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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date 11-20-03

Publication Date 11-21-03

Certifier A. Corbin

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 December 11, 2003, from 8 a.m. to 6:30 p.m.; and on December 12, 2003, from 8 a.m. to 3 p.m.

Location: Hilton DC North—Gaithersburg, Grand Ballrooms A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM-302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-3514, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 19516. Please call the Information Line for up-to-date information on this meeting.

Agenda: On December 11, 2003, the committee will hear presentations and discuss and provide recommendations on these topics: The American Association for Blood Banks (AABB) abbreviated donor questionnaire; and

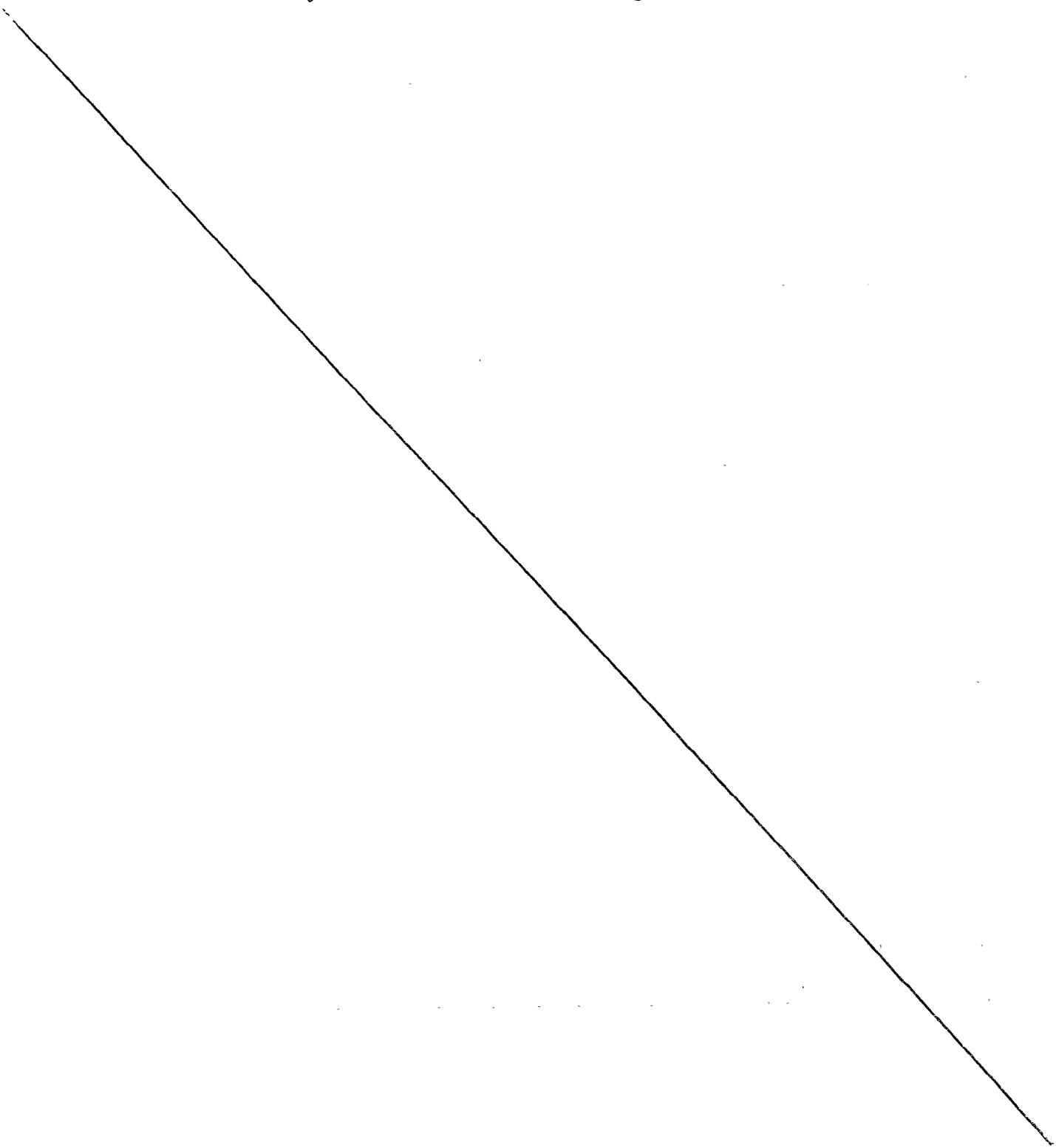
blood donor deferral for exposure to Leishmaniasis. In the afternoon, the committee will hear an update on the West Nile Virus (WNV) epidemic and donor testing in 2003 including updates on WNV testing under investigational new drug applications and plans for 2004. On December 12, 2003, the committee will hear updates on these topics: The Medical Device User Fee and Modernization Act of 2002 (MDUFMA), the use of secure e-mail, a summary of the factor VIII inhibitor workshop, platelet testing and evaluation guidance, and freezing and storage temperatures for source plasma (-25 °C and -30 °C). The committee will also hear presentations and discuss and provide recommendations on the review of plasma collection nomograms.

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 November 21, 2003. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11 a.m., 2 p.m. and 2:30 p.m., and 5:30 p.m. and 5:45 p.m. on December 11, 2003; and between approximately 9:30 a.m. and 10:15 a.m., and 12 noon and 12:30 p.m. on December 12, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 21, 2003, 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 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 Linda A. Smallwood, or Pearline K. Muckelvene at 301-827-1281 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: November 14, 2003
November 14, 2003.



~~William K. Hubbard,~~
Associate Commissioner for Policy and Planning.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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