

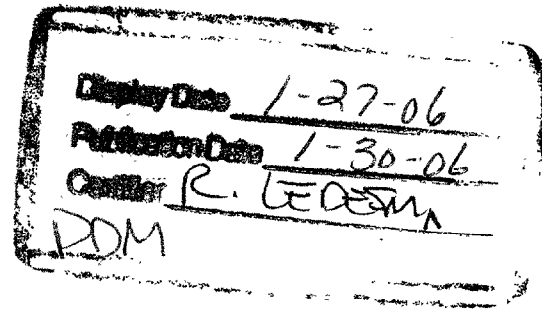
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 9, 2006, from 8 a.m. to 5 p.m. and March 10, 2006, from 8:30 a.m. to 4:30 p.m.

Location: Hilton Hotel Washington DC North/ Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: Donald W. Jehn, 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 March 9, 2006, in the morning the committee will hear updates on the following topics: (1) Summary of the Department of Health and Human Services Advisory Committee on Blood Safety and Availability January

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2006 meeting; (2) current considerations for blood donor screening for West Nile Virus; (3) classification of transfusion recipient identification (ID) systems; and (4) summary of the workshop on behavior-based donor deferrals in the Nucleic Acid Test (NAT) era. The committee will then discuss rapid tests for detection of bacterial contamination of platelets. In the afternoon, the committee will discuss public comments on the "Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (DRAFT)." On March 10, 2006, in the morning the committee will discuss proposed studies to support the approval of over-the-counter (OTC) home-use human immunodeficiency virus (HIV) test kits. 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 (CBER), as presented to a subcommittee of the Blood Products Advisory Committee during their site visit on July 22, 2005, and discuss a subcommittee report in closed session. Additionally, the committee will hear an overview of the research programs in the Laboratory of Biochemistry and Vascular Biology and the Laboratory of Cellular Hematology, Division of Hematology, Office of Blood Research and Review, CBER and in closed session discuss the report from the laboratory site visit of October 6, 2005.

Procedure: On March 9, 2006, the meeting is open to the public. On March 10, 2006, from 8:30 a.m. to 3:15 p.m. and again from 4:15 p.m. to 4:30 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 28, 2006. Oral presentations from the public will be scheduled on March 9, 2006, between approximately 9:45 a.m. to 11:30 a.m. and 2:30 p.m.

to 3:30 p.m. On March 10, 2006, oral presentations from the public will be scheduled between approximately 9:30 a.m. to 10:30 a.m. and 2:45 p.m. to 2:55 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 28, 2006, 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 10, 2006, from 3:15 p.m. to 4:15 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. In addition, the committee will discuss the site visit report for the Laboratory of Biochemistry and Vascular Biology and Laboratory of Cellular Hematology, Division of Hematology, Office of Blood Research and Review, CBER.

Following this closed session, the committee will provide summarized comments regarding the Office Site Visit Report in an open public session.

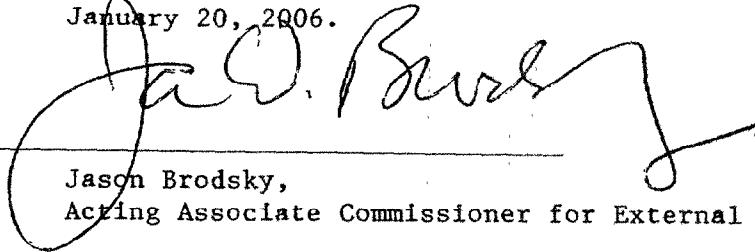
Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

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: 1-20-06

January 20, 2006.



Jason Brodsky,
Acting Associate Commissioner for External Relations.

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

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