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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 May 1, 2008, from 8:30 a.m. to 5:30 p.m. and on May 2, 2008, from 8:30 a.m. to 4 p.m.

Location: Hilton Hotel, Washington DC/Rockville Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Donald W. Jehn or Pearline K. Muckelvene, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike (HFM–71), 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. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and

call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On the morning of May 1, 2008, the committee will hear updates on the following: (1) Summaries of August 22–23, 2007, and January 9–10, 2008, meetings of the Department of Health and Human Services Advisory Committee on Blood Safety and Availability; (2) 2007 West Nile Virus Epidemiology and the use of nucleic acid tests to reduce the risk of transmission of West Nile Virus in Whole Blood and blood components for transfusion and Human Cells, Tissues, and Cellular and Tissue-based products (HCT/Ps); (3) implementation of blood donor screening for infection with *Trypanosoma cruzi* and the use of serological tests to reduce the risk of transmission of *T. cruzi* infection in Whole Blood and blood components for transfusion and HCT/Ps; (4) FDA's proposal to lower the minimum recommended lot release titer for measles antibodies in Immune Globulin Intravenous (Human) and Immune Globulin Subcutaneous (Human); (5) Gambro/Fenwal Post Approval Surveillance Study of Platelet Outcomes, Release Tested (PASSPORT) Post Marketing Study—7 Day Platelets; (6) Experience with 7 Day Platelets Versus 5 Day Platelets; and (7) FDA Perspective on the PASSPORT Study. These updates will be followed by informational presentations on FDA's Center for Biologics Evaluation and Research Safety Teams related to blood and tissue. In the afternoon, the committee will discuss the Biomedical Excellence for Safer Transfusion Committee Report on red blood cell recovery standards. On the morning of May 2, 2008, the committee will discuss Lev Pharmaceutical's plasma-derived C1 esterase inhibitor (CINRYZE). Then, in the afternoon the committee will review the research programs in the Laboratory of Hepatitis and Related

Emerging Agents, Division of Emerging and Transfusion Transmitted Diseases, Office of Blood Research and Review, CBER Site Visit of November 8, 2007.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2008 and scroll down to the appropriate advisory committee link.

Procedure: The entire day of May 1, 2008, and on May 2, 2008, from 8:30 a.m. to 3:15 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 on or before April 23, 2008. Oral presentations from the public will be scheduled between approximately 11:50 a.m. and 12:20 p.m. and between approximately 4:20 p.m. and 4:50 p.m. on May 1, 2008, and between approximately 10:40 a.m. and 11:10 a.m. and 2:40 p.m. and 3 p.m. on May 2, 2008. Those desiring to make formal oral presentations should notify the contact person 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 on or before April 15, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers

for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 16, 2008.

Closed Committee Deliberations: On May 2, 2008, between 3:15 p.m. and 4 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 reports of intramural research programs and make recommendations regarding personnel staffing decisions.

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.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: 3/20/08

March 20, 2008.

Randall W. Lutter,
Deputy Commissioner for Policy.

[FR Doc. 08–????? Filed ??–??–08; 8:45 am]

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Dawn P. Hawkins