(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,