year 2006 and scroll down to the above named committee meeting.)

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 September 13, 2006. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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 on or before September 13, 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 John Lauttman 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.

[FR Doc. E6–12269 Filed 7–31–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0312]

Meeting to Present Work-In-Progress on a Method for Ranking Feed Contaminants According to the Relative Risks They Pose to Animal and Public Health; Part 1: Health Consequence Scoring for Feed Contaminants

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting it will hold to present work-in-progress on a method for ranking animal feed contaminants by their relative risks to animal and human health. The relative risk posed by feed contaminants to animal and human health consists of two components, namely health consequence scoring and exposure scoring. At this meeting the agency will describe the methods it plans to use to develop animal and human health consequence scoring for chemical, physical, and biological feed contaminants. At one or more subsequent public meetings, FDA will present information about how the health consequence scoring will be combined with information about the exposure of animals and humans to feed contaminants to determine the relative risks of such contaminants in feed.

Date and Time: The public meeting will be held on September 12, 2006, from 9 a.m. to 4:30 p.m.

Location: The meeting will be held at the Center for Drug Evaluation and Research Conference Room, third floor, 7519 Standish Pl., Rockville, MD 20855.

ADDRESSES: You may submit written comments 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*. Follow the instructions for submitting comments.

FOR FURTHER INFORMATION CONTACT: Zoe Gill, Center for Veterinary Medicine (HFV–226), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–453–6867, FAX 240–453–6882, e-mail: *zoe.gill@fda.hhs.gov*.

Registration: You may register by telephone, fax, or e-mail by contacting Nanette Milton, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–453–6840, FAX 240–453–6880, e-mail: *nanette.milton@fda.hhs.gov*. Send registration information (including name, title, firm name, address, telephone, and fax number to Nanette Milton. To obtain the registration form via the Internet go to *http://www.fda.gov/cvm/AFSS.htm#Meetings*. Due to limited meeting space, registration will be required. We strongly encourage early registration.

SUPPLEMENTARY INFORMATION:

I. Background

The Animal Feed Safety System (AFSS) is FDA's program for animal feed aimed at protecting human and animal health by ensuring animal feed is safe. It covers the entire spectrum of agency activities from preapproval of food additives and drugs for use in feed, to establishing limits for feed contaminants, providing education and training, and conducting inspections and taking enforcement actions for ensuring compliance with agency regulations. AFSS includes oversight of all feed ingredients and mixed feed at all stages of manufacture, production, distribution, and use, whether at commercial or non-commercial establishments.

During the past several years, FDA has been considering changes that need to be made to AFSS to ensure that it is comprehensive, preventive, and risk-based. As part of this effort, the agency is developing a model for ranking the relative risks to human and animal health of contaminants in animal feed. An effective model will permit the agency to systematically distinguish among feed hazards based on the relative risks they pose to animals or humans. Such a model will consider the risks of hazards present in incoming materials or feed ingredients and will also consider how activities at feed manufacturing, storage, distribution, and transportation facilities may modify such risks. For the purpose of AFSS, FDA defines a feed hazard as a biological, chemical, or physical agent in, or condition of, feed with the potential to cause an adverse health effect in animals or humans.

Previously, FDA held two public meetings to discuss AFSS, including discussions of the agency's plan to develop a risk ranking model for determining the relative risks to animal or human health of feed hazards. The first meeting was held on September 23 and 24, 2003, in Herndon, VA, and the second meeting was held on April 5 and 6, 2005, in Omaha, NE. The public meetings included active participation by consumers, animal feed processors, animal producers, and State and other Federal Government agencies. Following the meetings, we placed a number of documents in FDA's docket for the AFSS project (found in brackets in the heading of this document). These documents included transcripts of the meetings, summaries of break-out discussion groups, presentations of invited speakers, and meeting summaries. We also placed in the docket a number of other documents relating to AFSS, including a framework for AFSS that lists the principal components of AFSS and the gaps the agency has identified which are being addressed by the agency team working on the AFSS project. These documents provide excellent, general background material on AFSS for the public meeting that will be held on September 12, 2006.

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.

[FR Doc. E6–12266 Filed 7–31–06; 8:45 am]

BILLING CODE 4160–01–S

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*, 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.

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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.

[FR Doc. E6–12270 Filed 7–31–06; 8:45 am]

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