DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood Products 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: Blood Products 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 March 18, 2004, from 8 a.m. to 5 p.m. and on March 19, 2004, from 8 a.m. to 3 p.m.

Location: Holiday Inn, Gaithersburg, Two Montgomery Ave., Gaithersburg, MD.

Contact Person: Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM–302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3514, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014519516. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 18, 2004, the committee will hear presentations, discuss, and provide recommendations on clinical trials for licensing hepatitis B immune globulin as treatment to prevent hepatitis B virus (HBV) liver disease following liver transplantation in HBV+ recipients. The committee will also hear updates on the following topics: (1) Summary of meeting of the Public Health Service Advisory Committee on Blood Safety and Availability; (2) summary of the meeting of the Transmissible Spongiform Encephalopathies Advisory Committee Meeting; (3) current thinking on draft guidance for nucleic acid testing (NAT) for human immunodeficiency virus (HIV) and hepatitis C virus (HCV): Testing, product disposition, and donor deferral and re-entry; (4) current thinking on guidance for use of NAT on pooled and individual samples from donors of whole blood and blood components to adequately and appropriately reduce the risk of transmission of HIV–1 and HCV; and (5) current thinking on variances to address the specificity issues of Ortho HBsAg 3.0 assays. In the afternoon, the committee will hear presentations, discuss, and provide recommendations on supplemental testing for HIV and HCV. On March 19, 2004, the committee will hear presentations, discuss, and provide recommendations on platelet apheresis quality control: A statistical quality control model, and hear presentations relevant to the site visit report on the review of the research programs of the Laboratory of Hepatitis and Emerging Bacterial Agents and the Laboratory of Bacterial, Parasitic, and Unconventional Agents.

Procedure: On March 18, 2004, from 8 a.m. to 5 p.m. and on March 19, 2004, from 8 a.m. to 2:15 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 February 27, 2004. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10 a.m., 3:45 p.m. and 4:15 p.m. on March 18, 2004; and between approximately 9:30 a.m. and 10 a.m. on March 19, 2004. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 27, 2004, 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 March 19, 2004, from 2:15 p.m. to 3 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss the reports of the review of individual research programs in the Division of Emerging and Transfusion Transmitted Diseases, Office of Blood Research and Review, Center for Biologics Evaluation and Research.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Linda A. Smallwood at 301–827–3514 or Pearline K. Muckelvene at 301–827–1281 at least 7 days in advance of the meeting.

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

Dated: February 19, 2004.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 04–4033 Filed 2–24–04; 8:45 am]

BILLING CODE 4160–01–S

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 March 17 and 18, 2004, from 9 a.m. to 5 p.m.

Location: Hilton Washington D.C. North/Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Geretta Wood, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8320, ext. 143, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512625. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 17, 2004, the committee will discuss, make recommendations, and vote on a premarket approval application for a Total Artificial Heart indicated for bridge to transplant usage in cardiac transplant-eligible candidates at risk of imminent death from non-reversible biventricular failure and replaces the patient's native ventricles and valves. The device is intended for use inside the hospital. On March 18, 2004, FDA will present to the committee the history, current medical practice, and regulatory background regarding Aortic Anastomotic Devices. The committee