

## 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.

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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 on September 6, 2006, from 8 a.m. to 5 p.m. and September 7, 2006, from 8 a.m. to 12 noon.

*Location:* Hilton, Washington DC/Silver Spring, Maryland Ballrooms, 8727 Colesville Rd., Silver Spring, 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, email: [cliffordj@cder.fda.gov](mailto: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:* On September 6, 2006, the committee will discuss two new drug applications (NDAs): (1) NDA 21-874, proposed trade name GENASENSE

(oblimersen sodium) Injection, Genta, Inc., proposed indication for the treatment of patients with chronic lymphocytic leukemia in combination with fludarabine and cyclophosphamide; and (2) NDA 020–287, FRAGMIN (dalteparin sodium), Pfizer, Inc., proposed indication for the extended treatment of symptomatic venous thromboembolism (VTE), proximal deep vein thrombosis, and/or pulmonary embolism to reduce the recurrence of VTE in patients with cancer. On September 7, 2006, the committee will discuss NDA 21–660, ABRAXANNE (paclitaxel protein-bound particles for injectible suspension) (albumin-bound), Abraxis Bioscience, Inc., including trial design issues for adjuvant treatment of node-positive breast cancer.

*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 August 22, 2006. Oral presentations from the public will be scheduled between approximately 10 a.m. to 10:30 a.m., and 2:30 p.m. to 3 p.m. on September 6, 2006, and between approximately 10 a.m. to 10:30 a.m. on September 7, 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 before August 22, 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

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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: July 18, 2006.

**Randall W. Lutter,**

*Associate Commissioner for Policy and Planning.*

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