a.m. and 11 a.m. and 1:45 p.m. and 2:15 p.m. on June 7, 1999, and between approximately 8:15 a.m. and 8:45 a.m. on June 8, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 28, 1999, 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. After the scientific presentations, a 15-minute open public session will be conducted for interested persons who have submitted their request to speak by May 28, 1999, to address issues specific to the submission or topic before the committee.

Closed Committee Deliberations: On June 7, 1999, from 8 a.m. to 10 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). This portion of the meeting will be closed to permit discussion of this information.

FDA regrets that it was unable to publish this notice 15 days prior to the June 7 and 8, 1999, Oncologic Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Oncologic Drugs Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: May 14, 1999.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 99–12852 Filed 5–18–99; 11:31 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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). At least one portion of the meeting will be closed 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 June 2, 1999, 8:30 a.m. to 5:30 p.m., and June 3, 1999, 8:30 a.m. to 4 p.m.

Location: Holiday Inn, Ballroom II, Montgomery Village Ave., Gaithersburg, MD.

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: On June 2, 1999, the committee will continue the discussion from its December 18, 1998, meeting on the possible deferral of blood or blood product donors based on geographical criteria linked to possible food-borne exposure to the agent of bovine spongiform encephalopathy as a measure to reduce the potential for transmission of new variant Creutzfeldt-Jakob Disease (nvCJD). The transcripts of the December meeting are available on the FDA home page (http://www.fda.gov/ohrms/dockets/ac/98tctm.htm). The potential effects of such deferrals on the supply of blood and blood products will be considered as part of the committee's deliberations. The results of a survey of blood donors for duration and time periods of their visits to U.K. countries are expected to be presented. On June 3, 1999, the committee will receive an update on dura mater allograft materials. The committee will then discuss precautions needed to assure safe sources of sheep-derived and goat-derived materials contained in or used to manufacture injectable or implantable FDA-regulated products.

Procedure: On June 2, 1999, from 8:30 a.m. to 5:30 p.m., and June 3, 1999, from 8:30 a.m. to 3:45 p.m., the meeting is open to the public. 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 May 26, 1999. Oral presentations from the public will be scheduled between approximately 1:45 p.m. and 2:45 p.m. on June 2, 1999, and between 1 p.m. and 1:30 p.m. on June 3, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 26, 1999, 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.

Closed Committee Deliberations: On June 3, 1999, from 3:45 p.m. to 4 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). This portion of the meeting will be closed to permit discussion of this material.

FDA regrets that it was unable to publish this notice 15 days prior to the June 2, 1999, Transmissible Spongiform Encephalopathies Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Transmissible Spongiform Encephalopathies Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: May 11, 1999.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 99–12653 Filed 5–19–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1171]

Draft ''Guidance for Industry: For Platelet Testing and Evaluation of Platelet Substitute Products;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled ''Guidance for Industry: For Platelet Testing and Evaluation of Platelet Substitute Products.'' Recent technological advances regarding platelet physiology

and biochemistry have altered the way that platelets can be evaluated. The draft guidance document, when finalized, is intended to provide manufacturers with updated guidance on the evaluation of platelets and of their substituted products.

DATES: Written comments may be submitted at any time, however, comments should be submitted by July 19, 1999, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Guidance for Industry: For Platelet Testing and Evaluation of Platelet Substitute Products'' 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 that 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.

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.

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: For Platelet Testing and Evaluation of Platelet Substitute Products.'' New instrumentation and information about platelet physiology and biochemistry have altered the way that platelets can be evaluated. These advances have prompted FDA's development of an updated draft guidance document regarding platelet testing. The draft guidance document provides recommendations on the evaluation of platelets and platelet substitute products including: In vitro evaluation of platelet biochemistry and function, evaluation of platelet survival in circulation, clinical hemostatic efficacy, and guidance for testing potential platelet substitutes. The draft guidance document, when finalized, is intended to delineate principles of general applicability for evaluation of platelets collected and processed by novel technologies and would replace the document entitled ''Platelet Testing Guidelines'' (July 1981) published in the **Federal Register** of October 2, 1981 (46 FR 48768).

The draft guidance document represents the agency's current thinking on platelet testing and evaluation of platelet substitute products. 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. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

This 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 the draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by July 19, 1999, to ensure adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments and requests for copies should be identified with the docket number found in brackets in the heading of this document. A copy of the draft 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.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance document by using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: May 10, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–12649 Filed 5–19–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0528]

''Guidance for Industry: Efficacy Studies to Support Marketing of Fibrin Sealant Products Manufactured for Commercial Use''; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance for Industry: Efficacy Studies to Support Marketing of Fibrin Sealant Products Manufactured for Commercial Use.'' FDA intends to consider, for licensure of commercially-produced fibrin sealants, data from pivotal studies in which the primary endpoint is hemostasis effectiveness. This document is intended to provide guidance to manufacturers of fibrin sealant products for the design of clinical trials intended to support licensure.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Guidance for Industry: Efficacy Studies to Support Marketing of Fibrin Sealant Products Manufactured for Commercial Use'' 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 that office in processing your requests. The guidance 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.

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: