

This meeting is the first of several planned by FDA to discuss aspects of the AFSS relative risk ranking model during the model's development by the agency. To determine the relative risks of chemical, physical, and biological contaminants in animal feed, information about the health consequences posed by the contaminant (represented by a health consequence scoring) is combined with information about the amount of the contaminant in animal feed (represented by an exposure scoring). This meeting will describe the methods used by the agency to develop the animal and human health consequence scoring for feed contaminants. At one or more subsequent meetings, FDA will present information about exposure of animals and humans to contaminants in feed and information about how health consequence scoring is combined with exposure scoring to determine the relative risks of contaminants in animal feed.

## II. Meeting

We are holding the meeting in an effort to gather further information from you, our stakeholders, on changes to AFSS that will help minimize risks to animal and human health associated with animal feed. Prior to the public meeting, FDA will place in the docket (found in brackets in the heading of this document) two documents, entitled "List of Potentially Hazardous Contaminants in Animal Feed and Feed Ingredients" and "Determining Health Consequence Scoring for Feed Contaminants." The documents will summarize the agency's methods for assigning animal and human health consequence scoring to physical, chemical, and biological contaminants that may be present in animal feed. Details of these methods will be discussed at the meeting. A draft agenda for the meeting will also be placed in the docket prior to the meeting.

## III. Comments

If you would like to submit written comments to the docket, please send you comments to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any written 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. You can view comments FDA has

received on the Internet at <http://www.fda.gov/ohrms/dockets/>.

Dated: July 24, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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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 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 injectable 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 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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