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 LaNise Giles at 301–827–7001, 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. 05–18366 Filed 9–14–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric Oncology Subcommittee of the Oncologic 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 Oncology Subcommittee of the Oncologic 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 20, 2005, from 8 a.m. to 5 p.m.

Location: Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Victoria Ferretti-Aceto, 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: *ferrettiv@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512542. Please call the Information Line for up-to-date information on this meeting.

Agenda: The subcommittee will do the following: (1) Present the structure and function of the Office of Oncology Drug Products in CDER, (2) discuss issues involved with the conduct of certain pediatric postmarketing studies for products approved for oncologic indications, (3) review status of studies for specific off-patent drugs for pediatric oncology, and (4) consider other off-patent oncology drugs for which pediatric studies are needed, as mandated by the Best Pharmaceuticals for Children Act. When available, background materials for this meeting will be posted 1 business day before the meeting on FDA's Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. (Click on the year 2005 and scroll down to Oncologic Drugs Advisory Committee; Pediatric Subcommittee.)

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 October 13, 2005. Oral presentations from the public will be scheduled between approximately 11:45 a.m. and 12:15 p.m., and between approximately 3 p.m. and 3:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 13, 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.

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 Victoria Ferretti-Aceto 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 6, 2005.

Scott Gottlieb,

Deputy Commissioner for Policy.

[FR Doc. 05–18330 Filed 9–14–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0348]

Draft Guidance for Industry and Food and Drug Administration Staff; Procedures for Handling Post-Approval Studies Imposed by Premarket Approval Application Order; 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 ''Procedures for Handling Post-Approval Studies Imposed by PMA Order.'' The draft guidance is designed to assist the Center for Devices and Radiological Health (CDRH) and sponsors to meet their responsibilities to track post-approval studies (sometimes called Condition of Approval Studies) that are mandated for market approval of medical devices.

DATES: Submit written or electronic comments on this draft guidance by November 14, 2005.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Procedures for Handling Post-Approval Studies Imposed by PMA Order'' 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 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

Submit written comments concerning this draft guidance 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: Steven H. Chasin, Office of Surveillance and Biometrics, Division of Postmarket Surveillance, Center for Devices and Radiological Health (HFZ–500), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3674

SUPPLEMENTARY INFORMATION:

I. Background

The draft guidance is designed to assist sponsors and CDRH to oversee post-approval studies. These studies are oftentimes mandated at the time the Center approves a Premarket Approval Application (PMA) to address additional concerns. This guidance aims to assure that:

- Sponsors submit clear, consistent and timely study reports;
- CDRH can track the status of the studies;
- CDRH staff reviews the studies and holds discussions with the sponsors in a timely manner;
- CDRH stakeholders can quickly learn about the status of these studies; and
- CDRH can take appropriate and timely action based on study results.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on ''Procedures for Handling Post-Approval Studies Imposed by PMA Order.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive ''Procedures for Post-Approval Studies Imposed by PMA Order'' by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1516) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 USC 3501–3520). The collections of information addressed in the draft guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket approval applications (21 CFR part 814, OMB control number 0910–0231).

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 9, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–18372 Filed 9–14–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0251]

Guidance for Industry, Food and Drug Administration Staff, and Food and Drug Administration-Accredited Third Parties; Requests for Inspection by an Accredited Person Under the Inspections by Accredited Persons Program Authorized by the Medical Device User Fee and Modernization Act of 2002; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Requests for Inspection by an Accredited Person under the Inspection by Accredited Persons Program Authorized by Section 201 of the Medical Device User Fee and Modernization Act of 2002.'' The Medical Device User Fee and Modernization Act of 2002 authorizes FDA to establish a voluntary inspection program under which manufacturers of class II or class III devices who meet certain eligibility criteria as defined by the statute can elect to have FDA-accredited third parties conduct some of their establishment inspections instead of FDA. This guidance document describes the establishment eligibility criteria and the process for establishments to follow when requesting FDA's approval to have an accredited person (AP) conduct an inspection of their establishment instead of FDA under the new Inspections by Accredited Persons Program (AP Program).

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Requests for Inspection by an Accredited Person under the Inspection by Accredited Persons Program Authorized by Section 201 of the Medical Device User Fee and Modernization Act of 2002'' 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 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance 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 medical device issues: Casper E. Uldriks, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD