

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier R. LEDESMA

Food and Drug Administration

Biological Response Modifiers 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: Biological Response Modifiers 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 February 27, 2003, from 8 a.m. to 6 p.m., and on February 28, 2003, from 8 a.m. to 4:30 p.m.

Location: Holiday Inn, 8777 Georgia Ave., Silver Spring, MD.

Contact Person: Gail Dapolito or Rosanna L. Harvey, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, 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 12389. Please call the Information Line for up-to-date information on this meeting.

Agenda: On February 27, 2003, from 8 a.m. to approximately 3:45 p.m., the committee will discuss efficacy data for the use of minimally manipulated hematopoietic stem cells from placental/umbilical cord blood for hematopoietic reconstitution for particular age groups. From approximately

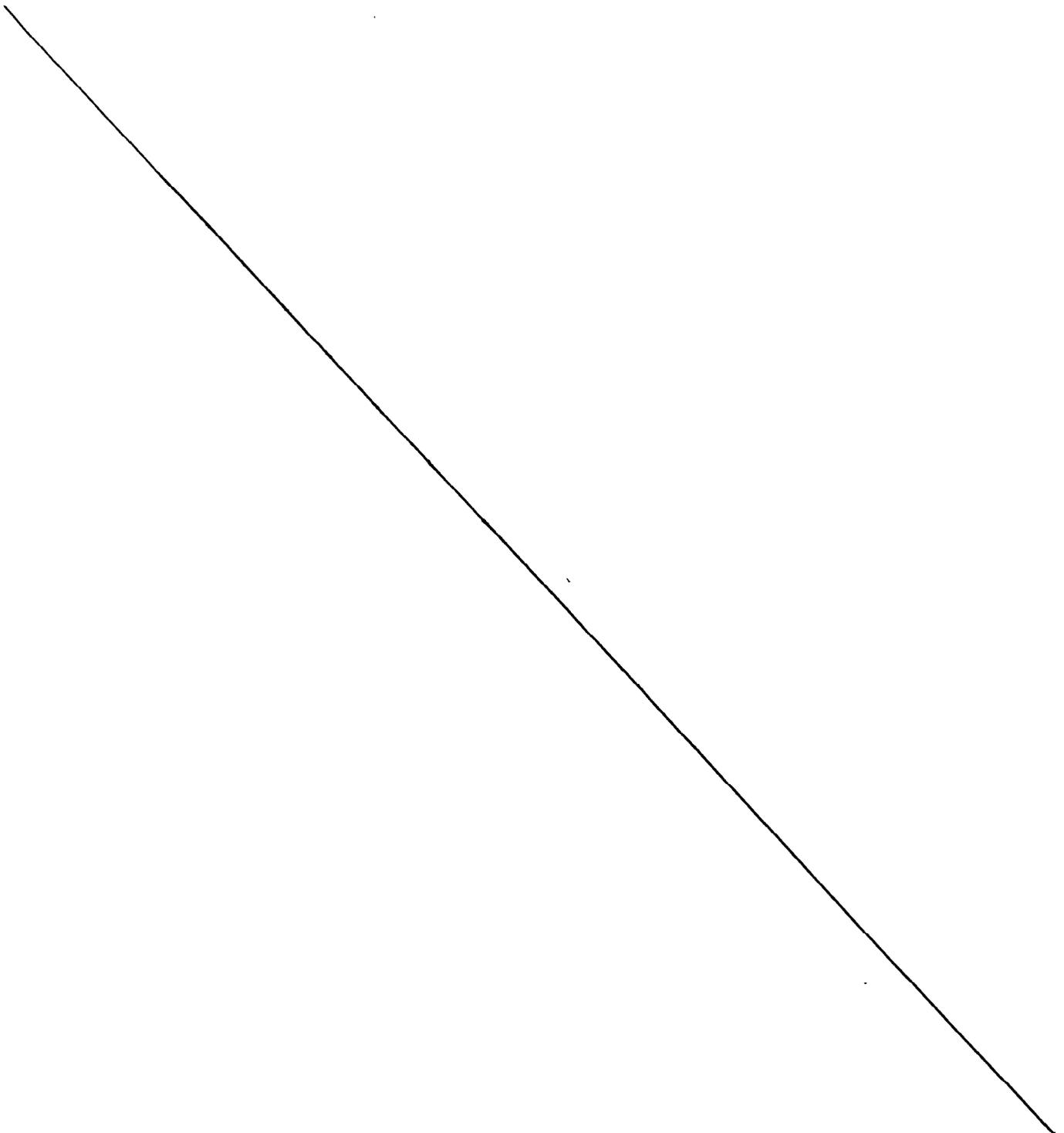
3:45 p.m. to 5:30 p.m., the committee will receive updates of research programs in the Division of Monoclonal Antibodies, Center for Biologics Evaluation and Research (CBER). On February 28, 2003, from 8 a.m. to approximately 4:30 p.m., the committee will discuss safety issues related to the use of retrovirus vectors in gene therapy clinical trials.

Procedure: On February 27, 2003, from 8 a.m. to 5:30 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 February 20, 2003. On February 27, oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m. On February 28, oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 20, 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.

Closed Committee Deliberations: On February 27, 2003, from approximately 5:30 p.m. to 6 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 a review of individual research programs in CBER.

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 Gail Dapolito or Rosanna L. Harvey 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: 1/24/03
January 24, 2003.



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

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

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