

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.

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 October 25, 2005, from 8 a.m. to 5 p.m. and on October 26, 2005, from 8 a.m. to 3 p.m.

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

Contact Person: Karen Templeton-Somers, 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, FAX: 301-827-6776, e-mail: somersk@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512544. Please call the Information Line for up-to-date information on this meeting. The background material will become available no later than the day before the meeting and will be posted on FDA's Web site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm> under the

heading “Psychopharmacologic Drugs Advisory Committee (PDAC)” (click on the year 2005 and scroll down to PDAC meetings).

Agenda: On October 25, 2005, the committee will discuss issues and questions pertinent to the need for longer-term efficacy data for proposed drug treatments for chronic psychiatric disorders, and issues and questions pertinent to optimal study designs for obtaining valid information about longer-term benefits of drug treatment. On October 26, 2005, the committee will discuss the question of whether or not dietary restrictions would be needed for the 20 milligrams (mg) dose for proposed trade name EMSAM (selegiline transdermal system) (new drug applications (NDAs): NDA 21–336, short-term claim, and NDA 21–708, longer-term claim, Somerset Pharmaceuticals), for the treatment of major depressive disorder.

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 October 12, 2005. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on October 25, 2005, and between approximately 11 a.m. and 11:30 a.m. on October 26, 2005. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 12, 2005, 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.

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

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disability, please contact Karen Templeton-Somers 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: September 8, 2005.

Scott Gottlieb,

Deputy Commissioner for Policy.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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