

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

2967 '00 MAR -2 A8 53

DMB

Display Date	3-1-00@9:46p
Publication Date	3-6-00
Certifier	S. Reese

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 16, 2000, from 8 a.m. to 6 p.m. and on March 17, 2000, from 8 a.m. to 3:30 p.m.

Location: Holiday Inn, 8777 Georgia Ave., Kennedy Grand Ballroom, Silver Spring, MD 20910.

Contact Person: 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 16, 2000, the following committee updates are tentatively scheduled: (1) Summaries of recent workshops on bacterial contamination of platelets, (2) criteria for safety and efficacy evaluation of oxygen therapeutics as red cell substitutes, (3) implementation of universal leukoreduction, and (4) the National Institutes of Health Workshop on Parvovirus B19. In the morning, the committee will hear presentations, and discuss and make recommendations on a

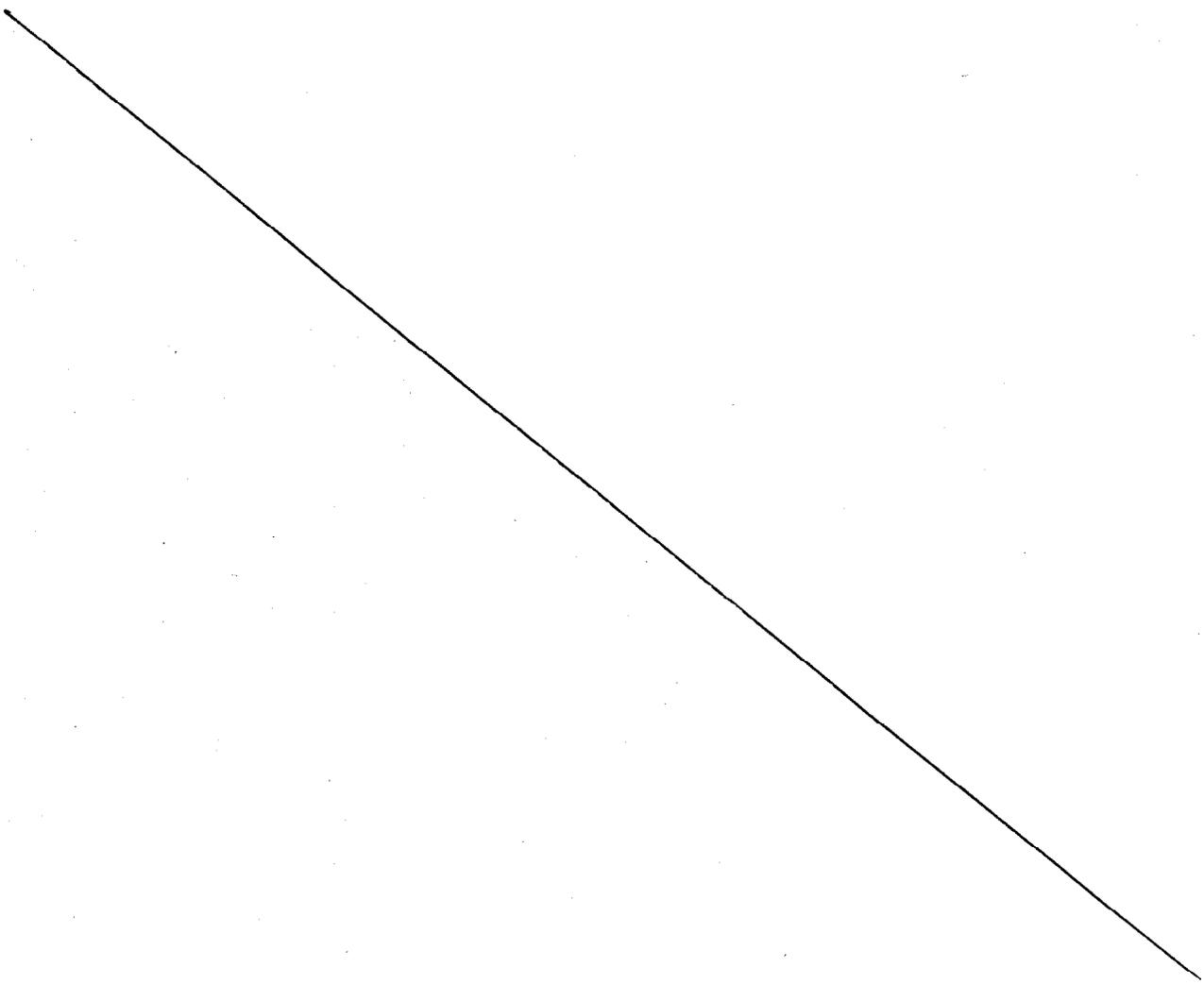
submitted proposal to revise the interpretation of indeterminate human immunodeficiency virus-1 Western Blots with only nonviral bands. In the afternoon, the committee will hear presentations, and discuss and make recommendations on the topics of a history of hepatitis in blood and plasma donors and hepatitis B virus nucleic acid testing. On March 17, the committee will hear updates on the following topics: (1) Summary of the January 2000 Public Health Service Advisory Committee Meeting on Blood Safety and Availability, (2) Creutzfeld-Jacob Disease policy, (3) hepatitis C virus lookback guidance, (4) postdonation information algorithm, and (5) immune globulin intravenous clinical endpoints. In the morning, the committee will hear an informational presentation on the blood action plan and supply issues, and discuss and make recommendations on donor deferral issues related to xenotransplantation. In the afternoon, the committee will be briefed on research programs in the Laboratory of Plasma Derivatives, Division of Hematology, Center for Biologics Evaluation and Research (CBER).

Procedure: On March 16, 2000, from 8 a.m. to 6 p.m. and on March 17, 2000, from 8 a.m. to 3 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 March 7, 2000. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11 a.m., 2:30 p.m. and 3 p.m., and 4:30 p.m. and 5 p.m. on March 16, 2000; and between approximately 9:30 a.m. and 10 a.m., and 11:30 a.m. and 12 noon on March 17, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 7, 2000, 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 17, 2000, from 3 p.m. to 3:30 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 the review of individual research programs in the Division of Hematology, CBER.

FDA regrets that it was unable to publish this notice 15 days prior to the March 16 and 17, 2000, 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, 2000


Linda A. Suydam
Senior Associate Commissioner

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL.

