

identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: January 5, 2004.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 04-551 Filed 1-9-04; 8:45 am]

BILLING CODE 4184-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Pediatric Subcommittee of the Anti-Infective 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:* Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee.

*General Function of the Subcommittee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on February 3, 2004, from 9 a.m. to 4:45 p.m., and February 4, 2004, from 8 a.m. to 12 noon.

*Location:* CDER Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

*Contact Person:* Thomas H. Perez, 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 by e-mail: [perezth@cder.fda.gov](mailto:perezth@cder.fda.gov). Please call the FDA Advisory Information Line, 1-800-741-8138

(301-443-0572 in the Washington, DC area), code 3014512530, for up-to-date information on this meeting.

*Agenda:* On February 3, 2004, the subcommittee will meet between 9 a.m. and 10:15 a.m., and the agency will report to the subcommittee on Adverse Event Reporting as mandated in Section 17 of the Best Pharmaceuticals for Children Act (BPCA). The products to be reported during this portion of the meeting include: Paxil (paroxetine), Celexa (citalopram), Pravachol (pravastatin), and Navelbine (vinorelbine). Following this, from approximately 10:30 a.m. to 4:45 p.m., the subcommittee will discuss the use of imaging drugs in conjunction with cardiac imaging procedures in the pediatric population.

On February 4, 2004, the subcommittee will meet between 8 a.m. and 12 noon to continue the discussion on the use of imaging drugs in conjunction with cardiac imaging procedures in the pediatric population.

The background material for this meeting will be posted on the Internet when available or 1 working day before the meeting at [www.fda.gov/ohrms/dockets/ac/menu.htm](http://www.fda.gov/ohrms/dockets/ac/menu.htm).

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by January 23, 2004. On February 3, 2004, oral presentations from the public will be scheduled between approximately 9:45 a.m. and 10:15 a.m. for issues related to the Section 17 adverse event reports. Also, on February 3, 2004, oral presentations from the public will be scheduled between approximately 3:45 p.m. and 4:45 p.m. for issues related to cardiac imaging in pediatric patients. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by January 23, 2004, 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 notify Thomas Perez

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: January 5, 2004.

**Peter J. Pitts,**

*Associate Commissioner for External Relations.*

[FR Doc. 04-503 Filed 1-9-04; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Psychopharmacologic Drugs Advisory Committee and the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee; Amendment of Notice

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

**ACTION:** Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of the meeting of the Psychopharmacologic Drugs Advisory Committee and the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee. This meeting was announced in the **Federal Register** of October 31, 2003 (68 FR 62088). The amendment is being made to reflect a change in the *Contact Person* for the FDA advisory committee telephone line extension codes (namely from 5-digit to a 10-digit format), *Agenda*, and *Procedure* portions of the document. There are no other changes.

#### FOR FURTHER INFORMATION CONTACT:

Anuja Patel, 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 or e-mail: [patela@cder.fda.gov](mailto:patela@cder.fda.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of October 31, 2003 (68 FR 62088), FDA announced that a meeting of the Psychopharmacologic Drugs Advisory Committee and the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee will be held on February 2, 2004. On page 62088, in the second and third columns, the *Contact Person*, *Agenda*, and *Procedure* portions of the meeting are amended to read as follows:

*Contact Person:* Anuja Patel, 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 or e-mail: [patelA@cder.fda.gov](mailto:patelA@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.

**Agenda:** The Psychopharmacologic Drugs Advisory Committee and the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee will discuss reports of the occurrence of suicidality (both suicidal ideation and suicide attempts) in clinical trials for various anti-depressant drugs in pediatric patients with major depressive disorder (MDD). The committee will consider optimal approaches to the analysis of data from these trials as well as further research needs to address these issues. The committee will not be considering options for definitive regulatory action at this meeting because definitive analyses of the data have not been completed. This topic will be covered in a second meeting to be scheduled by summer 2004.

**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 January 26, 2004. Oral presentations from the public will be scheduled between approximately 9:30 a.m. to 11:30 a.m., and 2 p.m. to 2:30 p.m.

This notice is given under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: January 5, 2004.

**Peter J. Pitts,**

*Associate Commissioner for External Relations.*

[FR Doc. 04-502 Filed 1-9-04; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center for Research Resources; Notice of 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 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 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:** Scientific and Technical Review Board on Biomedical and Behavioral Research Facilities.

**Date:** February 23-25, 2004.

**Open:** February 23, 2004, 8 a.m. to 9 a.m.

**Agenda:** To discuss planning and other issues.

**Place:** Gaithersburg Marriott, Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD 20878.

**Closed:** February 23, 2004, 9 a.m. to Adjournment.

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

**Place:** Gaithersburg Marriott, Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD 20878.

**Contact Person:** D.G. Patel, PhD, Scientific Review Administrator, National Institutes of Health, National Center for Research Resources, Office of Review, 6701 Democracy Boulevard, 1 Democracy Plaza, Room 1070, Bethesda, MD 20892, 301-435-0824, [pateldg@mail.nih.gov](mailto:pateldg@mail.nih.gov).

**Name of Committee:** National Center for Research Resources Special Emphasis Panel, Research Infrastructure.

**Date:** February 25-26, 2004.

**Time:** February 25, 2004, 8 a.m. to Adjournment.

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

**Place:** Marriott Gaithersburg, Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

**Contact Person:** Eric H. Brown, PhD, Scientific Review Administrator, Office of Review, National Center for Research Resources, National Institutes of Health, 6701 Democracy Blvd, MSC 4874, Room 1068, Bethesda, MD 20892-4874, 301-435-0815, [browne@mail.nih.gov](mailto:browne@mail.nih.gov).

**Name of Committee:** National Center for Research Resources Special Emphasis Panel, Research Infrastructure.

**Date:** March 10-11, 2004.

**Time:** March 10, 2004, 8 a.m. to Adjournment.

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

**Place:** Marriott Gaithersburg, Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

**Contact Person:** Eric H. Brown, PhD, Scientific Review Administrator, Office of Review, National Center for Research Resources, National Institutes of Health, 6701 Democracy Blvd, MSC 4874, Room 1068,

Bethesda, MD 20892, 301-435-0815, [browne@mail.nih.gov](mailto:browne@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure; 93.306, 93.333, National Institutes of Health, HHS)

Dated: January 6, 2004.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04-578 Filed 1-9-04; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Allergy and Infectious Diseases; 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 Allergy and Infectious Diseases Special Emphasis Panel, Unsolicited P01.

**Date:** January 21, 2004.

**Time:** 9 a.m. to 12 p.m.

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

**Place:** National Institutes of Health, Rockledge 6700, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

**Contact Person:** Cheryl K. Lapham, PhD, Scientific Review Administrator, Scientific Review Program, National Institute of Allergy and Infectious Diseases, DEA/NIH/DHHS, 6700-B Rockledge Drive, MSC 7616, Room 3127, Bethesda, MD 20892-7616, 301-402-4598, [clapham@niaid.nih.gov](mailto:clapham@niaid.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

**Name of Committee:** National Institute of Allergy and Infectious Diseases Special Emphasis Panel, Unsolicited Program Project Application.

**Date:** February 4, 2004.

**Time:** 9 a.m. to 1 p.m.