

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.

SMB

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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 March 15, 2001, from 8:30 a.m. to 6 p.m. and on March 16, 2001, from 8:30 a.m. to 12 noon.

Location: Hilton, 620 Perry Pkwy., Gaithersburg, MD.

Contact: Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM-302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 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 March 15, 2001, the committee will hear presentations, discuss and make recommendations on the comparative sensitivity of Hepatitis B Virus nucleic acid testing versus Hepatitis B Surface Antigen testing. In the afternoon, the committee will hear presentations, discuss and make recommendations on the implementation of nucleic acid testing for Hepatitis C Virus and human immunodeficiency virus, testing donor and product management, and blood bags for diversion of the initial collection. On March 16, 2001, the committee will hear updates on the

following topics: (1) Summaries of the Transmissible Spongiform Encephalopathies Advisory Committee Meeting and the Public Health Service Advisory Committee Meeting on blood safety and availability, and (2) The Office of Inspector General's report on tissue and organ regulation. The committee will additionally hear presentations, discuss and make recommendations on the topic of guidance on malaria, applicability to plasma.

Procedure: On March 15, 2001, from 8:30 a.m. to 6 p.m. and on March 16, 2001, from 8:30 a.m. to 12 noon, 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 March 9, 2001. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10:30 a.m., 1:30 p.m. and 2:30 p.m., and 4:30 p.m. and 5:30 p.m. on March 15, 2001, and 10:15 a.m. and 10:30 a.m. on March 16, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 9, 2001, 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.

FDA regrets that it was unable to publish this notice 15 days prior to the March 15 to 16, 2001, Blood Products Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Blood Products Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

2).

Dated: February 28, 2001.

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Linda A. Suydam
Linda A. Suydam,
Senior Associate Commissioner.

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Suzette N. Reese