(301–443–0572 in the Washington, DC area), code 19516. Please call the Information Line for up-to-date information on this meeting.

Agenda: On December 10, 1998, the committee will: (1) Hear updates on the Hepatitis C Virus (HCV) Lookback Guidance, malaria deferral, and supply issues regarding plasma derivatives; (2) hear informational summaries on the Donor Suitability Workshop and the Pilot Program for Streamlining the Licensure of Blood and Blood Components Workshop; and (3) discuss the topic of Hepatitis B Anti-Core (Anti-HBc) Re-entry. In the afternoon, the committee will discuss and provide recommendations on end user notification initiatives for plasma derivatives. On December 11, 1998, the committee will discuss and provide recommendations on the topic of inadvertent contamination of plasma pools for fractionation and recombinant B-Domain-Deleted Antihemophilic factor, sponsor: Genetics Institute.

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 November 30, 1998. Oral presentations from the public will be scheduled from approximately 9 a.m. to 9:30 a.m.; 11:30 a.m. to 12 m.; and 3 p.m. to 3:30 p.m. on December 10, 1998, and from approximately 9 a.m. to 9:30 a.m. and 12 m. to 12:30 p.m. on December 11, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 30, 1998, 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: November 9, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–30749 Filed 11–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0966]

Transmissible Spongiform Encephalopathies 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: Transmissible Spongiform Encephalopathies 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 December 18, 1998, 8 a.m. to 5:30 p.m. Written comments must be submitted on or before Friday, December 4, 1998.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Addresses: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, e-mail ''JBUTLER1@BANGATE.FDA.GOV''. Comments should be identified with the docket number found in brackets in the heading of this document.

Contact Person: William Freas or Sheila D. Langford, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12392. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss possible deferral of blood or plasma donors based on geographical criteria linked to possible foodborne exposure to the agent of Bovine Spongiform Encephalopathy as a measure to reduce the potential for transmission of new variant Creutzfeldt-Jakob Disease (nvCJD) through blood and blood products. The potential effects of such deferrals on the supply of blood and blood products will be considered as part of the committee's deliberations.

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 Dockets Management Branch (address above) on or before December 4, 1998, as described under the *Comments* caption. Oral presentations from the public will be scheduled between approximately 2:15 p.m. and 3:15 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 9, 1998, 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.

Comments: Interested persons may, on or before December 4, 1998, submit to the Dockets Management Branch (address above) written comments regarding this subject. Received comments will be given to the committee for review and made available to the public. Two copies of any comments 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. The received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

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

Dated: November 9, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–30748 Filed 11–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0813]

Guidance for Industry on Fast Track Drug Development Programs: Designation, Development, and Application Review; Availability; Collection of Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Fast Track Drug Development Programs: Designation, Development,

and Application Review.'' This document provides guidance to industry on FDA's fast track program, which seeks to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that have the potential to address unmet medical needs for such conditions. The guidance document is also intended to meet the requirement of section 112(b) of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act).

DATES: Written comments on the guidance document may be submitted by February 16, 1999. General comments on the agency guidance documents are welcome at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'' or ''http://www.fda.gov/cber/guidelines.htm''. Submit written requests for single copies to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–540), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on this guidance document to the Dockets Management Branch (HFD–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. After the comment period, comments may be submitted to one of the centers at the address below.

FOR FURTHER INFORMATION CONTACT: Andrea C. Masciale, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041; or Bette A. Goldman, Center for Biologics Evaluation and Research (HFM–500), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–5098.

SUPPLEMENTARY INFORMATION:

FDA is announcing the availability of a guidance for industry entitled ''Fast Track Drug Development Programs: Designation, Development, and Application Review.'' This guidance document is intended to meet the requirement of section 112(b) of the Modernization Act (Pub. L. 105–115), which amends the Federal Food, Drug, and Cosmetic Act (the act) by adding new section 506 (21 U.S.C. 356) and directs FDA to issue guidance describing its policies and procedures pertaining to fast track products.

FDA's fast track programs are designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs (fast track products). In this guidance document, FDA discusses the regulations, policies, and procedures of the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) that are related to fast track products. This guidance document describes and clarifies the criteria and processes for designating a new drug as a product in a fast track drug development program and describes the diverse activities and programs that can facilitate the development and expedite the review of drugs that demonstrate the potential to advance the treatment of serious and life-threatening illnesses.

This guidance document is being issued as a Level 1 guidance consistent with FDA's Good Guidance Practices (62 FR 8961, February 27, 1997). It is being implemented without prior public comment because the guidance document is needed to implement the Modernization Act. The agency understands the need for this document to be available immediately in order for there to be clear guidance to industry, the public, and agency reviewers about this very significant program. However, FDA also understands that many interested persons may wish to provide comments and suggest revisions to this guidance. FDA is, therefore, emphasizing that it is soliciting comment from all interested persons and is providing a 90-day comment period and establishing a docket for receipt of comments. The agency will give full consideration to all comments received and make any appropriate changes to the guidance in a timely manner.

This guidance document represents the agency's current thinking on its policies and procedures relating to products in fast track drug development programs. 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 requirements of the applicable statute, regulations, or both.

This guidance document contains collections of information that require clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction of 1995. In a notice published in the **Federal Register** of October 21, 1998 (63 FR 56195), FDA announced that this collection of information has been submitted to OMB for emergency processing. The notice also solicited comments on the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless a currently valid OMB control number has been displayed.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the guidance document. Two copies of any comments 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. The guidance 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.

Dated: November 11, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–30811 Filed 11–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0969]

''Guidance for Industry: Evaluation of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals''; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance for Industry: Evaluation of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals.'' This draft guidance announces that FDA now believes it is necessary to evaluate the human health impact of the microbial effects associated with all uses of all classes of antimicrobial new animal drugs intended for use in food-producing animals when approving such drugs.

DATES: Written comments should be submitted by December 18, 1998.

ADDRESSES: Submit written requests for single copies of this draft guidance to