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of the meeting of the Transmissible Spongiform Encephalopathies Advisory Committee Meeting; (3) current thinking on draft guidance for nucleic acid testing (NAT) for human immunodeficiency virus (HIV) and hepatitis C virus (HCV): Testing, product disposition, and donor deferral and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

will discuss and make recommendations regarding the type of data and study required to effectively evaluate performance of Aortic Anastomotic Devices for marketing, recognizing the significant public health impact on cardiac disease they represent. Background information for the day's topics, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at *http://www.fda.gov/cdrh/panelmtg.html*. Material for the March 17, 2004, session will be posted on March 16, 2004; material for the March 18, 2004, session will be posted on March 17, 2004.

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 March 8, 2004. On March 17, 2004, oral presentations from the public will be scheduled for approximately 30 minutes at both the beginning and near the end of committee deliberations. On March 18, 2004, oral presentations from the public will be scheduled from approximately 10 a.m. to 12:30 p.m. and for approximately 30 minutes near the end of the deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 8, 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.

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 AnnMarie Williams, Conference Management Staff, at 301–594–1283, ext. 113, 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. 04–4034 Filed 2–24–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0568]

Draft Guidance for Industry and FDA Staff on Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance for industry and FDA staff entitled ''Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices.'' It was developed as a special control to support the reclassification of the vascular embolization device and the neurovascular embolization device from class III (premarket approval) into class II (special controls). The draft guidance is not final nor is it in effect at this time. We are also announcing the withdrawal of the 1994 draft guidance document entitled ''Guidance on Biocompatibility Requirements for Long Term Neurological Implants: Part 3—Implant Model,'' dated September 12, 1994.

DATES: Submit written or electronic comments on the draft guidance by May 25, 2004.

ADDRESSES: Submit written requests for single copies of the draft guidance on a 3.5″ diskette to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Peter L. Hudson, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and FDA staff entitled ''Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices.''

On June 12, 1998, the Neurological Devices Panel (the Panel) considered the information in three submissions of safety and effectiveness under section 515(i) for the neurovascular embolization device, and recommended that this device be reclassified from class III into class II.

While the Panel's recommendation was specifically for the neurovascular embolization device, because of the similarity of the vascular (arterial) embolization device to the neurovascular (artificial) embolization device, with regard to its intended use, design, risks to health, and measures to mitigate the risks to health, FDA determined that the Panel reclassification recommendation for the neurovascular embolization device is relevant to the vascular embolization device.

We are withdrawing the guidance document entitled ''Guidance on Biocompatibility Requirements for Long Term Neurological Implants: Part 3—Implant Model'' because it contains outdated information. Archived copies of Center for Devices and Radiological Health (CDRH) guidance documents that have been withdrawn are available from the Division of Small Manufacturers, International, and Consumer Assistance (see **ADDRESSES**).

Elsewhere in this issue of the **Federal Register**, FDA is proposing to reclassify the vascular embolization device and the neurovascular embolization device into class II. The currently available guidance document entitled ''Guidance for Neurological Embolization Devices'' dated November 1, 2000, was revised as a draft class II special controls guidance document to support the reclassification of these device types. If finalized, the ''Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices'' will supersede the November 1, 2000, guidance document and will serve as the special control for these devices.

Following the effective date of any final reclassification rule based on this proposal, any firm submitting a premarket notification (510(k)) for a vascular embolization device or a neurovascular embolization device will need to address the issues covered in the special controls guidance document. However, the firm need only show that its device meets the recommendations of the guidance document or in some