

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 November 3, 2005, from 8 a.m. to 5:30 p.m., and on November 4, 2005, from 8 a.m. to 3:30 p.m.

Location: Holiday Inn Gaithersburg, 2 Montgomery Village Ave., Gaithersburg, MD 20879.

Contact Person: Donald W. Jehn or Pearline K. Muckelvene, Center for Biologics Evaluation and Research, 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On November 3, 2005, in the morning, the committee will hear updates on the following topics: (1) West Nile Virus; (2) draft guidance on nucleic acid testing (NAT) for human immunodeficiency virus (HIV)-1 and

hepatitis C virus (HCV): Testing, product disposition, and donor deferral and re-entry; (3) summary of the Department of Health and Human Services Advisory Committee on Blood Safety and Availability held on September 19 and 20, 2005; and (4) re-entry of donors deferred based on hepatitis B core antigen (anti-HBc) test results. The committee will discuss approaches to over-the-counter (OTC) home-use HIV test kits the rest of the day. On November 4, 2005, in the morning, the committee will hear information on serious adverse events resulting from interference with measurement of blood glucose following infusion of maltose-containing immune globulin intravenous (human) and will discuss Alpha-1-Proteinase Inhibitor products. In the afternoon, the committee will hear an overview of the research programs of the Office of Blood Research and Review, Center for Biologics Evaluation and Research, as presented to a subcommittee of the Blood Products Advisory Committee during their site visit on July 22, 2005, and discuss a subcommittee report.

Procedure: On November 3, 2005, the entire meeting is open to the public. On November 4, 2005, 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 October 25, 2005. Oral presentations from the public will be scheduled on November 3, 2005, between approximately 2 p.m. and 3:45 p.m. and on November 4, 2005, between 10:30 a.m. and 11 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 25, 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.

Closed Committee Deliberations: On November 4, 2005, 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)), and to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). The committee will discuss a subcommittee's report of the internal research programs in the Office of Blood Research and Review, CBER.

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 Donald W. Jehn 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: October 6, 2005.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

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

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