

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Endocrinologic and Metabolic Drugs 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). The meeting will be open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs 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 January 13, 14, and 15, 2003, from 8 a.m. to 5 p.m.

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

Contact Person: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301-827-7001, FAX 301-827-6776, e-mail: somersk@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12536. Please call the Information Line for up-to-date information on this meeting.

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Agenda: On January 13, 2003, the committee will discuss the safety and efficacy of biologic licensing application BL 103979, FABRAZYME (agalsidase beta, Genzyme Corp.) for the treatment of Fabry's disease. On January 14, 2003, the committee will discuss the safety and efficacy of biologic licensing application BL 103977, REPLAGAL (agalsidase alfa, Transkaryotic Therapies, Inc.) for the treatment of Fabry's disease. On January 15, 2003, the committee will discuss the safety and efficacy of biologic licensing application BL 125058, ALDURAZYME (laronidase, BioMarin Pharmaceutical, Inc.) for the treatment of mucopolysaccharidosis.

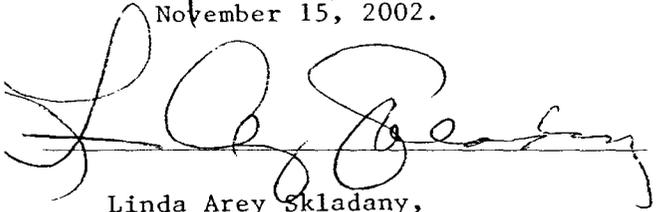
Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 6, 2003. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 6, 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.

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 Karen M. Templeton-Somers 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: Nov. 15, 2002
November 15, 2002.



Linda Arey Skladany,
Senior Associate Commissioner for External Relations.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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