

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier	Monique Oliver

Peripheral and Central Nervous System Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: 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: Peripheral and Central Nervous System 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 June 6, 2001, 8 a.m. to 5 p.m..

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

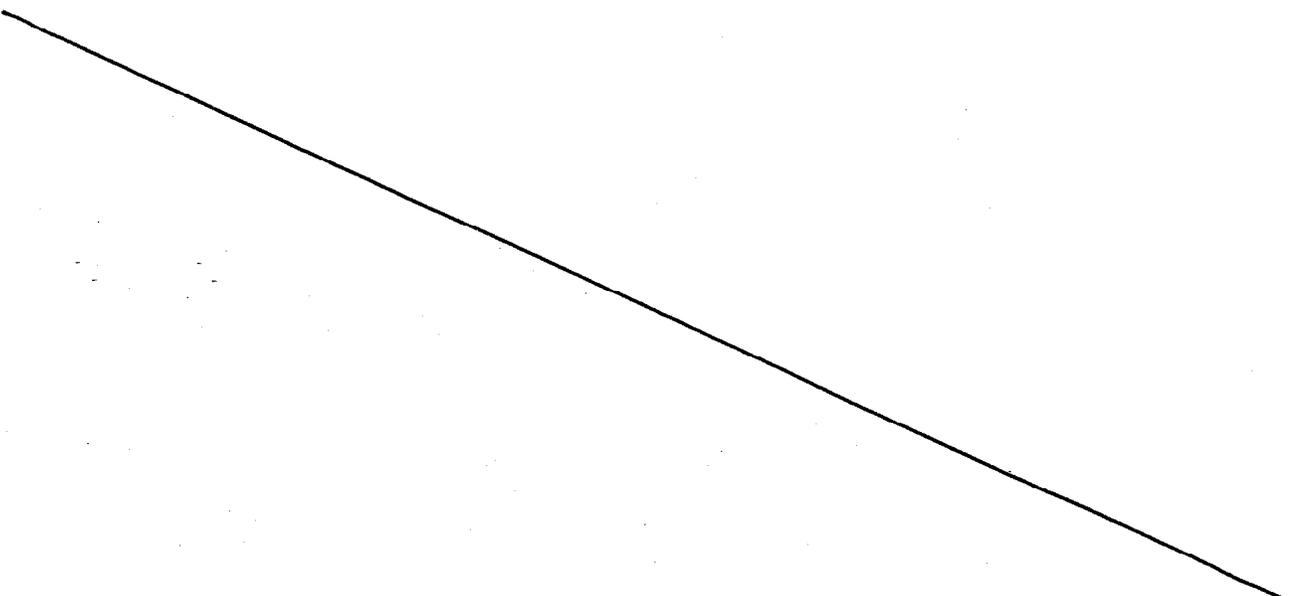
Contact: Sandra Titus, Food and Drug Administration, Center for Drug Evaluation and Research, (HFD-21), 5600 Fishers Lane, Rockville MD 20857, 301-827-7001, e-mail: Tituss@cder.fda.gov, FAX 301-827-6801, or FDA Advisory Committee Information Line at 1-800-741-8138 (301-443-0572 in the Washington, DC area) code 12543. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 6, 2001, the committee will consider the safety and efficacy of new drug application (NDA) 21-196, Xyrem® (sodium oxybate, Orphan Medical, Inc.) proposed to reduce the incidence of cataplexy and to improve the symptom of daytime sleepiness for persons with narcolepsy. A main focus of the deliberations will be on risk management issues.

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 May 29, 2001. 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 before May 29, 2001, 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.

Background material from the sponsor and FDA will be posted 24 hours before the meeting at the Peripheral and Central Nervous System Drugs Advisory Committee docket site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. (Click on the year 2001 and scroll down to the Peripheral and Central Nervous Systems Drugs meetings.) This is the same Web site where you can find the minutes, transcript, and slides from the meeting. This material is generally posted about 3 weeks after the meeting.



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

2).

Dated: 5/8/02
May 8, 2001.

Linda A. Suydam
Linda A. Suydam,
Senior Associate Commissioner.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

Monique Oliver

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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