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