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). The meeting will be open 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 October 21, 2004, from 8 a.m. to 5:30 p.m. and on October 22, 2004, from 8:30 a.m. to 12:45 p.m.

Location: Holiday Inn Gaithersburg, Two Montgomery Village 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 October 21, 2004, the committee will hear updates on the following topics: Summary of the Transmissible Spongiform Encephalopathies Advisory Committee (TSEAC) meeting discussion of new variant Creutzfeldt-

Jacob disease (vCJD) transmission by transfusion in the United Kingdom and supplemental testing for human immunodeficiency virus (HIV) and hepatitis C virus (HCV). In the morning, the committee will also discuss and provide recommendations on the agency's current thinking on re-entry of donors previously deferred for anti-HBc reactivity. In the afternoon, the committee will discuss and provide recommendations on the potential risk of transmission of Simian Foamy Virus (SFV) by blood transfusions. On October 22, 2004, the committee will hear updates on these topics: a summary of the Plasma Workshop held on August 31 through September 1, 2004, draft uniform donor health questionnaire acceptance guidance: review of public comments, and FDA current thinking on monitoring weight in source plasma donors. The committee will also hear presentations, discuss and provide recommendations on the agency's current thinking on donor deferral for potential or documented infection with West Nile Virus (WNV).

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 October 8, 2004. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11 a.m., 4 p.m. and 4:30 p.m. on October 21, 2004, and between approximately 11 a.m. and 11:45 a.m. on October 22, 2004. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 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 Linda A. Smallwood, 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: Sept 13, 2004

September 13, 2004.

Sheila Dearybury Walcoff,
Associate Commissioner for External Relations.

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