

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](mailto: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.

**Location:** Marriott Conference Centers, UMUC Inn and Conference Center, 3501 University Blvd. East, Adelphi, MD. The hotel telephone number is 301-985-7385.

**Contact Person:** Elaine Ferguson, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail: [elaine.ferguson@fda.hhs.gov](mailto:elaine.ferguson@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512533. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

**Agenda:** The committee will discuss new drug application (NDA) 22-425, dronedarone 400 milligrams oral tablets, Sanofi Aventis, for the proposed indication in patients with a history of, or current atrial fibrillation or atrial flutter, for the reduction of the risk of cardiovascular hospitalization or death. FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>, click on the year 2008 and scroll down to the appropriate advisory committee link.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written

submissions may be made to the contact person on or before March 4, 2009. Oral presentations from the public will be scheduled approximately between 1 p.m. to 2 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 24, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 25, 2009.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Elaine Ferguson at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/oc/advisory/default.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 4, 2009.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

[FR Doc. E9-2862 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]

#### Request for Nominations for Voting and Nonvoting Consumer Representative Members on Public Advisory Committee and Panels

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting nominations for voting and nonvoting consumer representatives to serve on the National Mammography Quality Assurance Advisory Committee (NMQAAC) and certain devices panels of the Medical Devices Advisory Committee in the Center for Devices and Radiological Health (CDRH).

FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, encourages nominations of qualified candidates from these groups.

**DATES:** Nominations will be accepted for current vacancies and for those that will or may occur through October 31, 2009. Because vacancies occur on various dates throughout the year, there is no cutoff date for the receipt of nominations.

**ADDRESSES:** All nominations for membership should be sent electronically to [CV@OC.FDA.GOV](mailto:CV@OC.FDA.GOV) or by mail to Advisory Committee Oversight and Management Staff (HF-4), 5600 Fishers Lane, Rockville, MD 20857. Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site at <http://www.fda.gov/oc/advisory/default.htm>.

**FOR FURTHER INFORMATION CONTACT:** For specific committee questions, contact the following persons listed in table 1 of this document:

TABLE 1

Contact Person	Committee/Panel
Geretta P. Wood, Center for Devices and Radiological Health (HFZ-400), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-3993, e-mail: <a href="mailto:Geretta.Wood@fda.hhs.gov">Geretta.Wood@fda.hhs.gov</a>	Certain Device Panels of the Medical Devices Advisory Committee
Nancy M. Wynne, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, e-mail: <a href="mailto:Nancy.Wynne@fda.hhs.gov">Nancy.Wynne@fda.hhs.gov</a>	National Mammography Quality Assurance Advisory Committee