

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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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 March 13, 14, and 15, 2001, 8 a.m. to 5 p.m.

*Location:* Holiday Inn, The Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

*Contact:* Sandra L. Titus or Lauren W. Parcover, 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, or e-mail: Tituss@cder.fda.gov, or FDA Advisory Committee Information Line, 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 March 13, 2001, the committee will discuss drug development for individuals with mild cognitive impairment (MCI). In the recent literature there has been a discussion of an entity referred to as MCI. While MCI is considered by some to be a distinct clinical entity, others consider that the majority of patients diagnosed with MCI have an early form of Alzheimer's Disease. It is critical for regulatory purposes that the issues surrounding this diagnosis are fully

explored. Toward that end the committee will listen to speakers and discuss the following and other related questions:

1. Can MCI be clearly defined in a clinical setting?
2. Are there valid criteria for the diagnosis of MCI?
3. Can MCI be distinguished from Alzheimer's Disease and other causes of dementia?
4. What outcome measures are appropriate to use in clinical drug trials conducted in MCI?
5. Should clinical drug trials in MCI incorporate any special features in their design?

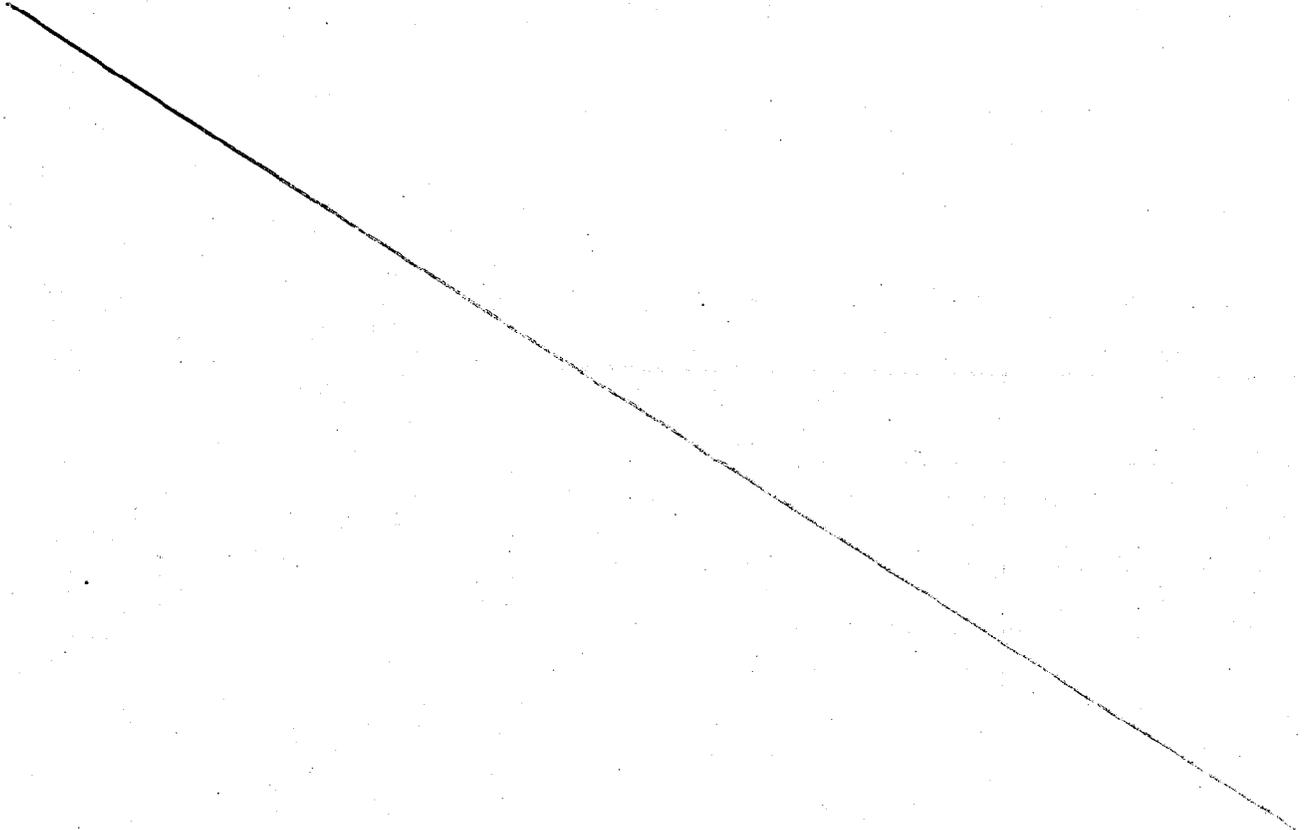
On March 14, 2001, the committee will discuss drug development for individuals with vascular dementia. While vascular dementia is considered by some to be a distinct entity others do not agree that it can be easily distinguished from Alzheimer's Disease and/or other dementias. It is critical for regulatory purposes that the issues surrounding this diagnosis are fully explored. Toward that end the committee will listen to presentations and then discuss the following and other related questions:

1. Can vascular dementia be clearly defined in a clinical setting?
2. Are there valid criteria for the diagnosis of vascular dementia?
3. Can vascular dementia be distinguished from Alzheimer's Disease and other causes of dementia?
4. What outcome measures are appropriate to use in clinical drug trials conducted in vascular dementia?
5. Should clinical drug trials in vascular dementia incorporate any special features in their design?

FDA will provide a background position paper on MCI and on vascular dementia prior to each meeting. When the background material becomes available, it will be posted under the Peripheral and Central Nervous Systems 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.)

On March 15, 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.

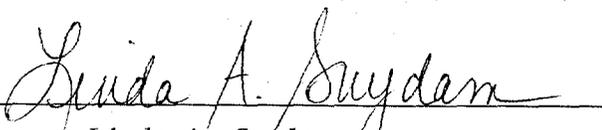
*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 1, 2001. On March 13 and 14, 2001, oral presentations from the public will be scheduled between approximately 10:30 a.m. and 12:30 p.m. Time allotted for each presentation may be limited. On March 15, 2001, oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 p.m. Those desiring to make formal oral presentations should notify the contact person before March 1, 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.



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

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Dated: February 6, 2001.

  
Linda A. Suydam,  
Senior Associate Commissioner.

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