

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Joint Meeting of the Endocrinologic and Metabolic Drugs Advisory
Committee and the Advisory Committee for Pharmaceutical Science; 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 Committees: Endocrinologic and Metabolic Drugs Advisory Committee and the Advisory Committee for Pharmaceutical Science.

General Function of the Committees: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 4, 2006, from 8 a.m. to 5 p.m.

Location: Hilton, The Ballrooms, 620 Perry Pkwy, Gaithersburg, MD. The hotel phone number is 301-977-8900.

Contact Person: Victoria Ferretti-Aceto, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1076), Rockville, MD 20857, 301-827-7001, e-mail: Victoria.FerrettiAceto@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), codes 3014512536 or 3014512539. Please call the Information Line for

up-to-date information on this meeting. When available, background materials for this meeting will be posted one business day prior to the meeting on the FDA Web site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. (Click on the year 2006 and scroll down to Endocrinologic and Metabolic Drugs Advisory Committee or the Advisory Committee for Pharmaceutical Science.)

Agenda: The joint committee will discuss FDA's efforts to assess the product quality of currently marketed levothyroxine sodium drug products. Earlier this year, FDA requested that manufacturers of currently marketed levothyroxine sodium products provide to it certain product release and stability information. The joint committee will consider FDA's analyses and any clinical significance.

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 on or before September 13, 2006. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person 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 on or before September 13, 2006.

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

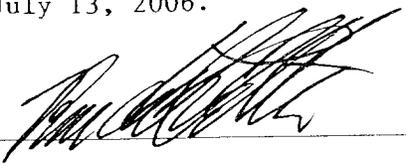
FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a

disability, please contact Victoria Ferretti-Aceto 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: July 13, 2006
July 13, 2006.

oc06159



Randall W. Lutter,
Associate Commissioner for Policy and Planning.

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