

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration 2966 00 MAR -2 A8:53

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 March 20, 2000, 9 a.m. to 5:30 p.m. and on March 21, 2000, 8 a.m. to 4 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

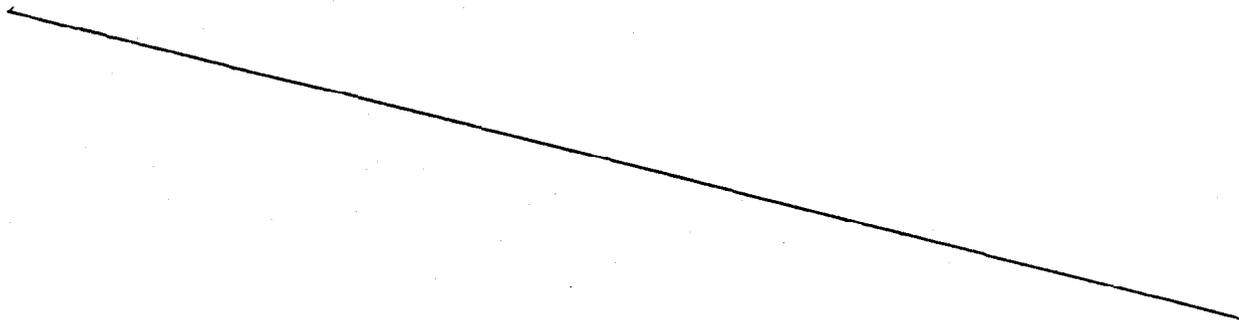
Contact Person: Gail Dapolito or Rosanna Harvey, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12389. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 20 and 21, 2000, the committee will discuss: (1) Issues related to the use of human pancreatic islets for the treatment of diabetes, including product development issues relating to the procurement, processing and characterization of islets, preclinical animal models for islets and a brief clinical perspective; (2) the report of the January 13, 2000, meeting of the Xenotransplantation Subcommittee; and (3) an update of research programs in the Division of Cellular and Gene Therapies and the Division of Therapeutic Proteins.

Procedure: On March 20, 2000, from 9 a.m. to 5:30 p.m. and on March 21, 2000, from 8 a.m. to 8:45 a.m. and from 9:30 a.m. to 5 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 10, 2000. Oral presentations from the public will be scheduled between approximately 1:45 p.m. and 2:15 p.m. on March 20, 2000, and between 11:30 a.m. and 12 noon on March 21, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 10, 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.

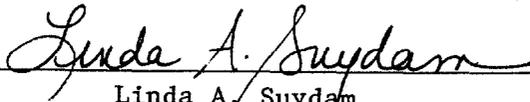
Closed Committee Deliberations: On March 21, 2000, from 8:45 a.m. to 9:30 a.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss reports of the review of individual research programs in the Division of Cellular and Gene Therapies and the Division of Therapeutic Proteins, Center for Biologics Evaluation and Research.

FDA regrets that it was unable to publish this notice 15 days prior to the March 20 and 21, 2000, Biological Response Modifiers Advisory Committee meeting. Because the agency believes there is some urgency to bring these issue to public discussion and qualified members of the Biological Response Modifiers 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]

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