DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

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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 August 16, 2007, from 8 a.m. to 5 p.m.

Location: Doubletree Hotel and Executive Meeting Center, 8120 Wisconsin Ave., Bethesda, MD 20814.

Contact Person: Donald W. Jehn or Pearline K. Muckelvene, Center for Biologics Evaluation and Research, 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 August 16, 2007, the Committee will hear updates on the following topics: (1) Summary of the May 10 through 11, 2007, and the August 6 through 7, 2007, meetings of the Department of Health and Human Services Advisory Committee on Blood Safety and Availability; (2) summary of the April 25 through 26, 2007, FDA Workshop on Immune Globulins for Primary Immune Deficiency Diseases: Antibody Specificity, Potency and Testing; and (3) summary of the August 15, 2007, FDA Workshop on Licensure of Apheresis Blood Products. The Committee will then hear informational presentations relating to World Health Organization (WHO) biological standards on the following topics: (1) Summary of the January 29 through 30, 2007, WHO meeting with WHO collaborating centers for biological standards and standardization to support the development of WHO biological reference preparations for high risk blood safety-related in vitro diagnostics; (2) potency and safety standards for plasma derivatives; and (3) joint FDA/WHO minimum potency standards for certain blood grouping reagents. The Committee will hear the response of the Office of Blood Research and Review to their office level site visit of July 22, 2005. In the afternoon the Committee will discuss measles antibody levels in U.S. Immune Globulin products.

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 2007 and scroll down to the appropriate advisory committee link.

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 on or before August 8, 2007. Oral presentations from the public will be scheduled between approximately 11:15 a.m. and 11:45 p.m. and between approximately 3:30 p.m. and 4 p.m. on August 16, 2007. 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 July 31, 2007. 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 August 1, 2007.

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: 7/16/07
July 16, 2007.

Randall W. Lutter,
Deputy Commissioner for Policy.

[FR Doc. 07–????? Filed ??–??–07; 8:45 am]

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