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: *perezt@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.*

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.*

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,