

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier G. Parley

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 October 9, 2003, from 8 a.m. to 6 p.m.; and on October 10, 2003, from 8 a.m. to 2 p.m.

Location: Holiday Inn, Grand Ballroom, Two Montgomery Village Ave., Gaithersburg, 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 October 9 and 10, 2003, the committee will discuss the following topics: (1) Issues related to manufacturing data and clinical evidence to be provided in a biologics license application (BLA) for marketing approval

of allogeneic islet transplantation to treat type 1 diabetes mellitus, (2) hear updates of individual research programs in the Office of Cellular, Tissue and Gene Therapies, and (3) reports of internal research programs in the Office of Cellular, Tissue and Gene Therapies.

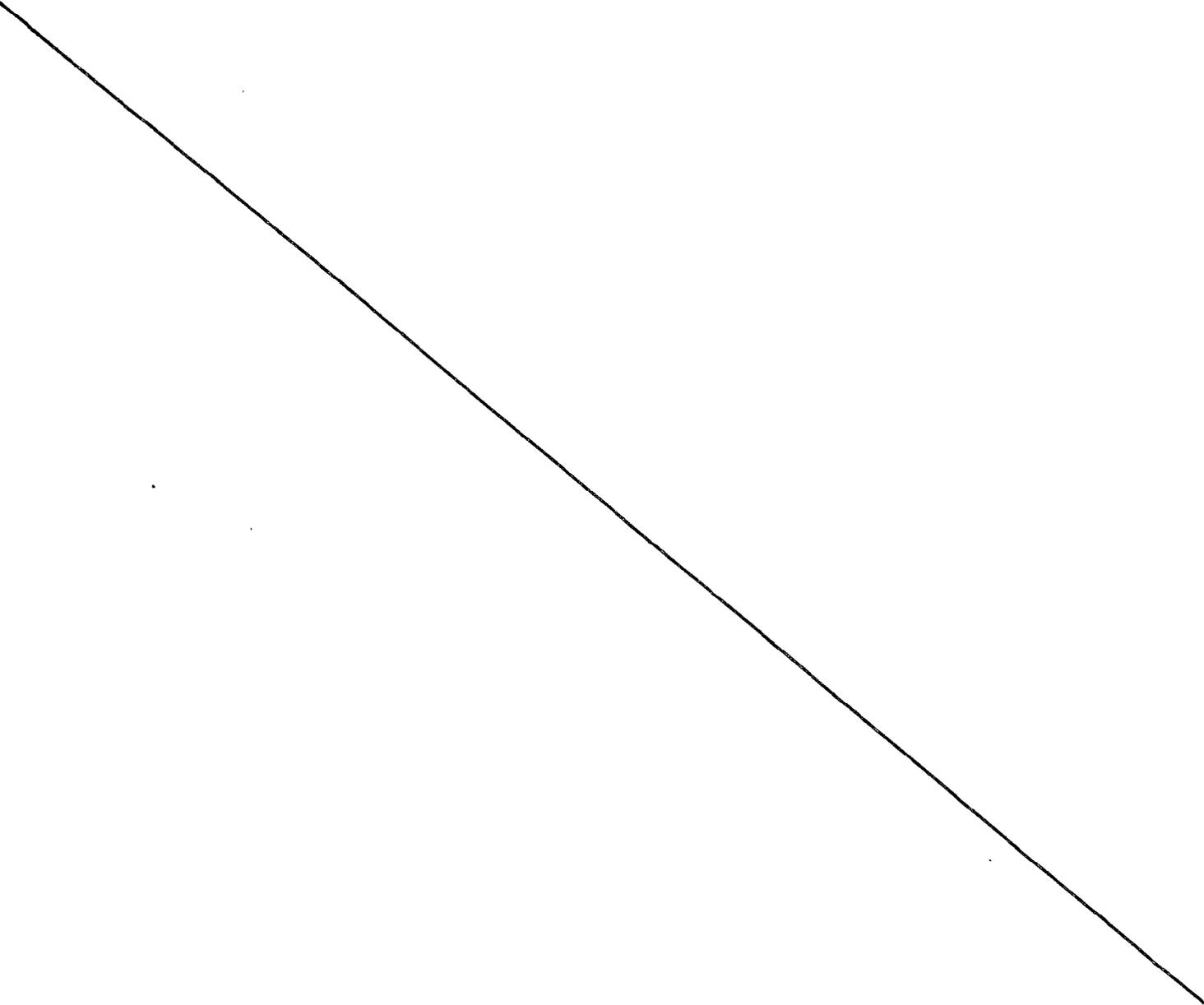
Procedure: On October 9, 2003, from 8 a.m. to approximately 5:15 p.m.; and on October 10, 2003, from 8 a.m. to approximately 2 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 2, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 p.m. on October 9 and between approximately 10:30 a.m. and 11 a.m. on October 10. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 2, 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 October 9, 2003, from approximately 5:15 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 a report of a review of internal research programs in the Office of Cellular, Tissue and Gene Therapies, Center for Biologics Evaluation and Research.

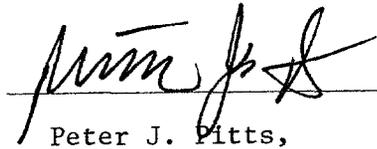
Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

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 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: 9/9/03
September 9, 2003.



Peter J. Pitts,
Associate Commissioner for External Relations.

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

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