Dated: October 23, 2006.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E6–17932 Filed 10–25–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric 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 Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues. The committee also advises and makes recommendations to the Secretary of Health and Human Services under 21 CFR 50.54 and 45 CFR 46.407 on research involving children as subjects that is conducted or supported by the Department of Health and Human Services, when that research is also regulated by FDA.

Date and Time: The meeting will be held on November 16, 2006, from 8 a.m. to 4 p.m.

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

Contact Person: Jan Johannessen, Office of Science and Health Coordination, Office of the Commissioner (HF–33), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, rm. 14B–08), Rockville, MD 20857, 301–827–6687, e-mail: *Jan.Johannessen@fda.hhs.gov* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 8732310001. Please call the Information Line for up to date information on this meeting.

Agenda: The Pediatric Advisory Committee will hear and discuss a report by the agency, as mandated in section 17 of the Best Pharmaceuticals for Children Act, on adverse event reports for ertapenem (INVANZ), gemcitabine (GEMZAR), glimepiride (AMARYL), insulin aspart recombinant (NOVOLOG), linezolid (ZYVOX), meloxicam (MOBIC), ondansetron (ZOFRAN), oxcarbazepine (TRILEPTAL), ritonavir (NORVIR), rosiglitazone (AVANDIA), sirolimus (RAPAMUNE). The committee will also receive updates to adverse event reports for atorvastatin (LIPITOR), citalopram (CELEXA), oseltamivir (TAMIFLU), oxybutynin (DITROPAN), and simvastatin (ZOCOR), which were requested by the Pediatric Advisory Committee or its predecessor, the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee, when the reports were first presented.

The background material will become available no later than 1 business day before the meeting and will be posted on FDA's Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. (Click on the year 2006 and scroll down to Pediatric Advisory Committee link.)

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 on or before November 1, 2006. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. on November 16, 2006. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person 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 on or before by November 1, 2006.

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 Jan N. Johannessen 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: October 23, 2006.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0408]

Draft Guidance for Industry and Food and Drug Administration Staff; Annual Reports for Approved Premarket Approval Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Annual Reports for Approved Premarket Approval Applications.'' This draft guidance document outlines the information required by a certain FDA regulation in periodic reports (usually referred to as annual reports) and FDA's recommendations for the level of detail that manufacturers should provide. This draft guidance is not final nor is it in effect at this time.

DATES: Submit written or electronic comments on this draft guidance by January 24, 2007. Submit written or electronic comments on the collection of information by December 26, 2006.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Annual Reports for Approved Premarket Approval Applications'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance and the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For device issues: Laura Byrd, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

For biologics issues: Leonard Wilson,