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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 July 15, 1999, 8 a.m. to 5:45 p.m.

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

Contact Person: Gail M. 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 July 15, 1999, the committee will discuss the following issues: (1) An update of FDA's regulatory policy concerning the implications on biological product development of fast track and the recent pediatric rule, (2) a scientific discussion concerning immune reactions to therapeutic and diagnostic biological products, (3) the report of the June 3 through 4, 1999, meeting of the xenotransplantation subcommittee, and (4) an update of research programs in the Laboratory of Cytokine Research, Office of Therapeutics Research and Review, Center for Biologics Evaluation and Research.

Procedure: On July 15, 1999, from 8 a.m. to approximately 1 p.m., and from 1:30 p.m. to approximately 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 July 8, 1999. Oral presentations from the public will be scheduled between approximately 8:10 a.m. to 9:10 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 8, 1999, 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 July 15, 1999, from 1 p.m. to 1:30 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). The meeting will be closed to discuss issues relating to pending or proposed investigational new drug applications. The meeting will also be closed from 5 p.m. to 5:45 p.m., to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). This portion of the meeting will be closed to permit discussion of this information.

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

2).

Dated: June 21, 1999
June 21, 1999


Linda A. Suydam
Senior Associate Commissioner

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