person by June 7, 1999. Oral presentations from the public will be scheduled between approximately 10 a.m. and 10:30 a.m.; 1:30 p.m. and 2 p.m.; and 4 p.m. and 4:30 p.m. on June 17, 1999, and between 10:30 a.m. and 11 a.m. and 2 p.m. and 2:30 p.m. on June 18, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 7, 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.

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. 99–12793 Filed 5–19–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System Devices Panel of the Medical Devices 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: Circulatory System Devices Panel of the Medical Devices 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 23, 1999, 8 a.m. to 6 p.m., and June 24, 1999, 8 a.m. to 5 p.m.

Location: Hilton Hotel, Salons C, D, and E, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: John E. Stuhlmuller, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8243, ext. 157, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12625. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 23, 1999, the committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for an endovascular graft for the treatment of abdominal aortic aneurysms. Subsequently, the committee will discuss, make recommendations, and vote on a PMA for an endovascular graft for the treatment of abdominal aortic or aorto-iliac aneurysms. On June 24, 1999, the committee will discuss, make recommendations, and vote on a PMA for a prosthetic heart valve. Subsequently, the committee will discuss, make recommendations, and vote on a PMA for a dual-chamber defibrillator for the treatment of atrial and ventricular tachyarrhythmias.

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 June 13, 1999. Oral presentations from the public will be scheduled between approximately 8 a.m. and 8:30 a.m. on June 23, 1999 and June 24, 1999. Near the end of committee deliberations on both days, a 30-minute open public hearing will be conducted for interested persons to address issues specific to the topics before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 13, 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.

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. 99–12792 Filed 5–19–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Oncologic 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 June 7 and 8, 1999, 8 a.m. to 5:30 p.m.

Location: Town Center Hotel, Maryland Ballroom, 8727 Colesville Rd., Silver Spring, MD.

Contact Person: Karen M. Templeton–Somers, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20057, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss: (1) The use of time-to-progression as the primary endpoint in breast cancer drug trials; and (2) new drug application (NDA) 21–010, epirubicin hydrochloride for injection, Pharmacia and Upjohn Co., indicated for use as a component of adjuvant therapy in patients with evidence of axillary-node-tumor involvement following resection of primary breast cancer (Stage II & III). Epirubicin is indicated for the therapy of patients with locally advanced or metastatic breast cancer. On June 8, 1999, the committee will discuss: (1) NDA 50–718/S–006, Doxil® (doxorubicin HCl liposome injection), Alza Corp., indicated for the treatment of patients with metastatic carcinoma of the ovary who are refractory to both paclitaxel- and platinum-based chemotherapy regimens and who may also be refractory to topotecan. Refractory is defined as a patient having progressive disease while on treatment, or within 6 months of completing treatment; and (2) NDA 20–221/S–012, Ethyol® (amifostine) for injection, U.S. Bioscience, Inc., indicated for use to reduce the incidence and severity of radiation induced xerostomia.

Procedure: On June 7, 1999, from 10:30 a.m. to 5:30 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 28, 1999. Oral presentations from the public will be scheduled between approximately 10:45

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