

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 July 21, 2005, from 8 a.m. to 6:30 p.m.

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

Contact Person: William Freas or Pearline K. Muckelvene, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, 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 July 21, 2005, in the morning, the committee will hear updates on the following topics: (1) Summary of the May 2005 meeting of the Department of Health and Human Services Advisory Committee on Blood

Safety and Availability; (2) disseminated intravascular coagulation associated with acute hemoglobinemia following anti-D Immune Globulin Intravenous administration for idiopathic thrombocytopenic purpura; (4) update on safety of albumin; (5) summary of June 2005 workshop on Biological Therapeutics for Rare Plasma Protein Disorders; (6) summary of July 2005 workshop on Leukoreduction and updates on West Nile Virus guidance. The committee will discuss management of donors and units that test positive for Hepatitis B Virus DNA by nucleic acid tests. In the afternoon, the committee will discuss the scientific basis for review of Varicella Zoster Immune Globulin and Dextran 1 pretreatment for safe use of Dextran 40/70.

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 July 5, 2005. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11 a.m., 2:30 p.m. and 3 p.m., and 5 p.m. and 5:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 13, 2005, 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 William Freas or Pearline K. Muckelvene 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: June 23, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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