

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 March 14, 2006, from 8 a.m. to 5 p.m.

Location: Gaithersburg Hilton, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Johanna M. Clifford, 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: cliffordj@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 discuss the following: (1) Clinical studies of methotrexate and daunomycin to be conducted under the Best Pharmaceuticals for Children Act; (2) phase 4 requirements for Deferasirox, Novartis Pharmaceuticals, as mandated under accelerated approval; and (3) the Center for Drug Evaluation and Research's process for handling drug shortages. The background material will become available no later than the day before the meeting and will be posted on FDA's Web site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm> under the heading "Oncologic Drugs Advisory Committee; Pediatric Oncology" (click on the year 2006 and scroll down to the previously named committee).

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 March 7, 2006. Oral presentations from the public will be scheduled between approximately 2 p.m. to 3 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 7, 2006, 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 Johanna M. Clifford 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: December 27, 2005.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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: 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 March 15, 2006, from 8 a.m. to 5 p.m.

Location: Gaithersburg Hilton, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Johanna M. Clifford, 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: cliffordj@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. The background material will become available no later than the day before the meeting and will be posted on FDA's Web site at <http://www.fda.gov/ohrms/dockets/ac/>

[acmenu.htm](#) under the heading "Oncologic Drugs Advisory Committee" (click on the year 2006 and scroll down to the above named committee meeting).

Agenda: The committee will discuss the following: (1) Receive and discuss pediatric update from the October 20, 2005, meeting of the Pediatric Oncology Subcommittee; (2) discuss pre-clinical requirements and phase 1 trial design issues for the development of oncologic products; and (3) discuss new drug application (NDA) 20-509, S-039, GEMZAR (gemcitabine hydrochloride) for Injection, Eli Lilly & Co., proposed indication for use in combination with carboplatin for the treatment of patients with advanced ovarian cancer that has relapsed at least 6 months after completion of platinum-based therapy.

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 by March 7, 2006. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m. and 2:30 p.m. to 3 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 7, 2006, 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 Johanna Clifford 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: December 27, 2005.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. E5-8333 Filed 1-5-06; 8:45 am]

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