

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.

9-14-05
Publication Date 9-15-05
Contact: L. CLAWSON
DDM

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

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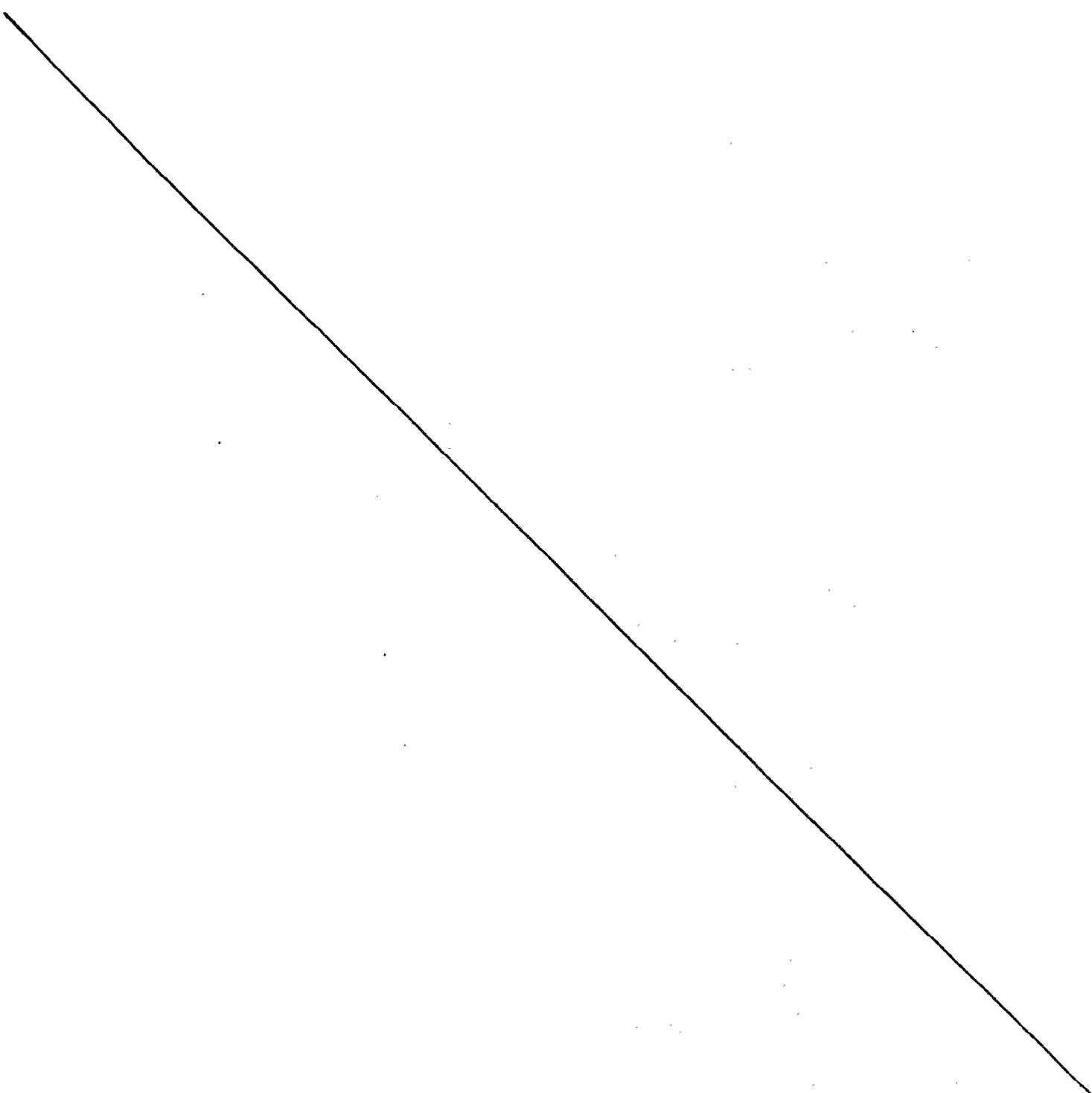
Washington, DC area), code 3014512542. Please call the Information Line for up-to-date information on this meeting.

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.

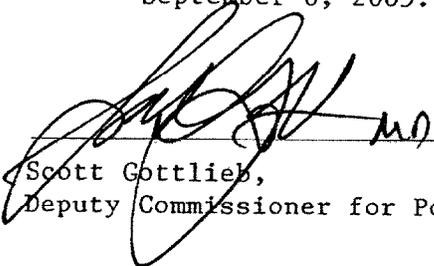
Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

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: 9/6/05
September 6, 2005.



Scott Gottlieb,
Deputy Commissioner for Policy.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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