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.