submitted on December 22, 2004.

3. *The date the application was approved*: October 30, 2006. FDA has verified the applicant's claim that PMA P040050 was approved on October 30, 2006.

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 1,640 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 April 13, 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 August 10, 2009. 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: January 17, 2009.

Jane A. Axelrad,

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

[FR Doc. E9–2903 Filed 2–10–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–D–0043] (formerly Docket No. 2004D–0510)

Guidance for Industry: Referral Program From the Food and Drug Administration to the National Oceanic and Atmospheric Administration Seafood Inspection Program for the Certification of Fish and Fishery Products for Export to the European Union and the European Free Trade Association; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance document entitled ''Guidance for Industry: Referral Program from the Food and Drug Administration to the National Oceanic and Atmospheric Administration Seafood Inspection Program for the Certification of Fish and Fishery Products for Export to the European Union and the European Free Trade Association.'' The revised guidance only changes the date on which FDA intends to stop issuing export certificates for fish or fishery products that are to be shipped to the European Union (EU) and the European Free Trade Association (EFTA). The date FDA now intends to stop issuing EU Export Certificates is June 17, 2009.

DATES: Submit written or electronic comments on the guidance at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Food Safety (HFS–300), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835. Send one self-addressed adhesive label to assist that office in processing your request. Submit written comments concerning the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the guidance to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: William Jones, Center for Food Safety and Applied Nutrition (HFS–325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–2300.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 15, 2009 (74 FR 2600) (the January 15 notice), FDA announced the availability of a guidance entitled ''Referral Program from the Food and Drug Administration to the National Oceanic and Atmospheric Administration Seafood Inspection Program for the Certification of Fish and Fishery Products for Export to the European Union and the European Free Trade Association.'' In the January 15 notice, FDA announced that it: (1) Intends to proceed with a Certification Referral Program to the National Oceanic and Atmospheric Administration Seafood Inspection Program (NOAA SIP), without a 24-month test period, (2) intends to expand the program to include all fish and fishery products for export to the EU and EFTA, and (3) intends to stop issuing EU Export Certificates effective February 17, 2009. The agency stated that it intends to adopt this approach because the industry's demand for EU Export Certificates continues to rise dramatically, and FDA can no longer justify the use of our limited food safety resources for issuance of EU Export Certificates. The implementation of this guidance should free up resources that the agency can allocate for higher priority public health activities that are intended to protect the U.S. consuming public, while still providing a mechanism for the industry to continue obtaining EU certification. Seafood processors and other entities involved in the exporting of seafood to the EU may obtain EU Export Certificates from the NOAA SIP.

After publication of the January 15 notice, FDA received comments and has determined it would be beneficial to have more time to deliberate further on the policy issues presented by this action. Consequently, FDA is revising the guidance to announce that it intends to stop issuing EU Export Certificates on June 17, 2009.

FDA is issuing this guidance document as a level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115(c)(2)). The guidance represents FDA'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, NOAA SIP, 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**) 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. The guidance and received comments maybe seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance document at *http://www.cfsan.fda.gov/guidance.html*.

Dated: February 5, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–2802 Filed 2–6–09; 12:00 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Improving Endpoints, Improving Care: Alpha-1 Antitrypsin Augmentation Therapy and Clinical Trials; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled: Improving Endpoints, Improving Care: Alpha-1 Antitrypsin Augmentation Therapy and Clinical Trials. The purpose of the public workshop is to identify the most useful clinical trial endpoints and surrogate markers for Alpha-1 antitrypsin (AAT) augmentation therapy. FDA, Alpha-1 Foundation, and the Department of Health and Human Services, Office of Public Health and Science are convening this workshop to facilitate the design of future clinical trials intended to establish clinical efficacy of AAT products. The public workshop will feature presentations and panel discussions led by experts from academic institutions, government, and industry.

Date and Time: The public workshop will be held on March 23, 2009, from 8:30 a.m. to 5:30 p.m. and March 24, 2009, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held at the Lister Hill Center Auditorium, Bldg. 38A, National Institutes of Health, 8800 Rockville Pike, Bethesda, MD 20894.

Contact Person: Rhonda Dawson, Center for Biologics Evaluation and Research (HFM–302), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6129, FAX: 301–827–2843, e-mail: *rhonda.dawson@fda.hhs.gov*.

Registration: Mail, fax, or e-mail your registration information (including name, title, firm name, address, telephone, and fax numbers) to the contact person by March 6, 2009. There is no registration fee for the public workshop. Early registration is recommended because seating is limited to 175 attendees. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Rhonda Dawson (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: AAT deficiency is a genetic condition that leads to decreased levels of alpha-1 antitrypsin in the blood and significantly increases the risk of serious lung disease in adults and liver disease in infants, children, and adults. Intravenous augmentation therapy with FDA-licensed, plasma-derived AAT products has become the standard of care for treatment in the subset of patients with AAT deficiency who have moderate pulmonary disease. Since the original product approvals, additional data collection and advances in understanding of AAT deficiency suggest the need to revisit and improve clinical trial efficacy endpoints.

The public workshop will facilitate scientific discussions to identify the most relevant and feasible, currently available and future clinical trial efficacy endpoints for AAT augmentation therapy and further evaluate its usefulness to a broader patient population. Topics to be discussed include: (1) AAT deficiency disease characteristics, progression and pulmonary pathophysiology; (2) patient selection for clinical trials; (3) current challenges to the development of endpoints for clinical trials; and (4) currently available and future clinical trial endpoints, including functional markers of disease progression, and radiological and biochemical endpoints.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at *http://www.fda.gov/cber/minutes/workshop-min.htm*.

Dated: February 6, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–2905 Filed 2–10–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Cardiovascular and Renal Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 18, 2009, from 8 a.m. to 5 p.m.