

listed in this document have repeatedly failed to submit reports required by § 314.81. In addition, under § 314.200, we find that the holders of the applications have waived any contentions concerning the legal status of the drug products. Therefore, under these findings, approval of the applications listed in this document, and all amendments and supplements thereto, is hereby withdrawn, effective September 21, 2005.

Dated: August 29, 2005.

**Steven Galson,**

*Director, Center for Drug Evaluation and Research.*

[FR Doc. 05-18873 Filed 9-20-05; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Industry Exchange Workshop on Food and Drug Administration Clinical Trial Requirements; Public Workshop

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

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA) Dallas District, in cooperation with the Society of Clinical Research Associates (SoCRA), is announcing a workshop on FDA clinical trial statutory and regulatory requirements. This 2-day workshop for the clinical research community targets sponsors, monitors, clinical investigators, institutional review boards, and those who interact with them for the purpose of conducting FDA-regulated clinical research. The workshop will include both industry and FDA perspectives on proper conduct of clinical trials regulated by FDA.

**Date and Time:** The public workshop is scheduled for Wednesday, February 8, 2006, from 8:15 a.m. to 5 p.m. and Thursday, February 9, 2006, from 8:15 a.m. to 4 p.m.

**Location:** The public workshop will be held at the Crowne Plaza Hotel Houston Medical Center, 6701 South Main, Houston, TX 77030, 713-797-1110, FAX: 713-796-8291.

**Contact:** David Arvelo, Food and Drug Administration, 4040 North Central Expressway, suite 900, Dallas, TX 75204, 214-253-4952, FAX: 214-253-4970, e-mail: [oraswrsbr@ora.fda.gov](mailto:oraswrsbr@ora.fda.gov).

**Registration:** Send registration information (including name, title, firm name, address, telephone, and fax number) and the registration fee of \$485

(member), \$560 (nonmember), or \$460 (government employee nonmember). (Registration fee for nonmembers includes a 1-year membership.) The registration fee for FDA employees is waived. Make the registration fee payable to SoCRA, P.O. Box 101, Furlong, PA 18925. To register via the Internet go to [http://www.socra.org/html/FDA\\_Conference.htm](http://www.socra.org/html/FDA_Conference.htm) (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**). The registrar will also accept payment by major credit cards. For more information on the meeting, or for questions on registration, contact 800-SoCRA92 (800-762-7292), or 215-345-7369, or via e-mail: [socramail@aol.com](mailto:socramail@aol.com). Attendees are responsible for their own accommodations. To make reservations at the Crowne Plaza Hotel Houston Medical Center at the reduced conference rate, contact the Crowne Plaza Hotel Houston Medical Center (see *Location*) before January 17, 2005. The registration fee will be used to offset the expenses of hosting the conference, including meals, refreshments, meeting rooms, and materials.

Space is limited, therefore interested parties are encouraged to register early. Limited onsite registration may be available. Please arrive early to ensure prompt registration. If you need special accommodations due to a disability, please contact David Arvelo (see *Contact*) at least 7 days in advance of the workshop.

**SUPPLEMENTARY INFORMATION:** The workshop on FDA clinical trials statutory and regulatory requirements, helps fulfill the Department of Health and Human Services and FDA's important mission to protect the public health by educating researchers on proper conduct of clinical trials. Topics for discussion include the following: (1) FDA regulation of the conduct of clinical research; (2) medical device, drug, and biological product aspects of clinical research; (3) investigator initiated research; (4) pre-investigational new drug application meetings and FDA meeting process; (5) informed consent requirements; (6) ethics in subject enrollment; (7) FDA regulation of institutional review boards; (8) electronic records requirements; (9) adverse event reporting; (10) how FDA conducts bioresarch inspections; and (11) what happens after the FDA inspection. FDA has made education of the research community a high priority to ensure the quality of clinical data and protect research subjects. The workshop

helps to implement the objectives of section 406 of the FDA Modernization Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which includes working more closely with stakeholders and ensuring access to needed scientific and technical expertise. The workshop also furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121) by providing outreach activities by Government agencies directed to small businesses.

Dated: September 15, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05-18871 Filed 9-20-05; 8:45 am]

BILLING CODE 4160-01-S

## 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](mailto: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](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 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. 05-18872 Filed 9-20-05; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Heart, Lung, and Blood Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

**Name of Committee:** National Heart, Lung, and Blood Advisory Council.

**Date:** October 26, 2005.

**Open:** 8:30 a.m. to 12 p.m.

**Agenda:** Discussion of program policies and issues.

**Place:** National Institutes of Health, Building 31, 31 Center Drive, Bethesda, MD 20892.

**Closed:** 1 p.m. to 4 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, Building 31, 31 Center Drive, Bethesda, MD 20892.

**Contact Person:** Deborah P. Beebe, PhD, Director, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, Two Rockledge Center, Room 7100, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435-0260.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign in at the security desk upon entering the building.

Information is also available on the Institute's/Center home page: <http://>

[nhlbi.gov/meetings/index.htm](http://nhlbi.gov/meetings/index.htm), where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: September 13, 2005.

**Anthony M. Coelho, Jr.,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 05-18864 Filed 9-20-05; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

**Name of Committee:** National Institute of Neurological Disorders and Stroke Special Emphasis Panel, Preclinical Studies of Gene Therapy for Parkinson's Disease.

**Date:** October 4, 2005.

**Time:** 2 p.m. to 3 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Suite 3208, Rockville, MD 20852, (Telephone Conference Call).

**Contact Person:** Shantadurga Rajaram, PhD, Scientific Review Administrator, Scientific Review Branch, NIH/NINDS/Neuroscience Center, 6001 Executive Blvd., Suite 3208, Msc 9529, Bethesda, MD 20852, (301) 435-6033, [rajarams@mail.nih.gov](mailto:rajarams@mail.nih.gov).

**Name of Committee:** National Institute of Neurological Disorders and Stroke Special Emphasis Panel, UDALL Center Review.

**Date:** October 27, 2005.

**Time:** 1:30 p.m. to 3 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, Neuroscience Center, 6001 Executive