215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3078.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of August 18, 2000 (65 FR 50543), FDA announced that a color additive petition (CAP 0C0272) had been filed by FEM, Inc., 1521 Laguna St., # 210, Santa Barbara, CA 93101. The petition proposed to amend the color additive regulations in § 73.2500 *Silver* (21 CFR 73.2500) to eliminate the limitation on the amount of silver used as a color additive in fingernail polish. FEM, Inc., has now withdrawn the petition without prejudice to a future filing (21 CFR 71.6(c)(2)).

Dated: August 13, 2001.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 01–21245 Filed 8–22–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anti-Infective 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: Anti-Infective 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 September 12, 2001, from 8:30 a.m. to 5 p.m.

Location: Holiday Inn, Kennedy Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Contact: Thomas H. Perez, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301– 827–6758, e-mail at PerezT@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will consider the safety and efficacy of Activated Protein C (human, recombinant, human kidney cells, new biologic license application (BLA) 125029), Eli Lilly & Co. for the treatment of severe sepsis.

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 by September 4, 2001. Oral presentations from the public will be scheduled on September 12, 2001, between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 4, 2001, 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.

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

Dated: August 16, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–21284 Filed 8–22–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0278]

Draft ''Guidance for Industry: Submitting Type V Drug Master Files to the Center for Biologics Evaluation and Research;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Submitting Type V Drug Master Files to the Center for Biologics Evaluation and Research '' dated August 2001. The draft guidance document discusses Type V Drug Master Files (DMF) submitted to the Center for Biologics Evaluation and Research (CBER). The draft guidance document describes the circumstances in which CBER will accept a Type V Drug Master File without a letter of intent from the DMF holder. The information in the DMF may be used to support an application or supplement, such as an investigational new drug application (IND), biologics license application (BLA), or a new drug application (NDA) submitted to CBER.

DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by November 21, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Submitting Type V Drug Master Files to the Center for Biologics Evaluation and Research '' dated August 2001. The draft guidance document discusses Type V DMFs submitted to CBER. The draft guidance document describes the circumstances in which CBER will accept a Type V DMF without a letter of intent to FDA from the DMF holder. A drug master file is a submission of information to FDA that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of human drugs and biological products. The information in the DMF may be used to support an application or supplement, such as an IND, BLA, or an NDA.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The

draft guidance document represents the agency's current thinking on submitting Type V Drug Master Files to CBER. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Comments

The draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Submit written or electronic comments to ensure adequate consideration in preparation of the final document by November 21, 2001. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cber/guidelines.htm.

Dated: August 13, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–21246 Filed 8–22–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1618]

''Guidance for Industry: Variances for Blood Collection From Individuals With Hereditary Hemochromatosis;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Variances for Blood Collection From Individuals With Hereditary Hemochromatosis'' dated August 2001. The guidance document provides recommendations to blood establishments that wish to distribute blood and blood components collected from individuals with diagnosed hereditary hemochromatosis without indicating the donor's disease on the container label, or collect blood more frequently from such individuals than every 8 weeks without a physical examination and certification of the donor's health by a physician on the day of donation. This guidance document identifies conditions under which FDA will consider approving the above as alternative procedures, or variances, to the current regulations, and provides guidance on what to submit when requesting these variances. These recommendations apply to all blood establishments, whether or not they hold a U.S. license for the manufacture of blood and blood components. The guidance document announced in this notice finalizes the draft guidance document entitled ''Guidance for Industry: Variances for Blood Collection From Individuals With Hereditary Hemochromatosis'' dated December 2000.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Variances for Blood Collection From Individuals With Hereditary Hemochromatosis'' dated August 2001. This guidance document identifies conditions under which FDA will consider approving the above as alternative procedures, or variances, to the current regulations, under the provisions of 21 CFR 640.120 and provides guidance on what to submit when requesting these variances.

On April 29, 1999, the Public Health Service Advisory Committee on Blood Safety and Availability (ACBSA) recommended that the Department of Health and Human Services (DHHS) ''create policies that eliminate incentives to seek [blood] donation for purposes of phlebotomy'' from patients with diagnosed hemochromatosis who require phlebotomy as therapy for their disease. Further, as undue incentives to donate blood for transfusion (rather than being therapeutically phlebotomized) are removed, DHHS ''should create policies that eliminate barriers to using this resource'' to augment the country's blood supply (Ref. 1).

On August 10, 1999, the Commissioner of Food and Drugs made a commitment to consider case-by-case exemptions to existing blood labeling and donor suitability regulations for blood establishments that can verify that therapeutic phlebotomy for hemachromatosis is performed at no expense to the patient (Ref. 2). FDA additionally committed itself to work with the Health Care Financing Administration in ensuring that the financial incentives for persons with hereditary hemochromatosis (HH) to donate blood for transfusion are removed. This issue was further discussed at the FDA Blood Products Advisory Committee meeting on September 16, 1999 (Ref. 3). For the foreseeable future, if blood establishments wish to distribute blood collected from donors with HH without disease labeling, they would be responsible for removing financial incentives for these donors. Each blood center should evaluate the advantages of entering these donors into their donor pool.

The guidance document announced in this notice finalizes the draft guidance document entitled ''Guidance for Industry: Variances for Blood Collection from Individuals with Hereditary Hemochromatosis'' dated December 2000. This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This guidance document represents the agency's current thinking on blood collection from individuals with hereditary hemochromatosis. It