

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DHB

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Certifier R. LEDESMA

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 November 18 and 19, 2002, from 8 a.m. to 5 p.m.

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

*Contact Person:* Sandra Titus, 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.

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*Agenda:* On November 18, 2002, the committee will discuss the role of brain imaging as an outcome measure in phase 3 trials of putative therapeutic drugs for Alzheimer's disease; the discussions will not focus on specific drugs or on specific applications to the agency. The agency is considering whether brain imaging modalities can be utilized as surrogate markers; that is, as primary outcomes in definitive clinical trials to measure drug effect in lieu of clinical outcomes. The committee will specifically discuss the following issues in reference to each imaging modality:

1. How is the surrogate imaging modality best validated?
2. If one uses an imaging modality to support a disease-modifying effect claim, how does one establish that such an effect occurs?
3. Has any surrogate imaging modality been validated at the present time?
4. Even if no surrogate imaging modality has currently been validated, is it appropriate to use one or more such modalities as primary or ancillary outcome measures of efficacy in phase 3 clinical trials?

On November 19, 2002, the committee will consider a supplemental new drug application (NDA) 20-306 for F-18 fluorodeoxyglucose (FDG) positron emission tomography (PET) imaging proposed to diagnose and/or identify progression of Alzheimer's disease and other forms of dementia. This application is based on published multi-center controlled clinical trials, additional information provided by some of the literature authors, and other supportive literature. Considerations will include the relevance of current practice, knowledge of Alzheimer's disease process, and clinical trial design to establish clinical usefulness of F-18 FDG PET in Alzheimer's disease. (Downstate Medical Center, Peoria, IL, is the sponsor of the new drug application. The Academy of Molecular Imaging provided the literature

references and the literature summary that formed the basis of the supplemental NDA.)

The background material will become available no later than the day before the meeting and 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 2002 and scroll down to the Peripheral and Central Nervous Systems Drugs Advisory Committee meetings.)

*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 November 6, 2002. Oral presentations from the public will be scheduled between approximately 11 a.m. and noon each day. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 6, 2002, 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.

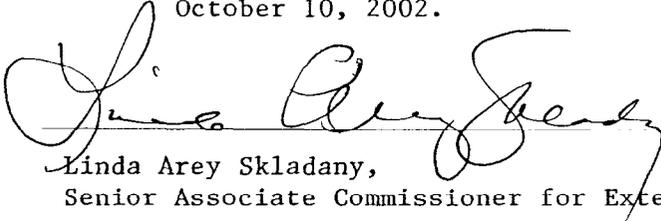
Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

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 Sandra Titus 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: Oct 10, 2002

October 10, 2002.



Linda Arey Skladany,  
Senior Associate Commissioner for External Relations.

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