

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Psychopharmacologic 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:* Psychopharmacologic 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 16, 2003, from 8 a.m. to 5 p.m.

*Location:* Marriott Washingtonian Center, Grand Ballroom, 9751 Washingtonian Blvd., Gaithersburg, MD.

*Contact Person:* Jayne E. Peterson, 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, e-mail: [petersonj@cder.fda.gov](mailto:petersonj@cder.fda.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12544. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On June 16, 2003, the committee will discuss the white blood cell (WBC) monitoring schedule for patients being treated long-term with

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clozapine. Currently, the WBC monitoring schedule is weekly for the first 6 months of continuous therapy and biweekly thereafter. The committee will consider the question of whether the frequency of WBC monitoring can be diminished further following some period of biweekly monitoring. When available, background materials for this meeting will be posted 1-business day prior to the meeting on the FDA Web site at: [www.fda.gov/ohrms/dockets/ac/acmenu.htm](http://www.fda.gov/ohrms/dockets/ac/acmenu.htm). (Click on the year 2003 and scroll down to Psychopharmacologic Drugs Advisory Committee.)

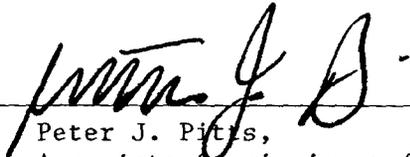
*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by June 9, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 9, 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 Jayne Peterson 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: 5/5/03  
May 5, 2003.

  
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Peter J. Pitts,  
Associate Commissioner for External Relations.

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